

14.3.4. Display of Laboratory Data (Each Subject)

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		D-A-C-B	16-JUL-2019	08:00	Creatinine	0.49	mg/dL	No	0.51-0.95
	EOS/ET		D-A-C-B	16-JUL-2019	08:00	Alkaline Phosphatase	130	U/L	No	30-120
	EOS/ET		D-A-C-B	16-JUL-2019	08:00	Chloride	109	mmol/L	No	98-107
	EOS/ET		D-A-C-B	16-JUL-2019	08:00	Blood Urea Nitrogen	7.6	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	16-JUL-2019	08:00	Glucose*	105.6	mg/dL	No	70-99
	Screening		B-C-A-D	30-APR-2019	18:05	Creatinine	0.48	mg/dL	No	0.51-0.95
	EOS/ET		B-C-A-D	16-JUL-2019	08:00	Creatinine	0.50	mg/dL	No	0.51-0.95
	EOS/ET		B-C-A-D	16-JUL-2019	08:00	Sodium	135	mmol/L	No	136-145
	EOS/ET		B-C-A-D	16-JUL-2019	08:00	Blood Urea Nitrogen	7.0	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:00	Glucose*	102.6	mg/dL	No	70-99
	Screening		C-D-B-A	30-APR-2019	17:28	Creatinine	0.50	mg/dL	No	0.51-0.95
	Screening		C-D-B-A	30-APR-2019	17:28	Protein	8.39	g/dL	No	6.6-8.3
	EOS/ET		C-D-B-A	16-JUL-2019	08:00	Chloride	108	mmol/L	No	98-107
	EOS/ET		C-D-B-A	16-JUL-2019	08:00	Blood Urea Nitrogen	7.3	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	02-MAY-2019	17:23	Creatinine	0.39	mg/dL	No	0.51-0.95
	Screening		A-B-D-C	02-MAY-2019	17:23	Chloride	108	mmol/L	No	98-107

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		A-B-D-C	02-MAY-2019	17:23	Bicarbonate	32.3	mmol/L	No	21.0-32.0
	Screening		A-B-D-C	02-MAY-2019	17:23	Blood Urea Nitrogen	4.0	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	02-MAY-2019	17:23	Calcium	8.68	mg/dL	No	8.80-10.60
	EOS/ET		A-B-D-C	16-JUL-2019	08:00	Creatinine	0.44	mg/dL	No	0.51-0.95
	EOS/ET		A-B-D-C	16-JUL-2019	08:00	Blood Urea Nitrogen	4.4	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	07-MAY-2019	16:24	Chloride	109	mmol/L	No	98-107
	EOS/ET		B-C-A-D	16-JUL-2019	08:02	Chloride	108	mmol/L	No	98-107
	EOS/ET		B-C-A-D	16-JUL-2019	08:02	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	08-MAY-2019	17:19	AST(SGOT)	54.8	U/L	No	<35
	Screening		D-A-C-B	08-MAY-2019	17:19	ALT(SGPT)	66.6	U/L	No	<35
	Screening		D-A-C-B	08-MAY-2019	17:19	Chloride	109	mmol/L	No	98-107
	EOS/ET		D-A-C-B	16-JUL-2019	08:02	AST(SGOT)	73.0	U/L	Yes	<35
	EOS/ET		D-A-C-B	16-JUL-2019	08:02	ALT(SGPT)	82.5	U/L	Yes	<35
	EOS/ET		D-A-C-B	16-JUL-2019	08:02	Blood Urea Nitrogen	7.0	mg/dL	No	7.9-20.0
	Screening		C-D-B-A	08-MAY-2019	17:15	Bilirubin	0.26	mg/dL	No	0.3-1.2
	Screening		C-D-B-A	08-MAY-2019	17:15	Potassium	5.2	mmol/L	No	3.5-5.1

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 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	08-MAY-2019	17:15	Chloride	109	mmol/L	No	98-107
	Screening		C-D-B-A	08-MAY-2019	17:15	Blood Urea Nitrogen	7.2	mg/dL	No	7.9-20.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Creatinine	1.12	mg/dL	No	0.51-0.95
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Albumin	2.93	g/dL	Yes	3.5-5.2
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Creatinine	1.02	mg/dL	No	0.51-0.95
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Glucose*	141.8	mg/dL	Yes	70-99
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Protein	6.49	g/dL	No	6.6-8.3
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Calcium	8.31	mg/dL	No	8.80-10.60
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Potassium	5.8	mmol/L	Yes	3.5-5.1
	Screening		C-D-B-A	08-MAY-2019	17:00	Sodium	135	mmol/L	No	136-145
	EOS/ET		C-D-B-A	16-JUL-2019	08:04	Alkaline Phosphatase	122	U/L	No	30-120
	EOS/ET		C-D-B-A	16-JUL-2019	08:04	Sodium	133	mmol/L	No	136-145
	EOS/ET		C-D-B-A	16-JUL-2019	08:04	Blood Urea Nitrogen	7.5	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	16-JUL-2019	08:04	Calcium	8.57	mg/dL	No	8.80-10.60
	Screening		B-C-A-D	30-APR-2019	17:00	Creatinine	0.47	mg/dL	No	0.51-0.95
	Screening		B-C-A-D	30-APR-2019	17:00	Cholesterol	211	mg/dL	No	<200
	Screening		B-C-A-D	30-APR-2019	17:00	Sodium	133	mmol/L	No	136-145

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Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	30-APR-2019	17:00	Blood Urea Nitrogen	7.3	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:04	Creatinine	0.47	mg/dL	No	0.51-0.95
	EOS/ET		B-C-A-D	16-JUL-2019	08:04	Blood Urea Nitrogen	7.0	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:04	Glucose*	100.7	mg/dL	No	70-99
	Screening		D-A-C-B	30-APR-2019	18:20	Cholesterol	225	mg/dL	No	<200
	Screening		D-A-C-B	30-APR-2019	18:20	Sodium	133	mmol/L	No	136-145
	Screening		D-A-C-B	30-APR-2019	18:20	Blood Urea Nitrogen	7.8	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	16-JUL-2019	08:04	Alkaline Phosphatase	134	U/L	No	30-120
	EOS/ET		D-A-C-B	16-JUL-2019	08:04	Blood Urea Nitrogen	6.0	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	16-JUL-2019	08:04	Glucose*	102.0	mg/dL	No	70-99
	Screening		A-B-D-C	30-APR-2019	17:44	Creatinine	0.46	mg/dL	No	0.51-0.95
	Screening		A-B-D-C	30-APR-2019	17:44	Cholesterol	207	mg/dL	No	<200
	Screening		A-B-D-C	30-APR-2019	17:44	Sodium	134	mmol/L	No	136-145
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	Creatinine	0.47	mg/dL	No	0.51-0.95
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	Cholesterol	203	mg/dL	No	<200

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Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	Alkaline Phosphatase	168	U/L	Yes	30-120
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	ALT(SGPT)	38.0	U/L	No	<35
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	Protein	8.32	g/dL	No	6.6-8.3
	EOS/ET		A-B-D-C	16-JUL-2019	08:04	Glucose*	100.4	mg/dL	No	70-99
	Safety Follow up		A-B-D-C	30-JUL-2019	11:02	Alkaline Phosphatase	152	U/L	Yes	30-120
	Safety Follow up 1		A-B-D-C	30-AUG-2019	10:38	Alkaline Phosphatase	130	U/L	No	30-120
	Screening		D-A-C-B	07-MAY-2019	16:14	Blood Urea Nitrogen	5.3	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	07-MAY-2019	16:14	Calcium	8.54	mg/dL	No	8.80-10.60
	EOS/ET		D-A-C-B	16-JUL-2019	08:06	Sodium	135	mmol/L	No	136-145
	EOS/ET		D-A-C-B	16-JUL-2019	08:06	Blood Urea Nitrogen	7.7	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	16-JUL-2019	08:06	Glucose*	106.8	mg/dL	No	70-99
	Screening		B-C-A-D	03-MAY-2019	16:52	Calcium	8.75	mg/dL	No	8.80-10.60
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Blood Urea Nitrogen	6.2	mg/dL	No	7.9-20.0

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Glucose*	151.8	mg/dL	Yes	70-99
	Screening		C-D-B-A	30-APR-2019	18:11	Cholesterol	215	mg/dL	No	<200
	EOS/ET		C-D-B-A	16-JUL-2019	09:00	Chloride	108	mmol/L	No	98-107
	EOS/ET		C-D-B-A	16-JUL-2019	09:00	Glucose*	103.2	mg/dL	No	70-99
	Screening		A-B-D-C	30-APR-2019	16:38	Creatinine	0.46	mg/dL	No	0.51-0.95
	Screening		A-B-D-C	30-APR-2019	16:38	Sodium	132	mmol/L	No	136-145
	EOS/ET		A-B-D-C	16-JUL-2019	09:00	Creatinine	0.45	mg/dL	No	0.51-0.95
	EOS/ET		A-B-D-C	16-JUL-2019	09:00	AST(SGOT)	42.0	U/L	No	<35
	EOS/ET		A-B-D-C	16-JUL-2019	09:00	ALT(SGPT)	43.0	U/L	No	<35
	EOS/ET		A-B-D-C	16-JUL-2019	09:00	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	16-JUL-2019	09:00	Glucose*	107.8	mg/dL	No	70-99
	Screening		D-A-C-B	07-MAY-2019	18:41	Cholesterol	223	mg/dL	No	<200
	EOS/ET		D-A-C-B	16-JUL-2019	09:00	Chloride	108	mmol/L	No	98-107
	EOS/ET		D-A-C-B	16-JUL-2019	09:00	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	16-JUL-2019	09:00	Glucose*	103.3	mg/dL	No	70-99
	Screening		C-D-B-A	07-MAY-2019	17:27	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	16-JUL-2019	09:02	Bilirubin	1.21	mg/dL	No	0.3-1.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	16-JUL-2019	09:02	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	16-JUL-2019	09:04	Blood Urea Nitrogen	6.8	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	07-MAY-2019	17:45	Bilirubin	1.30	mg/dL	No	0.3-1.2
	EOS/ET		A-B-D-C	16-JUL-2019	09:04	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	16-JUL-2019	09:04	Glucose*	101.5	mg/dL	No	70-99
	EOS/ET		B-C-A-D	16-JUL-2019	09:04	Creatinine	0.64	mg/dL	No	0.67-1.17
	EOS/ET		A-B-D-C	16-JUL-2019	09:06	Bicarbonate	32.7	mmol/L	No	21.0-32.0
	EOS/ET		A-B-D-C	16-JUL-2019	09:06	Glucose*	104.5	mg/dL	No	70-99
	Screening		C-D-B-A	07-MAY-2019	19:30	Bilirubin	1.47	mg/dL	No	0.3-1.2
	EOS/ET		C-D-B-A	16-JUL-2019	09:08	Bilirubin	1.41	mg/dL	No	0.3-1.2
	EOS/ET		C-D-B-A	16-JUL-2019	09:08	Blood Urea Nitrogen	7.8	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	16-JUL-2019	09:08	Glucose*	149.5	mg/dL	Yes	70-99
	Screening		C-D-B-A	07-MAY-2019	19:36	Cholesterol	208	mg/dL	No	<200
	Screening		C-D-B-A	07-MAY-2019	19:36	Blood Urea Nitrogen	6.0	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	16-JUL-2019	09:06	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0

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Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	08-MAY-2019	15:21	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	16-JUL-2019	09:06	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	16-JUL-2019	09:08	Potassium	5.2	mmol/L	No	3.5-5.1
	EOS/ET		A-B-D-C	16-JUL-2019	09:08	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	10-MAY-2019	17:36	Chloride	108	mmol/L	No	98-107
	EOS/ET		B-C-A-D	19-JUL-2019	08:00	ALT(SGPT)	36.2	U/L	No	<35
	EOS/ET		B-C-A-D	19-JUL-2019	08:00	Chloride	109	mmol/L	No	98-107
	EOS/ET		B-C-A-D	19-JUL-2019	08:00	Blood Urea Nitrogen	5.5	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	19-JUL-2019	08:00	Protein	6.56	g/dL	No	6.6-8.3
	EOS/ET		B-C-A-D	19-JUL-2019	08:00	Glucose*	101.3	mg/dL	No	70-99
	Screening		D-A-C-B	10-MAY-2019	17:41	Chloride	110	mmol/L	No	98-107
	Screening		D-A-C-B	10-MAY-2019	17:41	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	19-JUL-2019	08:00	Potassium	5.2	mmol/L	No	3.5-5.1
	EOS/ET		D-A-C-B	19-JUL-2019	08:00	Chloride	108	mmol/L	No	98-107
	EOS/ET		D-A-C-B	19-JUL-2019	08:00	Blood Urea Nitrogen	7.0	mg/dL	No	7.9-20.0

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Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

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Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		D-A-C-B	19-JUL-2019	08:00	Glucose*	103.1	mg/dL	No	70-99
	Screening		A-B-D-C	13-MAY-2019	17:34	Cholesterol	210	mg/dL	No	<200
	Screening		A-B-D-C	13-MAY-2019	17:34	ALT(SGPT)	51.6	U/L	No	<35
	Screening		A-B-D-C	13-MAY-2019	17:34	Chloride	108	mmol/L	No	98-107
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	Cholesterol	218	mg/dL	No	<200
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	Alkaline Phosphatase	140	U/L	Yes	30-120
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	AST(SGOT)	91.7	U/L	Yes	<35
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	ALT(SGPT)	137.2	U/L	Yes	<35
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	Sodium	135	mmol/L	No	136-145
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	Glucose*	110.7	mg/dL	Yes	70-99
	Safety Follow up		A-B-D-C	29-JUL-2019	11:09	Alkaline Phosphatase	128	U/L	Yes	30-120
	Safety Follow up		A-B-D-C	29-JUL-2019	11:09	ALT(SGPT)	45.1	U/L	No	<35
	Screening		C-D-B-A	10-MAY-2019	17:25	Chloride	110	mmol/L	No	98-107
	Screening		C-D-B-A	10-MAY-2019	17:25	Blood Urea Nitrogen	5.9	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Sodium	134	mmol/L	No	136-145
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Potassium	5.3	mmol/L	No	3.5-5.1
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Chloride	108	mmol/L	No	98-107

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	02-MAY-2019	17:41	Bilirubin	0.25	mg/dL	No	0.3-1.2
	Screening		B-C-A-D	02-MAY-2019	17:41	Cholesterol	204	mg/dL	No	<200
	Screening		B-C-A-D	02-MAY-2019	17:41	Chloride	110	mmol/L	No	98-107
	EOS/ET		B-C-A-D	19-JUL-2019	11:12	Alkaline Phosphatase	160	U/L	Yes	30-120
	EOS/ET		B-C-A-D	19-JUL-2019	11:12	ALT(SGPT)	47.4	U/L	No	<35
	EOS/ET		B-C-A-D	19-JUL-2019	11:12	Chloride	109	mmol/L	No	98-107
	EOS/ET		B-C-A-D	19-JUL-2019	11:12	Glucose*	109.1	mg/dL	No	70-99
	Screening		C-D-B-A	13-MAY-2019	17:40	Chloride	108	mmol/L	No	98-107
	Screening		C-D-B-A	13-MAY-2019	17:40	Blood Urea Nitrogen	7.7	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	AST(SGOT)	38.1	U/L	No	<35
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	ALT(SGPT)	37.3	U/L	No	<35
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Sodium	134	mmol/L	No	136-145
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Blood Urea Nitrogen	5.3	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	10-MAY-2019	17:05	Bilirubin	0.26	mg/dL	No	0.3-1.2
	Screening		A-B-D-C	10-MAY-2019	17:05	Chloride	109	mmol/L	No	98-107

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		A-B-D-C	06-JUN-2019	12:05	Bilirubin	0.27	mg/dL	No	0.3-1.2
	Screening		D-A-C-B	10-MAY-2019	17:30	Bilirubin	0.25	mg/dL	No	0.3-1.2
	Screening		D-A-C-B	10-MAY-2019	17:30	Chloride	109	mmol/L	No	98-107
	Screening		D-A-C-B	10-MAY-2019	17:30	Blood Urea Nitrogen	6.7	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	19-JUL-2019	08:09	Chloride	110	mmol/L	No	98-107
	EOS/ET		D-A-C-B	19-JUL-2019	08:09	Blood Urea Nitrogen	6.6	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	07-MAY-2019	18:18	Bilirubin	1.21	mg/dL	No	0.3-1.2
	EOS/ET		A-B-D-C	19-JUL-2019	08:04	Sodium	134	mmol/L	No	136-145
	EOS/ET		A-B-D-C	19-JUL-2019	08:04	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	19-JUL-2019	08:08	Blood Urea Nitrogen	3.8	mg/dL	No	7.9-20.0
	Screening		C-D-B-A	07-MAY-2019	20:09	Alkaline Phosphatase	140	U/L	No	30-120
	EOS/ET		C-D-B-A	19-JUL-2019	08:08	Alkaline Phosphatase	131	U/L	No	30-120
	EOS/ET		C-D-B-A	19-JUL-2019	08:08	Sodium	135	mmol/L	No	136-145
	EOS/ET		B-C-A-D	19-JUL-2019	08:12	Blood Urea Nitrogen	7.4	mg/dL	No	7.9-20.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	07-MAY-2019	17:23	Creatinine	0.61	mg/dL	No	0.67-1.17
	Screening		C-D-B-A	07-MAY-2019	17:23	Blood Urea Nitrogen	5.8	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:12	Creatinine	0.66	mg/dL	No	0.67-1.17
	EOS/ET		C-D-B-A	19-JUL-2019	08:12	Sodium	135	mmol/L	No	136-145
	EOS/ET		C-D-B-A	19-JUL-2019	08:12	Potassium	5.5	mmol/L	Yes	3.5-5.1
	EOS/ET		C-D-B-A	19-JUL-2019	08:12	Blood Urea Nitrogen	6.8	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	19-JUL-2019	08:12	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	08-MAY-2019	15:52	Creatinine	0.66	mg/dL	No	0.67-1.17
	Screening		D-A-C-B	08-MAY-2019	15:52	Chloride	109	mmol/L	No	98-107
	Screening		D-A-C-B	08-MAY-2019	15:52	Blood Urea Nitrogen	6.0	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	19-JUL-2019	09:00	ALT(SGPT)	63.8	U/L	No	<50
	EOS/ET		D-A-C-B	19-JUL-2019	09:00	Sodium	134	mmol/L	No	136-145
	EOS/ET		D-A-C-B	19-JUL-2019	09:00	Chloride	111	mmol/L	No	98-107
	EOS/ET		D-A-C-B	19-JUL-2019	09:00	Bicarbonate	20.0	mmol/L	No	21.0-32.0
	EOS/ET		D-A-C-B	19-JUL-2019	09:00	Blood Urea Nitrogen	5.0	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	09-MAY-2019	16:51	Creatinine	0.57	mg/dL	No	0.67-1.17

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		A-B-D-C	09-MAY-2019	16:51	Chloride	110	mmol/L	No	98-107
	Screening		A-B-D-C	09-MAY-2019	16:51	Blood Urea Nitrogen	6.4	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	Bilirubin	1.22	mg/dL	No	0.3-1.2
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	AST(SGOT)	51.0	U/L	No	<50
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	ALT(SGPT)	50.3	U/L	No	<50
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	Sodium	135	mmol/L	No	136-145
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	Chloride	110	mmol/L	No	98-107
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	Blood Urea Nitrogen	4.8	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	09-MAY-2019	17:21	Creatinine	0.66	mg/dL	No	0.67-1.17
	EOS/ET		D-A-C-B	19-JUL-2019	09:00	Sodium	133	mmol/L	No	136-145
	EOS/ET		C-D-B-A	19-JUL-2019	09:00	Sodium	135	mmol/L	No	136-145
	EOS/ET		C-D-B-A	19-JUL-2019	09:00	Blood Urea Nitrogen	5.6	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	10-MAY-2019	17:57	Bicarbonate	35.0	mmol/L	No	21.0-32.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:03	Alkaline Phosphatase	121	U/L	No	30-120
	EOS/ET		B-C-A-D	19-JUL-2019	09:03	ALT(SGPT)	53.8	U/L	No	<50
	EOS/ET		B-C-A-D	19-JUL-2019	09:03	Sodium	135	mmol/L	No	136-145

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	19-JUL-2019	09:03	Potassium	5.5	mmol/L	Yes	3.5-5.1
	EOS/ET		B-C-A-D	19-JUL-2019	09:03	Blood Urea Nitrogen	5.3	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	19-JUL-2019	09:03	Glucose*	105.4	mg/dL	No	70-99
	Safety Follow up		B-C-A-D	26-JUL-2019	11:33	Potassium	5.2	mmol/L	No	3.5-5.1
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	Cholesterol	207	mg/dL	No	<200
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	Alkaline Phosphatase	132	U/L	No	30-120
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	ALT(SGPT)	92.2	U/L	Yes	<50
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	Potassium	5.3	mmol/L	No	3.5-5.1
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	Protein	8.41	g/dL	No	6.6-8.3
	Safety Follow up		C-D-B-A	25-JUL-2019	12:20	ALT(SGPT)	70.1	U/L	Yes	<50
	Safety Follow up 1		C-D-B-A	01-AUG-2019	10:50	ALT(SGPT)	80.6	U/L	Yes	<50
	EOS/ET		A-B-D-C	19-JUL-2019	09:03	Chloride	108	mmol/L	No	98-107
	Screening		B-C-A-D	10-MAY-2019	18:50	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	19-JUL-2019	09:06	Chloride	111	mmol/L	No	98-107
	EOS/ET		B-C-A-D	19-JUL-2019	09:06	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	19-JUL-2019	09:06	Protein	6.59	g/dL	No	6.6-8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	13-MAY-2019	18:10	Sodium	135	mmol/L	No	136-145
	Screening		D-A-C-B	13-MAY-2019	18:10	Blood Urea Nitrogen	5.4	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	19-JUL-2019	09:06	Sodium	134	mmol/L	No	136-145
	EOS/ET		D-A-C-B	19-JUL-2019	09:06	Potassium	5.3	mmol/L	No	3.5-5.1
	EOS/ET		D-A-C-B	19-JUL-2019	09:06	Blood Urea Nitrogen	5.5	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	27-JUN-2019	10:41	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	27-JUN-2019	10:41	Glucose*	107.2	mg/dL	No	70-99
	Screening		D-A-C-B	13-MAY-2019	18:22	Blood Urea Nitrogen	7.4	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	13-MAY-2019	17:48	Creatinine	0.62	mg/dL	No	0.67-1.17
	Screening		B-C-A-D	13-MAY-2019	17:48	Protein	6.51	g/dL	No	6.6-8.3
	EOS/ET		B-C-A-D	19-JUL-2019	09:10	Sodium	133	mmol/L	No	136-145
	EOS/ET		B-C-A-D	19-JUL-2019	09:10	Blood Urea Nitrogen	7.4	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	19-JUL-2019	09:10	Glucose*	104.8	mg/dL	No	70-99
	Screening		A-B-D-C	13-MAY-2019	17:52	Sodium	134	mmol/L	No	136-145
	Screening		A-B-D-C	13-MAY-2019	17:52	Potassium	5.3	mmol/L	No	3.5-5.1
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Sodium	130	mmol/L	No	136-145

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Potassium	5.6	mmol/L	Yes	3.5-5.1
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Bicarbonate	20.1	mmol/L	No	21.0-32.0
	Screening		D-A-C-B	02-MAY-2019	17:11	Chloride	108	mmol/L	No	98-107
	Screening		D-A-C-B	02-MAY-2019	17:11	Bicarbonate	37.3	mmol/L	Yes	21.0-32.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:00	ALT(SGPT)	43.5	U/L	No	<35
	EOS/ET		D-A-C-B	25-JUL-2019	08:00	Blood Urea Nitrogen	6.2	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:00	Glucose*	105.7	mg/dL	No	70-99
	Screening		C-D-B-A	20-MAY-2019	15:41	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:00	Sodium	135	mmol/L	No	136-145
	EOS/ET		C-D-B-A	25-JUL-2019	08:00	Blood Urea Nitrogen	6.1	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	20-MAY-2019	15:55	Chloride	112	mmol/L	No	98-107
	Screening		B-C-A-D	20-MAY-2019	15:55	Protein	6.59	g/dL	No	6.6-8.3
	EOS/ET		B-C-A-D	25-JUL-2019	08:00	Sodium	134	mmol/L	No	136-145
	EOS/ET		B-C-A-D	25-JUL-2019	08:00	Chloride	108	mmol/L	No	98-107
	EOS/ET		B-C-A-D	25-JUL-2019	08:00	Blood Urea Nitrogen	7.3	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	25-JUL-2019	08:00	Calcium	8.53	mg/dL	No	8.80-10.60

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	25-JUL-2019	08:00	Protein	6.44	g/dL	No	6.6-8.3
	Screening		A-B-D-C	21-MAY-2019	15:55	Chloride	108	mmol/L	No	98-107
	Screening		A-B-D-C	21-MAY-2019	15:55	Bicarbonate	33.6	mmol/L	No	21.0-32.0
	Screening		A-B-D-C	21-MAY-2019	15:55	Blood Urea Nitrogen	6.2	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:00	Sodium	133	mmol/L	No	136-145
	EOS/ET		A-B-D-C	25-JUL-2019	08:00	Blood Urea Nitrogen	4.5	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	21-MAY-2019	15:36	Creatinine	0.48	mg/dL	No	0.51-0.95
	Screening		B-C-A-D	21-MAY-2019	15:36	Chloride	109	mmol/L	No	98-107
	Screening		B-C-A-D	21-MAY-2019	15:36	Calcium	8.64	mg/dL	No	8.80-10.60
	EOS/ET		B-C-A-D	25-JUL-2019	08:03	Creatinine	0.48	mg/dL	No	0.51-0.95
	EOS/ET		B-C-A-D	25-JUL-2019	08:03	Chloride	108	mmol/L	No	98-107
	EOS/ET		B-C-A-D	25-JUL-2019	08:03	Blood Urea Nitrogen	6.2	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	25-JUL-2019	08:03	Calcium	8.47	mg/dL	No	8.80-10.60
	Screening		D-A-C-B	08-MAY-2019	15:32	Bilirubin	1.32	mg/dL	No	0.3-1.2
	Screening		D-A-C-B	08-MAY-2019	15:32	Blood Urea Nitrogen	7.3	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:03	Alkaline Phosphatase	128	U/L	No	30-120

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		D-A-C-B	25-JUL-2019	08:03	Sodium	135	mmol/L	No	136-145
	EOS/ET		D-A-C-B	25-JUL-2019	08:03	Blood Urea Nitrogen	7.7	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	10-MAY-2019	18:07	Blood Urea Nitrogen	6.4	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:03	Chloride	110	mmol/L	No	98-107
	EOS/ET		A-B-D-C	25-JUL-2019	08:03	Blood Urea Nitrogen	6.2	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:03	Blood Urea Nitrogen	7.4	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:06	Chloride	110	mmol/L	No	98-107
	EOS/ET		D-A-C-B	25-JUL-2019	08:06	Blood Urea Nitrogen	6.6	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	15-MAY-2019	18:22	Blood Urea Nitrogen	7.1	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	25-JUL-2019	08:06	Blood Urea Nitrogen	7.8	mg/dL	No	7.9-20.0
	Screening		C-D-B-A	15-MAY-2019	18:18	Blood Urea Nitrogen	7.8	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:06	Blood Urea Nitrogen	5.1	mg/dL	No	7.9-20.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		A-B-D-C	15-MAY-2019	18:31	Alkaline Phosphatase	134	U/L	No	30-120
	Screening		A-B-D-C	15-MAY-2019	18:31	Chloride	109	mmol/L	No	98-107
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Alkaline Phosphatase	162	U/L	Yes	30-120
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	AST(SGOT)	70.2	U/L	Yes	<50
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Chloride	113	mmol/L	No	98-107
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Blood Urea Nitrogen	4.5	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Calcium	8.49	mg/dL	No	8.80-10.60
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Protein	6.58	g/dL	No	6.6-8.3
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Glucose*	139.8	mg/dL	Yes	70-99
	Safety Follow up		A-B-D-C	20-AUG-2019	11:40	Alkaline Phosphatase	137	U/L	No	30-120
	Screening		C-D-B-A	15-MAY-2019	18:13	Creatinine	0.63	mg/dL	No	0.67-1.17
	Screening		C-D-B-A	15-MAY-2019	18:13	Bicarbonate	26.8	mmol/L	No	21.0-32.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:10	Creatinine	0.65	mg/dL	No	0.67-1.17
	EOS/ET		C-D-B-A	25-JUL-2019	08:10	Bicarbonate	27.0	mmol/L	No	21.0-32.0
	Screening		A-B-D-C	15-MAY-2019	17:35	Alkaline Phosphatase	129	U/L	No	30-120
	EOS/ET		A-B-D-C	25-JUL-2019	08:08	Creatinine	0.65	mg/dL	No	0.67-1.17

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		A-B-D-C	25-JUL-2019	08:08	Alkaline Phosphatase	122	U/L	No	30-120
	EOS/ET		A-B-D-C	25-JUL-2019	08:08	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	25-JUL-2019	09:00	Blood Urea Nitrogen	7.5	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	16-MAY-2019	16:06	Bilirubin	1.31	mg/dL	No	0.3-1.2
	Screening		D-A-C-B	16-MAY-2019	16:06	Protein	6.56	g/dL	No	6.6-8.3
	EOS/ET		D-A-C-B	25-JUL-2019	09:00	Chloride	108	mmol/L	No	98-107
	EOS/ET		D-A-C-B	25-JUL-2019	09:00	Protein	6.44	g/dL	No	6.6-8.3
	Screening		B-C-A-D	16-MAY-2019	16:45	Chloride	108	mmol/L	No	98-107
	EOS/ET		B-C-A-D	25-JUL-2019	09:00	Blood Urea Nitrogen	6.7	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	16-MAY-2019	16:03	Bilirubin	1.45	mg/dL	No	0.3-1.2
	Screening		C-D-B-A	16-MAY-2019	17:02	Chloride	108	mmol/L	No	98-107
	Screening		C-D-B-A	16-MAY-2019	17:02	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:03	Blood Urea Nitrogen	6.6	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:03	Alkaline Phosphatase	123	U/L	No	30-120

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		A-B-D-C	25-JUL-2019	09:03	Potassium	5.3	mmol/L	No	3.5-5.1
	Screening		A-B-D-C	16-MAY-2019	16:12	Blood Urea Nitrogen	7.1	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:03	Cholesterol	225	mg/dL	No	<200
	EOS/ET		A-B-D-C	25-JUL-2019	09:03	Blood Urea Nitrogen	7.4	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	16-MAY-2019	16:51	Creatinine	0.61	mg/dL	No	0.67-1.17
	Screening		C-D-B-A	16-MAY-2019	16:36	Blood Urea Nitrogen	7.7	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:06	Blood Urea Nitrogen	5.3	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	16-MAY-2019	17:10	Creatinine	0.66	mg/dL	No	0.67-1.17
	Screening		D-A-C-B	16-MAY-2019	17:10	Alkaline Phosphatase	141	U/L	No	30-120
	Screening		D-A-C-B	16-MAY-2019	17:10	Chloride	109	mmol/L	No	98-107
	Screening		D-A-C-B	16-MAY-2019	17:10	Blood Urea Nitrogen	7.2	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Alkaline Phosphatase	147	U/L	No	30-120
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Sodium	134	mmol/L	No	136-145
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	16-MAY-2019	16:09	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:07	Sodium	135	mmol/L	No	136-145
	EOS/ET		C-D-B-A	25-JUL-2019	09:07	Blood Urea Nitrogen	6.6	mg/dL	No	7.9-20.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:07	Glucose*	101.0	mg/dL	No	70-99
	Screening		D-A-C-B	15-MAY-2019	19:01	Sodium	135	mmol/L	No	136-145
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Chloride	109	mmol/L	No	98-107
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Blood Urea Nitrogen	7.5	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Glucose*	104.7	mg/dL	No	70-99
	Screening		A-B-D-C	16-MAY-2019	16:53	Creatinine	0.66	mg/dL	No	0.67-1.17
	Screening		A-B-D-C	16-MAY-2019	16:53	Sodium	134	mmol/L	No	136-145
	Screening		A-B-D-C	16-MAY-2019	16:53	Blood Urea Nitrogen	7.3	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:08	Blood Urea Nitrogen	5.7	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	15-MAY-2019	17:27	Cholesterol	216	mg/dL	No	<200
	Screening		C-D-B-A	10-MAY-2019	18:42	Sodium	135	mmol/L	No	136-145
	Screening		A-B-D-C	10-MAY-2019	18:54	Sodium	135	mmol/L	No	136-145
	Screening		B-C-A-D	10-MAY-2019	19:07	Chloride	108	mmol/L	No	98-107

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	29-JUL-2019	08:00	Potassium	5.6	mmol/L	Yes	3.5-5.1
	Screening		A-B-D-C	10-MAY-2019	18:11	Bilirubin	1.57	mg/dL	Yes	0.3-1.2
	Screening Repeat		A-B-D-C	16-MAY-2019	14:34	Bilirubin	1.33	mg/dL	No	0.3-1.2
	EOS/ET		A-B-D-C	29-JUL-2019	08:03	Alkaline Phosphatase	125	U/L	No	30-120
	EOS/ET		A-B-D-C	29-JUL-2019	08:03	Potassium	5.4	mmol/L	No	3.5-5.1
	EOS/ET		A-B-D-C	29-JUL-2019	08:03	Chloride	108	mmol/L	No	98-107
	EOS/ET		A-B-D-C	29-JUL-2019	08:03	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	13-MAY-2019	18:26	Sodium	134	mmol/L	No	136-145
	Screening		D-A-C-B	13-MAY-2019	18:26	Calcium	8.32	mg/dL	No	8.80-10.60
	EOS/ET		D-A-C-B	29-JUL-2019	08:02	Chloride	108	mmol/L	No	98-107
	EOS/ET		D-A-C-B	29-JUL-2019	08:02	Blood Urea Nitrogen	6.4	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	29-JUL-2019	08:02	Calcium	8.63	mg/dL	No	8.80-10.60
	Screening		C-D-B-A	13-MAY-2019	18:06	Cholesterol	223	mg/dL	No	<200
	EOS/ET		C-D-B-A	29-JUL-2019	08:03	Cholesterol	217	mg/dL	No	<200
	EOS/ET		C-D-B-A	29-JUL-2019	08:03	Chloride	109	mmol/L	No	98-107
	EOS/ET		C-D-B-A	29-JUL-2019	08:03	Blood Urea Nitrogen	6.2	mg/dL	No	7.9-20.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	15-MAY-2019	18:57	Chloride	108	mmol/L	No	98-107
	Screening		B-C-A-D	15-MAY-2019	18:57	Blood Urea Nitrogen	7.2	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	29-JUL-2019	08:03	Chloride	108	mmol/L	No	98-107
	Screening		A-B-D-C	15-MAY-2019	18:08	Blood Urea Nitrogen	7.5	mg/dL	No	7.9-20.0
	EOS/ET		A-B-D-C	29-JUL-2019	08:06	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	EOS/ET		B-C-A-D	29-JUL-2019	08:06	Chloride	108	mmol/L	No	98-107
	Screening		C-D-B-A	20-MAY-2019	17:06	Cholesterol	210	mg/dL	No	<200
	Screening		C-D-B-A	20-MAY-2019	17:06	Protein	8.44	g/dL	No	6.6-8.3
	EOS/ET		C-D-B-A	08-AUG-2019	13:32	Bicarbonate	33.2	mmol/L	No	21.0-32.0
	EOS/ET		C-D-B-A	08-AUG-2019	13:32	Glucose*	99.5	mg/dL	No	70-99
	Safety Follow up		C-D-B-A	29-JUL-2019	09:46	Sodium	135	mmol/L	No	136-145
	Screening		D-A-C-B	20-MAY-2019	16:41	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	EOS/ET		D-A-C-B	29-JUL-2019	08:06	Chloride	108	mmol/L	No	98-107
	EOS/ET		D-A-C-B	29-JUL-2019	08:06	Blood Urea Nitrogen	6.0	mg/dL	No	7.9-20.0
	Screening		C-D-B-A	20-MAY-2019	17:10	Chloride	109	mmol/L	No	98-107
	EOS/ET		C-D-B-A	29-JUL-2019	11:39	Chloride	110	mmol/L	No	98-107

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	20-MAY-2019	16:21	Cholesterol	233	mg/dL	No	<200
	EOS/ET		B-C-A-D	29-JUL-2019	09:00	Blood Urea Nitrogen	6.1	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	21-MAY-2019	17:20	Alkaline Phosphatase	125	U/L	No	30-120
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	Alkaline Phosphatase	156	U/L	Yes	30-120
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	ALT(SGPT)	54.0	U/L	No	<50
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	Blood Urea Nitrogen	7.3	mg/dL	No	7.9-20.0
	Safety Follow up		A-B-D-C	19-AUG-2019	11:43	Alkaline Phosphatase	161	U/L	Yes	30-120
	Safety Follow up1		A-B-D-C	26-AUG-2019	10:17	Alkaline Phosphatase	171	U/L	Yes	30-120
	Screening		C-D-B-A	21-MAY-2019	15:07	Cholesterol	233	mg/dL	No	<200
	Screening		C-D-B-A	21-MAY-2019	15:07	Bicarbonate	33.0	mmol/L	No	21.0-32.0
	EOS/ET		C-D-B-A	29-JUL-2019	09:00	ALT(SGPT)	67.7	U/L	Yes	<50
	EOS/ET		C-D-B-A	29-JUL-2019	09:00	Sodium	135	mmol/L	No	136-145
	EOS/ET		C-D-B-A	29-JUL-2019	09:00	Blood Urea Nitrogen	6.3	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	21-MAY-2019	16:44	Sodium	133	mmol/L	No	136-145

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	21-MAY-2019	17:05	Sodium	133	mmol/L	No	136-145
	Screening		B-C-A-D	21-MAY-2019	17:40	ALT(SGPT)	53.6	U/L	No	<50
	Screening		B-C-A-D	21-MAY-2019	17:40	Sodium	134	mmol/L	No	136-145
	EOS/ET		B-C-A-D	29-JUL-2019	09:02	Chloride	108	mmol/L	No	98-107
	EOS/ET		C-D-B-A	29-JUL-2019	09:02	Sodium	135	mmol/L	No	136-145
	EOS/ET		A-B-D-C	29-JUL-2019	09:04	Blood Urea Nitrogen	6.5	mg/dL	No	7.9-20.0
	Screening		D-A-C-B	23-MAY-2019	16:01	Creatinine	0.62	mg/dL	No	0.67-1.17
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	Sodium	135	mmol/L	No	136-145
	Screening		D-A-C-B	23-MAY-2019	15:36	Creatinine	0.61	mg/dL	No	0.67-1.17
	Screening		D-A-C-B	23-MAY-2019	15:36	Chloride	108	mmol/L	No	98-107
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	Blood Urea Nitrogen	7.4	mg/dL	No	7.9-20.0
	Screening		A-B-D-C	23-MAY-2019	15:18	Bilirubin	1.28	mg/dL	No	0.3-1.2
	Screening		A-B-D-C	23-MAY-2019	15:18	Creatinine	0.63	mg/dL	No	0.67-1.17
	EOS/ET		A-B-D-C	29-JUL-2019	09:04	Blood Urea Nitrogen	6.9	mg/dL	No	7.9-20.0
	Screening		B-C-A-D	20-MAY-2019	16:58	Protein	6.59	g/dL	No	6.6-8.3
	EOS/ET		B-C-A-D	29-JUL-2019	09:06	Cholesterol	203	mg/dL	No	<200

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 12:01 PM by Table 14.3.4.1.sas
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Table 14.3.4.1. Out of range Laboratory Values - Serum Chemistry, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	29-JUL-2019	09:06	Blood Urea Nitrogen	6.6	mg/dL	No	7.9-20.0
Source: Listing 16.2.8.2 *Note: Screening : Random Glucose test was done EOS/ET & Safety Follow up visit: Fasting Glucose test was done Safety Follow up & Safety Follow up1: Follow up visits										

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
[REDACTED]	Screening	[REDACTED]	D-A-C-B	30-APR-2019	17:38	Hemoglobin	11.1	g/dL	No	12.0-15.0
	Screening		D-A-C-B	30-APR-2019	17:38	Hematocrit	33.9	%	No	35.0-47.0
	EOS/ET		D-A-C-B	16-JUL-2019	08:00	Hemoglobin	11.1	g/dL	No	12.0-15.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:00	RBC	4.85	10 ⁶ /uL	No	3.80-4.80
	Screening		C-D-B-A	30-APR-2019	17:28	RBC	4.95	10 ⁶ /uL	No	3.80-4.80
	Screening		C-D-B-A	30-APR-2019	17:28	Hemoglobin	11.3	g/dL	No	12.0-15.0
	Screening		C-D-B-A	30-APR-2019	17:28	Platelets	526	10 ³ /uL	No	150-400
	EOS/ET		C-D-B-A	16-JUL-2019	08:00	Hemoglobin	10.0	g/dL	Yes	12.0-15.0
	EOS/ET		C-D-B-A	16-JUL-2019	08:00	Hematocrit	32.3	%	No	35.0-47.0
	EOS/ET		C-D-B-A	16-JUL-2019	08:00	Platelets	525	10 ³ /uL	No	150-400
	Safety Follow up		C-D-B-A	28-AUG-2019	12:42	Hemoglobin	9.8	g/dL	Yes	12.0-15.0
	Safety Follow up		C-D-B-A	27-SEP-2019	16:26	Hemoglobin	11.3	g/dL	No	12.0-15.0
	EOS/ET		A-B-D-C	16-JUL-2019	08:00	RBC	4.86	10 ⁶ /uL	No	3.80-4.80
	Screening		B-C-A-D	07-MAY-2019	16:24	RBC	3.74	10 ⁶ /uL	No	3.80-4.80
	Screening		B-C-A-D	07-MAY-2019	16:24	Hemoglobin	11.2	g/dL	No	12.0-15.0
	Screening		B-C-A-D	07-MAY-2019	16:24	Hematocrit	33.6	%	No	35.0-47.0
EOS/ET	B-C-A-D	16-JUL-2019	08:02	Hemoglobin	11.3	g/dL	No	12.0-15.0		

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	16-JUL-2019	08:02	Hematocrit	34.7	%	No	35.0-47.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:02	Platelets	444	10 ³ /uL	No	150-400
	Screening		A-B-D-C	08-MAY-2019	16:43	RBC	4.83	10 ⁶ /uL	No	3.80-4.80
	Screening		A-B-D-C	08-MAY-2019	16:43	Hemoglobin	11.3	g/dL	No	12.0-15.0
	EOS/ET		A-B-D-C	16-JUL-2019	08:02	Hemoglobin	10.1	g/dL	No	12.0-15.0
	EOS/ET		A-B-D-C	16-JUL-2019	08:02	Hematocrit	32.1	%	No	35.0-47.0
	Screening		C-D-B-A	08-MAY-2019	17:15	Hemoglobin	11.8	g/dL	No	12.0-15.0
	Screening		C-D-B-A	08-MAY-2019	17:15	Platelets	425	10 ³ /uL	No	150-400
	Screening		C-D-B-A	08-MAY-2019	17:15	Eosinophils/Leukocytes	6.3	%	No	1.0-6.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Leukocytes	16.0	10 ³ /uL	Yes	4.0-11.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Hemoglobin	9.9	g/dL	Yes	12.0-15.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Hematocrit	30.6	%	Yes	35.0-47.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	MCV	77	fL	Yes	83.0-101.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	MCH	24.8	pg	Yes	27.0-32.0

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 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Neutrophils	11.84	10 ⁹ /L	Yes	2.00-7.00
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Eosinophils/Leukocytes	00	%	No	1.0-6.0
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Eosinophils	0.00	10 ⁹ /L	No	0.02-0.50
	Safety Follow up		C-D-B-A	13-JUL-2019	16:15	Lymphocytes	3.52	10 ⁹ /L	No	1.00-3.00
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Leukocytes	25.7	10 ³ /uL	Yes	4.0-11.0
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Hemoglobin	11.1	g/dL	No	12.0-15.0
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Hematocrit	34.7	%	No	35.0-47.0
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	MCV	77	fL	No	83.0-101.0
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	MCH	24.8	pg	No	27.0-32.0
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Platelets	512	10 ⁹ /L	No	150-400
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Neutrophils/Leukocytes	90	%	Yes	40.0-75.0

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 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Neutrophils	23.13	10 ⁹ /L	Yes	2.00-7.00
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Lymphocytes/Leukocytes	05	%	No	20.0-40.0
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:45	Monocytes	1.03	10 ⁹ /L	No	0.20-1.00
	Screening		C-D-B-A	08-MAY-2019	17:00	Hemoglobin	11.9	g/dL	No	12.0-15.0
	Screening		C-D-B-A	08-MAY-2019	17:00	Monocytes/Leukocytes	11.5	%	No	2.0-10.0
	Screening		B-C-A-D	30-APR-2019	17:00	Hemoglobin	10.8	g/dL	No	12.0-15.0
	Screening		B-C-A-D	30-APR-2019	17:00	Hematocrit	32.8	%	No	35.0-47.0
	Screening		B-C-A-D	30-APR-2019	17:00	Eosinophils/Leukocytes	0.8	%	No	1.0-6.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:04	Hemoglobin	10.9	g/dL	No	12.0-15.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:04	Hematocrit	33.5	%	No	35.0-47.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:04	Platelets	415	10 ³ /uL	No	150-400
	Screening		D-A-C-B	30-APR-2019	18:20	RBC	5.68	10 ⁶ /uL	No	3.80-4.80
	EOS/ET		D-A-C-B	16-JUL-2019	08:04	RBC	5.35	10 ⁶ /uL	No	3.80-4.80
	Screening		D-A-C-B	07-MAY-2019	16:14	RBC	3.77	10 ⁶ /uL	No	3.80-4.80
	Screening		D-A-C-B	07-MAY-2019	16:14	Hemoglobin	11.1	g/dL	No	12.0-15.0
	Screening		D-A-C-B	07-MAY-2019	16:14	Hematocrit	33.6	%	No	35.0-47.0

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 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	07-MAY-2019	16:14	Eosinophils/Leukocytes	6.1	%	No	1.0-6.0
	Screening		B-C-A-D	03-MAY-2019	16:52	Hemoglobin	11.9	g/dL	No	12.0-15.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Platelets	139	10 ³ /uL	No	150-400
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Neutrophils/Leukocytes	79.9	%	No	40.0-75.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Eosinophils/Leukocytes	0.9	%	No	1.0-6.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Lymphocytes/Leukocytes	17.3	%	No	20.0-40.0
	EOS/ET		B-C-A-D	16-JUL-2019	08:32	Monocytes/Leukocytes	1.9	%	No	2.0-10.0
	Screening		C-D-B-A	30-APR-2019	18:11	Lymphocytes/Leukocytes	44.2	%	No	20.0-40.0
	Screening		A-B-D-C	30-APR-2019	16:38	Lymphocytes/Leukocytes	40.1	%	No	20.0-40.0
	Screening		D-A-C-B	07-MAY-2019	18:41	Hemoglobin	11.6	g/dL	No	12.0-15.0
	Screening		D-A-C-B	07-MAY-2019	18:41	Platelets	404	10 ³ /uL	No	150-400
	EOS/ET		D-A-C-B	16-JUL-2019	09:00	RBC	3.77	10 ⁶ /uL	No	3.80-4.80
	EOS/ET		D-A-C-B	16-JUL-2019	09:00	Hemoglobin	11.2	g/dL	No	12.0-15.0
	EOS/ET		D-A-C-B	16-JUL-2019	09:00	Hematocrit	34.0	%	No	35.0-47.0
	Screening		C-D-B-A	07-MAY-2019	17:27	RBC	4.47	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	16-JUL-2019	09:02	Eosinophils/Leukocytes	6.5	%	No	1.0-6.0
	Screening		B-C-A-D	07-MAY-2019	16:44	Eosinophils/Leukocytes	7.9	%	No	1.0-6.0
	Screening		B-C-A-D	07-MAY-2019	16:44	Lymphocytes/Leukocytes	42.3	%	No	20.0-40.0

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 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	07-MAY-2019	18:28	Lymphocytes/Leukocytes	42.4	%	No	20.0-40.0
	EOS/ET		D-A-C-B	16-JUL-2019	09:06	Platelets	441	10 ³ /uL	No	150-400
	Screening		A-B-D-C	07-MAY-2019	19:57	Lymphocytes/Leukocytes	47.8	%	No	20.0-40.0
	EOS/ET		A-B-D-C	16-JUL-2019	09:06	RBC	5.53	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		A-B-D-C	16-JUL-2019	09:06	Lymphocytes/Leukocytes	46.9	%	No	20.0-40.0
	Screening		C-D-B-A	07-MAY-2019	19:30	Lymphocytes/Leukocytes	43.2	%	No	20.0-40.0
	Screening		C-D-B-A	07-MAY-2019	19:36	Lymphocytes/Leukocytes	42.1	%	No	20.0-40.0
	EOS/ET		C-D-B-A	16-JUL-2019	08:32	Lymphocytes/Leukocytes	43.5	%	No	20.0-40.0
	EOS/ET		D-A-C-B	16-JUL-2019	09:06	Lymphocytes/Leukocytes	44.9	%	No	20.0-40.0
	Screening		A-B-D-C	08-MAY-2019	15:27	Eosinophils/Leukocytes	8.1	%	No	1.0-6.0
	Screening		A-B-D-C	08-MAY-2019	15:27	Lymphocytes/Leukocytes	43.6	%	No	20.0-40.0
	EOS/ET		A-B-D-C	16-JUL-2019	09:08	Lymphocytes/Leukocytes	48.4	%	No	20.0-40.0
	Screening		B-C-A-D	10-MAY-2019	17:36	RBC	4.85	10 ⁶ /uL	No	3.80-4.80
	Screening		D-A-C-B	10-MAY-2019	17:41	RBC	5.14	10 ⁶ /uL	No	3.80-4.80
	EOS/ET		D-A-C-B	19-JUL-2019	08:00	RBC	4.85	10 ⁶ /uL	No	3.80-4.80
	EOS/ET		D-A-C-B	19-JUL-2019	08:00	Hemoglobin	11.4	g/dL	No	12.0-15.0
	Screening		A-B-D-C	13-MAY-2019	17:34	Hemoglobin	11.7	g/dL	No	12.0-15.0
	EOS/ET		A-B-D-C	19-JUL-2019	08:01	RBC	4.85	10 ⁶ /uL	No	3.80-4.80

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 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	10-MAY-2019	17:25	Lymphocytes/Leukocytes	40.1	%	No	20.0-40.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Lymphocytes/Leukocytes	42.5	%	No	20.0-40.0
	Screening		C-D-B-A	13-MAY-2019	17:40	Hemoglobin	11.6	g/dL	No	12.0-15.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Hemoglobin	11.0	g/dL	No	12.0-15.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:03	Hematocrit	34.6	%	No	35.0-47.0
	Screening		A-B-D-C	10-MAY-2019	17:05	Hemoglobin	11.0	g/dL	No	12.0-15.0
	EOS/ET		A-B-D-C	06-JUN-2019	12:05	RBC	4.85	10 ⁶ /uL	No	3.80-4.80
	EOS/ET		A-B-D-C	06-JUN-2019	12:05	Hemoglobin	11.6	g/dL	No	12.0-15.0
	Screening		D-A-C-B	10-MAY-2019	17:30	Hemoglobin	11.1	g/dL	No	12.0-15.0
	Screening		D-A-C-B	10-MAY-2019	17:30	Hematocrit	34.8	%	No	35.0-47.0
	Screening		D-A-C-B	10-MAY-2019	17:30	Lymphocytes/Leukocytes	45.3	%	No	20.0-40.0
	EOS/ET		D-A-C-B	19-JUL-2019	08:09	Hemoglobin	11.2	g/dL	No	12.0-15.0
	EOS/ET		D-A-C-B	19-JUL-2019	08:09	Platelets	444	10 ³ /uL	No	150-400
	EOS/ET		A-B-D-C	19-JUL-2019	08:04	Platelets	429	10 ³ /uL	No	150-400
	Screening		D-A-C-B	07-MAY-2019	20:27	Eosinophils/Leukocytes	6.5	%	No	1.0-6.0
	Screening		D-A-C-B	07-MAY-2019	20:27	Lymphocytes/Leukocytes	19.8	%	No	20.0-40.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:08	Neutrophils/Leukocytes	39.6	%	No	40.0-75.0
	EOS/ET		C-D-B-A	19-JUL-2019	08:08	Lymphocytes/Leukocytes	51.8	%	No	20.0-40.0

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 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
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Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	07-MAY-2019	17:23	RBC	3.72	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	19-JUL-2019	08:12	RBC	3.76	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	19-JUL-2019	08:12	Eosinophils/Leukocytes	8.9	%	No	1.0-6.0
	Screening		B-C-A-D	07-MAY-2019	16:59	RBC	5.97	10 ⁶ /uL	No	4.50-5.50
	Screening		B-C-A-D	07-MAY-2019	16:59	Lymphocytes/Leukocytes	43.8	%	No	20.0-40.0
	EOS/ET		B-C-A-D	19-JUL-2019	08:12	RBC	6.24	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	08-MAY-2019	15:52	RBC	4.32	10 ⁶ /uL	No	4.50-5.50
	Screening		A-B-D-C	09-MAY-2019	16:51	RBC	3.20	10 ⁶ /uL	No	4.50-5.50
	Screening		A-B-D-C	09-MAY-2019	16:51	Hemoglobin	12.2	g/dL	No	13.0-17.0
	Screening		A-B-D-C	09-MAY-2019	16:51	Hematocrit	36.6	%	No	40.0-54.0
	Screening		A-B-D-C	09-MAY-2019	16:51	Lymphocytes/Leukocytes	49.8	%	No	20.0-40.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	RBC	3.36	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	Platelets	114	10 ³ /uL	Yes	150-400
	EOS/ET		A-B-D-C	19-JUL-2019	09:00	Lymphocytes/Leukocytes	43.1	%	No	20.0-40.0
	Screening		D-A-C-B	09-MAY-2019	17:21	Eosinophils/Leukocytes	6.9	%	No	1.0-6.0
	Screening		C-D-B-A	10-MAY-2019	17:45	RBC	4.45	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	10-MAY-2019	17:45	Lymphocytes/Leukocytes	47.3	%	No	20.0-40.0
	EOS/ET		C-D-B-A	19-JUL-2019	09:00	Leukocytes	3.5	10 ³ /uL	Yes	4.0-11.0

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 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	19-JUL-2019	09:00	Lymphocytes/Leukocytes	47.2	%	No	20.0-40.0
	EOS/ET		C-D-B-A	19-JUL-2019	09:00	Neutrophils	1.51	10 ⁹ /L	Yes	2.00-7.00
	Screening		A-B-D-C	10-MAY-2019	17:57	Neutrophils/Leukocytes	35.8	%	No	40.0-75.0
	Screening		A-B-D-C	10-MAY-2019	17:57	Lymphocytes/Leukocytes	45.2	%	No	20.0-40.0
	Screening		A-B-D-C	10-MAY-2019	17:57	Monocytes/Leukocytes	17.0	%	No	2.0-10.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:03	Hemoglobin	17.5	g/dL	No	13.0-17.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:03	Eosinophils/Leukocytes	18	%	Yes	1.0-6.0
	Safety Follow up		A-B-D-C	29-JUL-2019	10:41	Eosinophils/Leukocytes	8.8	%	No	1.0-6.0
	Screening		B-C-A-D	10-MAY-2019	18:01	RBC	4.40	10 ⁶ /uL	No	4.50-5.50
	Screening		B-C-A-D	10-MAY-2019	18:01	Hemoglobin	12.8	g/dL	No	13.0-17.0
	Screening		B-C-A-D	10-MAY-2019	18:01	Hematocrit	39.4	%	No	40.0-54.0
	Screening		B-C-A-D	10-MAY-2019	18:01	Lymphocytes/Leukocytes	41.0	%	No	20.0-40.0
	Screening		C-D-B-A	10-MAY-2019	18:16	RBC	5.67	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	10-MAY-2019	18:16	Eosinophils/Leukocytes	6.5	%	No	1.0-6.0
	Screening		C-D-B-A	10-MAY-2019	18:16	Lymphocytes/Leukocytes	44.3	%	No	20.0-40.0
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	RBC	6.04	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	Platelets	401	10 ³ /uL	No	150-400

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 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	19-JUL-2019	09:03	Lymphocytes/Leukocytes	40.7	%	No	20.0-40.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:03	Lymphocytes/Leukocytes	50.7	%	No	20.0-40.0
	Screening		B-C-A-D	10-MAY-2019	18:50	Hemoglobin	12.7	g/dL	No	13.0-17.0
	EOS/ET		B-C-A-D	19-JUL-2019	09:06	Hemoglobin	12.2	g/dL	No	13.0-17.0
	EOS/ET		B-C-A-D	19-JUL-2019	09:06	Hematocrit	38.4	%	No	40.0-54.0
	Screening		D-A-C-B	13-MAY-2019	18:10	Neutrophils/Leukocytes	39.8	%	No	40.0-75.0
	Screening		D-A-C-B	13-MAY-2019	18:10	Eosinophils/Leukocytes	7.7	%	No	1.0-6.0
	Screening		D-A-C-B	13-MAY-2019	18:10	Lymphocytes/Leukocytes	43.8	%	No	20.0-40.0
	Screening		C-D-B-A	13-MAY-2019	18:18	Eosinophils/Leukocytes	6.2	%	No	1.0-6.0
	Screening		C-D-B-A	13-MAY-2019	18:18	Lymphocytes/Leukocytes	43.7	%	No	20.0-40.0
	EOS/ET		C-D-B-A	27-JUN-2019	10:41	Eosinophils/Leukocytes	6.4	%	No	1.0-6.0
	Screening		D-A-C-B	13-MAY-2019	18:22	Eosinophils/Leukocytes	6.4	%	No	1.0-6.0
	Screening		B-C-A-D	13-MAY-2019	17:48	Platelets	441	10 ³ /uL	No	150-400
	EOS/ET		B-C-A-D	19-JUL-2019	09:10	Platelets	407	10 ³ /uL	No	150-400
	Screening		A-B-D-C	13-MAY-2019	17:52	RBC	3.88	10 ⁶ /uL	No	4.50-5.50
	Screening		A-B-D-C	13-MAY-2019	17:52	Hemoglobin	12.1	g/dL	No	13.0-17.0
	Screening		A-B-D-C	13-MAY-2019	17:52	Hematocrit	37.0	%	No	40.0-54.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Hemoglobin	12.7	g/dL	No	13.0-17.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Platelets	415	10 ³ /uL	No	150-400
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Neutrophils/Leukocytes	76	%	Yes	40.0-75.0
	EOS/ET		A-B-D-C	19-JUL-2019	09:10	Lymphocytes/Leukocytes	15	%	Yes	20.0-40.0
	Screening		D-A-C-B	02-MAY-2019	17:11	Hemoglobin	10.8	g/dL	No	12.0-15.0
	Screening		D-A-C-B	02-MAY-2019	17:11	Hematocrit	34.5	%	No	35.0-47.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:00	RBC	4.99	10 ⁶ /uL	No	3.80-4.80
	EOS/ET		D-A-C-B	25-JUL-2019	08:00	Lymphocytes/Leukocytes	43.6	%	No	20.0-40.0
	Screening		C-D-B-A	20-MAY-2019	15:41	RBC	4.82	10 ⁶ /uL	No	3.80-4.80
	Screening		C-D-B-A	20-MAY-2019	15:41	Hemoglobin	11.9	g/dL	No	12.0-15.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:00	Hemoglobin	11.3	g/dL	No	12.0-15.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:00	Platelets	427	10 ³ /uL	No	150-400
	Screening		A-B-D-C	21-MAY-2019	15:55	RBC	3.79	10 ⁶ /uL	No	3.80-4.80
	Screening		A-B-D-C	21-MAY-2019	15:55	Hemoglobin	10.9	g/dL	No	12.0-15.0
	Screening		A-B-D-C	21-MAY-2019	15:55	Hematocrit	32.4	%	No	35.0-47.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:00	Leukocytes	11.2	10 ³ /uL	No	4.0-11.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:00	Hemoglobin	10.9	g/dL	No	12.0-15.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:00	Hematocrit	34.1	%	No	35.0-47.0
	Screening		B-C-A-D	21-MAY-2019	15:36	Lymphocytes/Leukocytes	46.2	%	No	20.0-40.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas

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Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	25-JUL-2019	08:03	Neutrophils/Leukocytes	36.9	%	No	40.0-75.0
	EOS/ET		B-C-A-D	25-JUL-2019	08:03	Lymphocytes/Leukocytes	54.1	%	No	20.0-40.0
	Screening		D-A-C-B	08-MAY-2019	15:32	RBC	4.39	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	08-MAY-2019	15:32	Eosinophils/Leukocytes	7.8	%	No	1.0-6.0
	Screening		D-A-C-B	08-MAY-2019	15:32	Lymphocytes/Leukocytes	41.3	%	No	20.0-40.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:03	Eosinophils/Leukocytes	7.6	%	No	1.0-6.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:03	Lymphocytes/Leukocytes	45.3	%	No	20.0-40.0
	Screening		A-B-D-C	10-MAY-2019	18:07	RBC	4.40	10 ⁶ /uL	No	4.50-5.50
	Screening		A-B-D-C	10-MAY-2019	18:07	Hemoglobin	12.8	g/dL	No	13.0-17.0
	Screening		A-B-D-C	10-MAY-2019	18:07	Hematocrit	39.0	%	No	40.0-54.0
	Screening		A-B-D-C	10-MAY-2019	18:07	Neutrophils/Leukocytes	39.6	%	No	40.0-75.0
	Screening		A-B-D-C	10-MAY-2019	18:07	Lymphocytes/Leukocytes	49.1	%	No	20.0-40.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:03	Hematocrit	39.6	%	No	40.0-54.0
	EOS/ET		A-B-D-C	25-JUL-2019	08:03	Lymphocytes/Leukocytes	45.0	%	No	20.0-40.0
	Screening		C-D-B-A	10-MAY-2019	17:53	RBC	5.98	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	10-MAY-2019	17:53	Lymphocytes/Leukocytes	42.2	%	No	20.0-40.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:03	RBC	6.02	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	10-MAY-2019	18:46	Hemoglobin	12.4	g/dL	No	13.0-17.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	10-MAY-2019	18:46	Hematocrit	38.7	%	No	40.0-54.0
	Screening		D-A-C-B	10-MAY-2019	18:46	Neutrophils/Leukocytes	38.6	%	No	40.0-75.0
	Screening		D-A-C-B	10-MAY-2019	18:46	Eosinophils/Leukocytes	9.0	%	No	1.0-6.0
	Screening		D-A-C-B	10-MAY-2019	18:46	Lymphocytes/Leukocytes	45.0	%	No	20.0-40.0
	EOS/ET		D-A-C-B	25-JUL-2019	08:06	Platelets	438	10 ³ /uL	No	150-400
	EOS/ET		D-A-C-B	25-JUL-2019	08:06	Eosinophils/Leukocytes	9.2	%	No	1.0-6.0
	Screening		B-C-A-D	15-MAY-2019	18:22	RBC	4.28	10 ⁶ /uL	No	4.50-5.50
	Screening		A-B-D-C	15-MAY-2019	18:31	Lymphocytes/Leukocytes	43.0	%	No	20.0-40.0
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Leukocytes	3.7	10 ³ /uL	No	4.0-11.0
	EOS/ET		A-B-D-C	25-JUL-2019	10:22	Lymphocytes/Leukocytes	44.3	%	No	20.0-40.0
	Screening		C-D-B-A	15-MAY-2019	18:13	RBC	4.34	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	15-MAY-2019	18:13	Lymphocytes/Leukocytes	46.5	%	No	20.0-40.0
	EOS/ET		C-D-B-A	25-JUL-2019	08:10	Leukocytes	3.9	10 ³ /uL	No	4.0-11.0
	Screening		A-B-D-C	15-MAY-2019	17:35	Eosinophils/Leukocytes	6.2	%	No	1.0-6.0
	Screening		D-A-C-B	16-MAY-2019	16:06	RBC	4.44	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	16-MAY-2019	16:06	Eosinophils/Leukocytes	9.8	%	No	1.0-6.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:00	RBC	4.38	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		D-A-C-B	25-JUL-2019	09:00	Eosinophils/Leukocytes	10.9	%	No	1.0-6.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
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 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	16-MAY-2019	16:45	Lymphocytes/Leukocytes	47.6	%	No	20.0-40.0
	Screening		D-A-C-B	16-MAY-2019	16:03	RBC	4.16	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	16-MAY-2019	16:03	Hemoglobin	12.9	g/dL	No	13.0-17.0
	Screening		D-A-C-B	16-MAY-2019	16:03	Hematocrit	38.7	%	No	40.0-54.0
	Screening		D-A-C-B	16-MAY-2019	16:03	Lymphocytes/Leukocytes	41.4	%	No	20.0-40.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:00	Lymphocytes/Leukocytes	40.1	%	No	20.0-40.0
	Safety Follow up		D-A-C-B	23-JUL-2019	11:13	RBC	4.28	10 ¹² /L	No	4.50-5.50
	Safety Follow up		D-A-C-B	23-JUL-2019	11:13	Eosinophils/Leukocytes	0.6	%	No	1.0-6.0
	Safety Follow up		D-A-C-B	23-JUL-2019	11:13	Lymphocytes/Leukocytes	15.1	%	No	20.0-40.0
	Safety Follow up		D-A-C-B	23-JUL-2019	11:13	Monocytes/Leukocytes	14.7	%	No	2.0-10.0
	Screening		C-D-B-A	16-MAY-2019	17:02	RBC	5.64	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	16-MAY-2019	17:02	Lymphocytes/Leukocytes	41.3	%	No	20.0-40.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:03	RBC	5.55	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	25-JUL-2019	09:03	Lymphocytes/Leukocytes	19.5	%	No	20.0-40.0
	Screening		A-B-D-C	16-MAY-2019	16:48	Lymphocytes/Leukocytes	41.5	%	No	20.0-40.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:03	RBC	5.73	10 ⁶ /uL	No	4.50-5.50

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		A-B-D-C	16-MAY-2019	16:12	Hemoglobin	12.7	g/dL	No	13.0-17.0
	Screening		A-B-D-C	16-MAY-2019	16:12	Hematocrit	39.6	%	No	40.0-54.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:03	RBC	5.69	10 ⁶ /uL	No	4.50-5.50
	Screening		B-C-A-D	16-MAY-2019	16:51	Hemoglobin	12.5	g/dL	No	13.0-17.0
	Screening		B-C-A-D	16-MAY-2019	16:51	Hematocrit	38.9	%	No	40.0-54.0
	Screening		B-C-A-D	16-MAY-2019	16:51	Eosinophils/Leukocytes	6.3	%	No	1.0-6.0
	Screening		B-C-A-D	16-MAY-2019	16:51	Lymphocytes/Leukocytes	40.7	%	No	20.0-40.0
	EOS/ET		B-C-A-D	25-JUL-2019	09:03	RBC	6.14	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		B-C-A-D	25-JUL-2019	09:03	Eosinophils/Leukocytes	7.5	%	No	1.0-6.0
	Screening		C-D-B-A	16-MAY-2019	16:36	Hemoglobin	12.0	g/dL	No	13.0-17.0
	Screening		C-D-B-A	16-MAY-2019	16:36	Hematocrit	37.6	%	No	40.0-54.0
	Screening		C-D-B-A	16-MAY-2019	16:36	Lymphocytes/Leukocytes	43.0	%	No	20.0-40.0
	Screening		D-A-C-B	16-MAY-2019	17:10	RBC	4.40	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	16-MAY-2019	17:10	Eosinophils/Leukocytes	7.1	%	No	1.0-6.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	RBC	4.35	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Lymphocytes/Leukocytes	44.7	%	No	20.0-40.0
	Screening		C-D-B-A	16-MAY-2019	16:09	Hemoglobin	11.9	g/dL	No	13.0-17.0
	Screening		C-D-B-A	16-MAY-2019	16:09	Hematocrit	36.9	%	No	40.0-54.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
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 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	25-JUL-2019	09:07	Hemoglobin	12.5	g/dL	No	13.0-17.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:07	Hematocrit	38.6	%	No	40.0-54.0
	EOS/ET		C-D-B-A	25-JUL-2019	09:07	Platelets	465	10 ³ /uL	No	150-400
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Leukocytes	17.4	10 ³ /uL	Yes	4.0-11.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Neutrophils/Leukocytes	77	%	Yes	40.0-75.0
	EOS/ET		D-A-C-B	25-JUL-2019	09:06	Lymphocytes/Leukocytes	18	%	No	20.0-40.0
	Screening		B-C-A-D	15-MAY-2019	19:09	RBC	5.51	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		B-C-A-D	25-JUL-2019	09:09	RBC	5.79	10 ⁶ /uL	No	4.50-5.50
	Screening		A-B-D-C	16-MAY-2019	16:53	Hemoglobin	12.7	g/dL	No	13.0-17.0
	Screening		A-B-D-C	16-MAY-2019	16:53	Hematocrit	38.2	%	Yes	40.0-54.0
	Screening		A-B-D-C	16-MAY-2019	16:53	Lymphocytes/Leukocytes	45.5	%	No	20.0-40.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:08	Hemoglobin	12.9	g/dL	No	13.0-17.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:08	Hematocrit	39.3	%	No	40.0-54.0
	EOS/ET		A-B-D-C	25-JUL-2019	09:08	Lymphocytes/Leukocytes	46.0	%	No	20.0-40.0
	Screening		D-A-C-B	15-MAY-2019	17:27	Eosinophils/Leukocytes	9.0	%	No	1.0-6.0
	EOS/ET		D-A-C-B	29-JUL-2019	08:00	Eosinophils/Leukocytes	8.8	%	No	1.0-6.0
	Screening		C-D-B-A	10-MAY-2019	18:42	RBC	5.56	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	29-JUL-2019	08:00	RBC	5.75	10 ⁶ /uL	No	4.50-5.50

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
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 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	29-JUL-2019	08:00	Lymphocytes/Leukocytes	40.3	%	No	20.0-40.0
	Screening		A-B-D-C	10-MAY-2019	18:54	Neutrophils/Leukocytes	33.8	%	No	40.0-75.0
	Screening		A-B-D-C	10-MAY-2019	18:54	Lymphocytes/Leukocytes	58.0	%	Yes	20.0-40.0
	Screening Repeat		A-B-D-C	22-MAY-2019	09:28	Lymphocytes/Leukocytes	40.1	%	No	20.0-40.0
	EOS/ET		A-B-D-C	29-JUL-2019	08:00	Hemoglobin	17.4	g/dL	No	13.0-17.0
	Screening		B-C-A-D	10-MAY-2019	19:07	RBC	5.59	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		B-C-A-D	29-JUL-2019	08:00	RBC	6.16	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		A-B-D-C	29-JUL-2019	08:03	Lymphocytes/Leukocytes	53.3	%	No	20.0-40.0
	Screening		D-A-C-B	13-MAY-2019	18:26	Monocytes/Leukocytes	10.7	%	No	2.0-10.0
	Screening		C-D-B-A	13-MAY-2019	18:06	Hemoglobin	12.3	g/dL	No	13.0-17.0
	Screening		C-D-B-A	13-MAY-2019	18:06	Hematocrit	38.1	%	No	40.0-54.0
	Screening		C-D-B-A	13-MAY-2019	18:06	Lymphocytes/Leukocytes	48.8	%	No	20.0-40.0
	EOS/ET		C-D-B-A	29-JUL-2019	08:03	Hemoglobin	12.1	g/dL	No	13.0-17.0
	EOS/ET		C-D-B-A	29-JUL-2019	08:03	Hematocrit	37.6	%	No	40.0-54.0
	EOS/ET		C-D-B-A	29-JUL-2019	08:03	Lymphocytes/Leukocytes	47.6	%	No	20.0-40.0
	Screening		B-C-A-D	15-MAY-2019	18:57	Platelets	145	10 ³ /uL	No	150-400
	EOS/ET		B-C-A-D	29-JUL-2019	08:03	Leukocytes	3.8	10 ³ /uL	No	4.0-11.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		B-C-A-D	29-JUL-2019	08:03	Neutrophils/Leukocytes	37.6	%	Yes	40.0-75.0
	EOS/ET		B-C-A-D	29-JUL-2019	08:03	Lymphocytes/Leukocytes	46.8	%	No	20.0-40.0
	EOS/ET		B-C-A-D	29-JUL-2019	08:03	Monocytes/Leukocytes	12.1	%	No	2.0-10.0
	Screening		A-B-D-C	15-MAY-2019	18:08	RBC	4.33	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		A-B-D-C	29-JUL-2019	08:06	RBC	4.32	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		B-C-A-D	29-JUL-2019	08:06	RBC	5.62	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	20-MAY-2019	17:06	Eosinophils/Leukocytes	6.4	%	No	1.0-6.0
	EOS/ET		C-D-B-A	08-AUG-2019	13:32	Platelets	531	10 ³ /uL	No	150-400
	Safety Follow up		C-D-B-A	29-JUL-2019	09:46	RBC	4.33	10 ¹² /L	No	4.50-5.50
	Safety Follow up		C-D-B-A	29-JUL-2019	09:46	Eosinophils/Leukocytes	0.9	%	No	1.0-6.0
	Screening		D-A-C-B	20-MAY-2019	16:41	Hematocrit	39.2	%	No	40.0-54.0
	Screening		D-A-C-B	20-MAY-2019	16:41	Lymphocytes/Leukocytes	49.9	%	No	20.0-40.0
	EOS/ET		D-A-C-B	29-JUL-2019	08:06	RBC	5.59	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	20-MAY-2019	16:45	RBC	5.63	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		D-A-C-B	29-JUL-2019	08:09	RBC	5.96	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		D-A-C-B	29-JUL-2019	08:09	Eosinophils/Leukocytes	0.9	%	No	1.0-6.0
	EOS/ET		D-A-C-B	29-JUL-2019	08:09	Lymphocytes/Leukocytes	42.1	%	No	20.0-40.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	20-MAY-2019	17:10	RBC	6.38	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	29-JUL-2019	11:39	RBC	6.54	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	29-JUL-2019	11:39	Lymphocytes/Leukocytes	40.3	%	No	20.0-40.0
	Screening		B-C-A-D	20-MAY-2019	16:21	Lymphocytes/Leukocytes	45.9	%	No	20.0-40.0
	EOS/ET		B-C-A-D	29-JUL-2019	09:00	RBC	5.56	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		B-C-A-D	29-JUL-2019	09:00	Lymphocytes/Leukocytes	45.8	%	No	20.0-40.0
	Screening		A-B-D-C	21-MAY-2019	17:20	Eosinophils/Leukocytes	7.7	%	No	1.0-6.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	Hematocrit	39.7	%	No	40.0-54.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	Eosinophils/Leukocytes	7.6	%	No	1.0-6.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	Monocytes/Leukocytes	13.6	%	No	2.0-10.0
	Screening		C-D-B-A	21-MAY-2019	15:07	RBC	6.07	10 ⁶ /uL	No	4.50-5.50
	Screening		C-D-B-A	21-MAY-2019	15:07	Lymphocytes/Leukocytes	41.3	%	No	20.0-40.0
	EOS/ET		C-D-B-A	29-JUL-2019	09:00	RBC	6.26	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	29-JUL-2019	09:00	Eosinophils/Leukocytes	6.3	%	No	1.0-6.0
	Screening		A-B-D-C	21-MAY-2019	17:44	Hemoglobin	12.6	g/dL	No	13.0-17.0
	Screening		A-B-D-C	21-MAY-2019	17:44	Hematocrit	38.9	%	No	40.0-54.0
	Screening		A-B-D-C	21-MAY-2019	17:44	Lymphocytes/Leukocytes	46.4	%	No	20.0-40.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:00	Platelets	478	10 ³ /uL	No	150-400

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas

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Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	21-MAY-2019	16:44	RBC	4.39	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	21-MAY-2019	16:44	Hemoglobin	12.7	g/dL	No	13.0-17.0
	Screening		D-A-C-B	21-MAY-2019	16:44	Hematocrit	39.1	%	No	40.0-54.0
	Screening		B-C-A-D	21-MAY-2019	17:05	RBC	4.44	10 ⁶ /uL	No	4.50-5.50
	Screening		B-C-A-D	21-MAY-2019	17:05	Eosinophils/Leukocytes	6.2	%	No	1.0-6.0
	Screening		B-C-A-D	21-MAY-2019	17:40	RBC	4.37	10 ⁶ /uL	No	4.50-5.50
	Screening		B-C-A-D	21-MAY-2019	17:40	Lymphocytes/Leukocytes	43.6	%	No	20.0-40.0
	EOS/ET		B-C-A-D	29-JUL-2019	09:02	Eosinophils/Leukocytes	6.2	%	No	1.0-6.0
	EOS/ET		B-C-A-D	29-JUL-2019	09:02	Lymphocytes/Leukocytes	45.2	%	No	20.0-40.0
	Screening		C-D-B-A	07-MAY-2019	20:23	Lymphocytes/Leukocytes	41.6	%	No	20.0-40.0
	Screening		A-B-D-C	23-MAY-2019	15:44	Lymphocytes/Leukocytes	45.4	%	No	20.0-40.0
	Screening		D-A-C-B	23-MAY-2019	16:01	RBC	3.86	10 ⁶ /uL	No	4.50-5.50
	Screening		D-A-C-B	23-MAY-2019	16:01	Hematocrit	38.6	%	No	40.0-54.0
	Screening		D-A-C-B	23-MAY-2019	16:01	Lymphocytes/Leukocytes	43.4	%	No	20.0-40.0
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	RBC	4.27	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	Neutrophils/Leukocytes	39.1	%	No	40.0-75.0
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	Lymphocytes/Leukocytes	48.0	%	No	20.0-40.0
	Screening		D-A-C-B	23-MAY-2019	15:36	Hemoglobin	12.9	g/dL	No	13.0-17.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	23-MAY-2019	15:36	Hematocrit	39.3	%	No	40.0-54.0
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	Hemoglobin	12.9	g/dL	No	13.0-17.0
	EOS/ET		D-A-C-B	29-JUL-2019	09:04	Eosinophils/Leukocytes	6.2	%	No	1.0-6.0
	Screening		A-B-D-C	23-MAY-2019	15:18	Hemoglobin	12.4	g/dL	No	13.0-17.0
	Screening		A-B-D-C	23-MAY-2019	15:18	Hematocrit	38.7	%	No	40.0-54.0
	Screening		A-B-D-C	23-MAY-2019	15:18	Eosinophils/Leukocytes	7.7	%	No	1.0-6.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:04	Hemoglobin	12.5	g/dL	No	13.0-17.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:04	Hematocrit	39.9	%	No	40.0-54.0
	EOS/ET		A-B-D-C	29-JUL-2019	09:04	Eosinophils/Leukocytes	12.3	%	Yes	1.0-6.0
	Safety follow up		A-B-D-C	08-AUG-2019	10:44	Eosinophils/Leukocytes	13.3	%	Yes	1.0-6.0
	Safety follow up		A-B-D-C	27-AUG-2019	09:49	Leukocytes	3.8	10 ³ /uL	No	4.0-11.0
	Safety follow up		A-B-D-C	27-AUG-2019	09:49	Eosinophils/Leukocytes	6.5	%	No	1.0-6.0
	Screening		C-D-B-A	15-MAY-2019	17:38	RBC	5.73	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	29-JUL-2019	09:06	RBC	5.87	10 ⁶ /uL	No	4.50-5.50
	EOS/ET		C-D-B-A	29-JUL-2019	09:06	Hemoglobin	17.2	g/dL	No	13.0-17.0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
 23 April 2020 Final

Table 14.3.4.2. Out of range Laboratory Values - Hematology, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	20-MAY-2019	16:58	Lymphocytes/Leukocytes	43.3	%	No	20.0-40.0
Source: Listing 16.2.8.3 Safety Follow up & Safety Follow up1: Follow up visits										

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
Table Generation 04FEB2020 at 11:02 AM by Table 14.3.4.2.sas
23 April 2020 Final

Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		D-A-C-B	30-APR-2019	17:35	Occult Blood	4+		Yes	Negative
	Screening		D-A-C-B	30-APR-2019	17:35	Leukocytes	3+		Yes	Negative
	Screening Repeat		D-A-C-B	10-MAY-2019	13:33	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		D-A-C-B	16-JUL-2019	07:52	Occult Blood	1+		Yes	Negative
	EOS/ET		D-A-C-B	16-JUL-2019	07:52	Leukocytes	3+		Yes	Negative
	EOS/ET		D-A-C-B	16-JUL-2019	07:52	Leukocytes(Microscopic Examination)	60	/HPF	Yes	00-05
	EOS/ET		D-A-C-B	16-JUL-2019	07:52	Erythrocytes	10	/HPF	Yes	0-2
	EOS/ET		D-A-C-B	16-JUL-2019	07:52	Epithelial Cells	40	/HPF	Yes	0-5
	EOS/ET		D-A-C-B	16-JUL-2019	07:52	Bacteria	BACTERIA+		Yes	Occasional
	EOS/ET		B-C-A-D	16-JUL-2019	07:52	Leukocytes	1+		Yes	Negative
	EOS/ET		B-C-A-D	16-JUL-2019	07:52	Leukocytes(Microscopic Examination)	08	/HPF	Yes	00-05
	EOS/ET		B-C-A-D	16-JUL-2019	07:52	Bacteria	BACTERIA+		Yes	Occasional
	Safety Follow up		B-C-A-D	24-JUL-2019	11:54	Leukocytes	1+		Yes	Negative
	Safety Follow up		B-C-A-D	24-JUL-2019	11:54	Leukocytes(Microscopic Examination)	06	/HPF	Yes	00-05
	Safety Follow up		B-C-A-D	24-JUL-2019	11:54	Bacteria	BACTERIA+		Yes	Occasional
	Screening		C-D-B-A	30-APR-2019	17:24	Leukocytes	1+		Yes	Negative

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
 23 April 2020 Final

Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	16-JUL-2019	07:52	Epithelial Cells	10	/HPF	No	0-5
	Screening		A-B-D-C	02-MAY-2019	17:21	pH	8		No	4.8-7.4
	Screening		B-C-A-D	07-MAY-2019	16:18	pH	8		No	4.8-7.4
	EOS/ET		D-A-C-B	16-JUL-2019	07:54	Epithelial Cells	08	/HPF	No	0-5
	Screening		A-B-D-C	08-MAY-2019	16:40	Leukocytes	1+		No	Negative
	EOS/ET		A-B-D-C	16-JUL-2019	07:54	Epithelial Cells	10	/HPF	No	0-5
	Safety Follow up		C-D-B-A	13-JUL-2019	16:12	Protein	1+		Yes	Negative
	Safety Follow up		C-D-B-A	13-JUL-2019	16:12	Occult Blood	2+		Yes	Negative
	Safety Follow up		C-D-B-A	13-JUL-2019	16:12	Leukocytes	3+		Yes	Negative
	Safety Follow up		C-D-B-A	13-JUL-2019	16:12	Leukocytes(Microscopic Examination)	110	/HPF	Yes	00-05
	Safety Follow up		C-D-B-A	13-JUL-2019	16:12	Erythrocytes	10	/HPF	Yes	0-2
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:43	pH	8		No	4.8-7.4
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:43	Occult Blood	1+		No	Negative
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:43	Leukocytes	1+		Yes	Negative
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:43	Leukocytes(Microscopic Examination)	20	/HPF	Yes	00-05
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:43	Erythrocytes	04	/HPF	No	0-2
	Safety Follow up1		C-D-B-A	16-JUL-2019	08:43	Bacteria	BACTERIA+		Yes	Occasional

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
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 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
 23 April 2020 Final

Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		C-D-B-A	16-JUL-2019	07:56	Epithelial Cells	20	/HPF	No	0-5
	EOS/ET		B-C-A-D	16-JUL-2019	07:56	Leukocytes(Microscopic Examination)	30	/HPF	Yes	00-05
	EOS/ET		B-C-A-D	16-JUL-2019	07:56	Bacteria	BACTERIA+		Yes	Occasional
	Safety Follow up		B-C-A-D	24-JUL-2019	10:30	Leukocytes	1+		Yes	Negative
	Safety Follow up		B-C-A-D	24-JUL-2019	10:30	Leukocytes(Microscopic Examination)	80	/HPF	Yes	00-05
	Safety Follow up		B-C-A-D	24-JUL-2019	10:30	Bacteria	BACTERIA+		Yes	Occasional
	EOS/ET		D-A-C-B	16-JUL-2019	07:56	pH	8		No	4.8-7.4
	Screening		A-B-D-C	30-APR-2019	17:40	Occult Blood	1+		Yes	Negative
	Screening		A-B-D-C	30-APR-2019	17:40	Crystals	CALCIUM OXALATE+		Yes	Occasional
	EOS/ET		D-A-C-B	16-JUL-2019	07:59	Epithelial Cells	08	/HPF	No	0-5
	EOS/ET		B-C-A-D	16-JUL-2019	08:30	Protein	1+		Yes	Negative
	EOS/ET		B-C-A-D	16-JUL-2019	08:30	Leukocytes	3+		Yes	Negative
	EOS/ET		B-C-A-D	16-JUL-2019	08:30	Leukocytes(Microscopic Examination)	60	/HPF	Yes	00-05
	EOS/ET		B-C-A-D	16-JUL-2019	08:30	Epithelial Cells	30	/HPF	Yes	0-5
	EOS/ET		B-C-A-D	16-JUL-2019	08:30	Bacteria	BACTERIA+		Yes	Occasional
	Screening		C-D-B-A	30-APR-2019	18:08	Occult Blood	2+		Yes	Negative

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
 23 April 2020 Final

Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		A-B-D-C	30-APR-2019	16:35	Leukocytes	3+		Yes	Negative
	EOS/ET		D-A-C-B	16-JUL-2019	08:54	Leukocytes	1+		Yes	Negative
	EOS/ET		D-A-C-B	16-JUL-2019	08:54	Leukocytes(Microscopic Examination)	20	/HPF	Yes	00-05
	EOS/ET		D-A-C-B	16-JUL-2019	08:54	Epithelial Cells	10	/HPF	Yes	0-5
	EOS/ET		D-A-C-B	16-JUL-2019	08:54	Bacteria	BACTERIA+		Yes	Occasional
	Screening		C-D-B-A	07-MAY-2019	17:25	Specific Gravity	1.005		No	1.010-1.030
	Screening		B-C-A-D	07-MAY-2019	16:41	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	07-MAY-2019	17:42	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		B-C-A-D	16-JUL-2019	08:56	Spermatozoa	SPERMATOZOA NOTED		No	Occasional
	EOS/ET		D-A-C-B	16-JUL-2019	09:02	Protein	1+		Yes	Negative
	EOS/ET		D-A-C-B	16-JUL-2019	09:02	Occult Blood	3+		Yes	Negative
	EOS/ET		D-A-C-B	16-JUL-2019	09:02	Bilirubin	1+		Yes	
	Screening		A-B-D-C	07-MAY-2019	19:54	Epithelial Cells	08	/HPF	No	0-5
	Screening		D-A-C-B	10-MAY-2019	17:38	Leukocytes	1+		No	Negative
	EOS/ET		D-A-C-B	19-JUL-2019	07:50	Epithelial Cells	06	/HPF	No	0-5
	Screening		A-B-D-C	13-MAY-2019	17:29	Leukocytes	3+		Yes	Negative

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
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 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
 23 April 2020 Final

Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		A-B-D-C	13-MAY-2019	17:29	Leukocytes(Microscopic Examination)	20	/HPF	Yes	00-05
	Screening		B-C-A-D	02-MAY-2019	17:39	Occult Blood	5+		Yes	Negative
	Screening		B-C-A-D	02-MAY-2019	17:39	Leukocytes	1+		Yes	Negative
	Screening		B-C-A-D	02-MAY-2019	17:39	Leukocytes(Microscopic Examination)	10	/HPF	Yes	00-05
	EOS/ET		B-C-A-D	19-JUL-2019	11:10	Epithelial Cells	06	/HPF	No	0-5
	Screening		C-D-B-A	13-MAY-2019	17:37	Leukocytes	1+		Yes	Negative
	Screening		C-D-B-A	13-MAY-2019	17:37	Glucose	1+		Yes	Negative
	EOS/ET		C-D-B-A	19-JUL-2019	07:52	Epithelial Cells	06	/HPF	No	0-5
	Screening		D-A-C-B	10-MAY-2019	17:27	Occult Blood	1+		No	Negative
	EOS/ET		D-A-C-B	19-JUL-2019	07:51	Epithelial Cells	08	/HPF	No	0-5
	Screening		A-B-D-C	07-MAY-2019	18:14	Occult Blood	1+		Yes	Negative
	EOS/ET		A-B-D-C	19-JUL-2019	08:03	Occult Blood	1+		Yes	Negative
	EOS/ET		A-B-D-C	19-JUL-2019	08:03	Glucose	1+		No	Negative
	EOS/ET		A-B-D-C	19-JUL-2019	08:03	Epithelial Cells	08	/HPF	Yes	0-5
	Screening		B-C-A-D	07-MAY-2019	17:06	Specific Gravity	1.005		No	1.010-1.030
	Screening		C-D-B-A	07-MAY-2019	17:21	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		C-D-B-A	19-JUL-2019	08:10	Occult Blood	1+		No	Negative

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		B-C-A-D	07-MAY-2019	16:56	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		B-C-A-D	19-JUL-2019	08:05	Protein	1+		No	Negative
	Screening		D-A-C-B	08-MAY-2019	15:49	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	09-MAY-2019	16:48	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	10-MAY-2019	17:55	pH	8		No	4.8-7.4
	EOS/ET		C-D-B-A	19-JUL-2019	08:57	Epithelial Cells	08	/HPF	No	0-5
	Screening		B-C-A-D	10-MAY-2019	18:48	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		B-C-A-D	19-JUL-2019	08:58	Occult Blood	1+		No	Negative
	Screening		A-B-D-C	13-MAY-2019	17:50	Specific Gravity	1.005		No	1.010-1.030
	Screening		D-A-C-B	02-MAY-2019	17:07	Leukocytes	2+		Yes	Negative
	Screening		D-A-C-B	02-MAY-2019	17:07	Leukocytes(Microscopic Examination)	20	/HPF	Yes	00-05
	Screening		D-A-C-B	02-MAY-2019	17:07	Epithelial Cells	10	/HPF	Yes	0-5
	Screening		D-A-C-B	02-MAY-2019	17:07	Casts	GRANULAR CASTS+	/LPF	No	Occasional
	Screening		D-A-C-B	02-MAY-2019	17:07	Bacteria	BACTERIA+		Yes	Occasional
	EOS/ET		D-A-C-B	25-JUL-2019	07:50	Epithelial Cells	10	/HPF	No	0-5
	Screening		B-C-A-D	20-MAY-2019	15:52	pH	8		No	4.8-7.4
	Screening		D-A-C-B	08-MAY-2019	15:29	pH	8		No	4.8-7.4

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
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Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	EOS/ET		D-A-C-B	25-JUL-2019	07:53	pH	8		No	4.8-7.4
	Screening		C-D-B-A	10-MAY-2019	17:51	Specific Gravity	1.005		No	1.010-1.030
	Screening		D-A-C-B	10-MAY-2019	18:44	Specific Gravity	1.005		No	1.010-1.030
	Screening		B-C-A-D	15-MAY-2019	18:20	Occult Blood	2+		No	Negative
	EOS/ET		B-C-A-D	25-JUL-2019	07:56	Occult Blood	2+		No	Negative
	Screening		B-C-A-D	15-MAY-2019	18:39	Crystals	CALCIUM OXALATE+		No	Occasional
	Screening		D-A-C-B	16-MAY-2019	16:04	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	16-MAY-2019	16:46	Specific Gravity	1.005		No	1.010-1.030
	Screening		D-A-C-B	16-MAY-2019	17:08	Occult Blood	2+		No	Negative
	EOS/ET		D-A-C-B	25-JUL-2019	08:56	Occult Blood	1+		No	Negative
	Screening		C-D-B-A	16-MAY-2019	16:07	pH	8		No	4.8-7.4
	EOS/ET		D-A-C-B	25-JUL-2019	08:58	pH	8		No	4.8-7.4
	Screening		A-B-D-C	10-MAY-2019	18:52	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	10-MAY-2019	18:09	Leukocytes	1+		No	Negative
	EOS/ET		A-B-D-C	29-JUL-2019	07:52	Specific Gravity	1.005		No	1.010-1.030
	Screening		C-D-B-A	13-MAY-2019	18:04	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		C-D-B-A	29-JUL-2019	07:53	Specific Gravity	1.005		No	1.010-1.030

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
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Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
	Screening		C-D-B-A	20-MAY-2019	17:04	pH	8		No	4.8-7.4
	Safety Follow up		C-D-B-A	29-JUL-2019	09:44	Specific Gravity	1.005		No	1.010-1.030
	Screening		D-A-C-B	20-MAY-2019	16:39	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		D-A-C-B	29-JUL-2019	08:06	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		B-C-A-D	29-JUL-2019	08:50	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	21-MAY-2019	17:18	Occult Blood	1+		No	Negative
	EOS/ET		A-B-D-C	29-JUL-2019	08:50	Occult Blood	1+		No	Negative
	Screening		C-D-B-A	21-MAY-2019	15:05	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		C-D-B-A	29-JUL-2019	08:50	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		A-B-D-C	29-JUL-2019	08:50	Occult Blood	1+		Yes	Negative
	EOS/ET		A-B-D-C	29-JUL-2019	08:50	Epithelial Cells	10	/HPF	Yes	0-5
	Safety Follow up		A-B-D-C	19-AUG-2019	15:34	Occult Blood	1+		No	Negative
	EOS/ET		B-C-A-D	29-JUL-2019	08:52	Occult Blood	1+		No	Negative
	EOS/ET		B-C-A-D	29-JUL-2019	08:52	Leukocytes(Microscopic Examination)	20	/HPF	Yes	00-05
	EOS/ET		C-D-B-A	29-JUL-2019	08:52	Occult Blood	1+		No	Negative
	EOS/ET		A-B-D-C	29-JUL-2019	08:52	Specific Gravity	1.005		No	1.010-1.030
	Screening		D-A-C-B	23-MAY-2019	15:59	Specific Gravity	1.005		No	1.010-1.030

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
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Table 14.3.4.3. Out of range Laboratory Values - Urinalysis, Safety Analysis Set

Subject	Visit	Sex	Sequence	Date of Collection	Time of Collection	Lab Parameter	Result	Unit	Clinically Significant Yes/No	Normal Range
[REDACTED]	EOS/ET	[REDACTED]	D-A-C-B	29-JUL-2019	08:54	Specific Gravity	1.005		No	1.010-1.030
	Screening		A-B-D-C	23-MAY-2019	15:14	pH	8		No	4.8-7.4
	EOS/ET		A-B-D-C	29-JUL-2019	08:56	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		C-D-B-A	29-JUL-2019	08:56	Specific Gravity	1.005		No	1.010-1.030
	EOS/ET		B-C-A-D	29-JUL-2019	08:56	Specific Gravity	1.005		No	1.010-1.030
Source: Listing 16.2.8.4 Safety Follow up & Safety Follow up1: Follow up visits										

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:03 AM by Table 14.3.4.3.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
ALT(SGPT)	Screening	N	112
		MEAN	20.12
		SD	11.02
		MINIMUM	6.50
		MEDIAN	16.25
		MAXIMUM	66.60
	EOS/ET	N	109
		MEAN	24.87
		SD	18.60
		MINIMUM	4.60
		MEDIAN	19.20
		MAXIMUM	137.2
	Change from Baseline	N	109
		MEAN	4.636
		SD	13.00
		MINIMUM	-27.2
		MEDIAN	1.80
		MAXIMUM	85.60

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
AST(SGOT)	Screening	N	112
		MEAN	22.00
		SD	5.645
		MINIMUM	13.70
		MEDIAN	21.15
		MAXIMUM	54.80
	EOS/ET	N	109
		MEAN	24.79
		SD	12.16
		MINIMUM	13.10
		MEDIAN	21.30
		MAXIMUM	91.70
	Change from Baseline	N	109
		MEAN	2.705
		SD	10.54
		MINIMUM	-13.1
		MEDIAN	0.50
		MAXIMUM	68.10

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Albumin	Screening	N	112
		MEAN	4.505
		SD	0.281
		MINIMUM	3.62
		MEDIAN	4.50
		MAXIMUM	5.13
	EOS/ET	N	109
		MEAN	4.385
		SD	0.239
		MINIMUM	3.70
		MEDIAN	4.39
		MAXIMUM	4.94
	Change from Baseline	N	109
		MEAN	-0.127
		SD	0.226
		MINIMUM	-0.78
		MEDIAN	-0.10
		MAXIMUM	0.45

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Alkaline Phosphatase	Screening	N	112
		MEAN	82.50
		SD	20.83
		MINIMUM	33.00
		MEDIAN	80.00
		MAXIMUM	141.0
	EOS/ET	N	109
		MEAN	91.34
		SD	25.77
		MINIMUM	37.00
		MEDIAN	86.00
		MAXIMUM	168.0
	Change from Baseline	N	109
		MEAN	9.101
		SD	12.73
		MINIMUM	-32.0
		MEDIAN	7.00
		MAXIMUM	73.00

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Bicarbonate	Screening	N	112
		MEAN	27.13
		SD	2.346
		MINIMUM	21.50
		MEDIAN	27.00
		MAXIMUM	35.00
	EOS/ET	N	109
		MEAN	27.11
		SD	2.338
		MINIMUM	20.00
		MEDIAN	27.10
		MAXIMUM	33.20
	Change from Baseline	N	109
		MEAN	-0.44
		SD	3.104
		MINIMUM	-9.40
		MEDIAN	0.10
		MAXIMUM	5.70

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Bilirubin	Screening	N	112
		MEAN	0.636
		SD	0.281
		MINIMUM	0.25
		MEDIAN	0.56
		MAXIMUM	1.47
	EOS/ET	N	109
		MEAN	0.586
		SD	0.225
		MINIMUM	0.27
		MEDIAN	0.55
		MAXIMUM	1.41
	Change from Baseline	N	109
		MEAN	-0.053
		SD	0.200
		MINIMUM	-0.85
		MEDIAN	-0.04
		MAXIMUM	0.45

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Blood Urea Nitrogen	Screening	N	112
		MEAN	9.003
		SD	2.366
		MINIMUM	4.00
		MEDIAN	8.75
		MAXIMUM	19.10
	EOS/ET	N	109
		MEAN	7.386
		SD	1.787
		MINIMUM	3.80
		MEDIAN	7.00
		MAXIMUM	12.90
	Change from Baseline	N	109
		MEAN	-1.66
		SD	2.079
		MINIMUM	-11.1
		MEDIAN	-1.60
		MAXIMUM	3.80

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Calcium	Screening	N	112
		MEAN	9.362
		SD	0.339
		MINIMUM	8.32
		MEDIAN	9.33
		MAXIMUM	10.07
	EOS/ET	N	109
		MEAN	9.438
		SD	0.371
		MINIMUM	8.47
		MEDIAN	9.47
		MAXIMUM	10.41
	Change from Baseline	N	109
		MEAN	0.072
		SD	0.355
		MINIMUM	-0.72
		MEDIAN	0.04
		MAXIMUM	1.33

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Chloride	Screening	N	112
		MEAN	106.2
		SD	2.085
		MINIMUM	100.0
		MEDIAN	106.0
		MAXIMUM	112.0
	EOS/ET	N	109
		MEAN	106.2
		SD	2.138
		MINIMUM	101.0
		MEDIAN	106.0
		MAXIMUM	113.0
	Change from Baseline	N	109
		MEAN	0.092
		SD	2.343
		MINIMUM	-5.00
		MEDIAN	0.00
		MAXIMUM	6.00

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Cholesterol	Screening	N	112
		MEAN	160.3
		SD	31.52
		MINIMUM	93.00
		MEDIAN	160.5
		MAXIMUM	233.0
	EOS/ET	N	109
		MEAN	151.3
		SD	29.46
		MINIMUM	69.00
		MEDIAN	154.0
		MAXIMUM	225.0
	Change from Baseline	N	109
		MEAN	-9.00
		SD	20.72
		MINIMUM	-77.0
		MEDIAN	-9.00
		MAXIMUM	44.00

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Creatinine	Screening	N	112
		MEAN	0.730
		SD	0.137
		MINIMUM	0.39
		MEDIAN	0.74
		MAXIMUM	1.08
	EOS/ET	N	109
		MEAN	0.748
		SD	0.146
		MINIMUM	0.44
		MEDIAN	0.77
		MAXIMUM	1.07
	Change from Baseline	N	109
		MEAN	0.021
		SD	0.062
		MINIMUM	-0.10
		MEDIAN	0.02
		MAXIMUM	0.20

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Glucose	Screening	N	112
		MEAN	96.87
		SD	10.39
		MINIMUM	74.20
		MEDIAN	96.40
		MAXIMUM	128.7
	EOS/ET	N	109
		MEAN	96.42
		SD	10.49
		MINIMUM	81.60
		MEDIAN	94.00
		MAXIMUM	151.8
Source: Listing 16.2.8.2			
Glucose test was non-fasting at screening and fasting at EOS/ET. Therefore these results were not comparable and change from baseline was not reported.			

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value	
Potassium	Screening	N	112	
		MEAN	4.366	
		SD	0.352	
		MINIMUM	3.60	
		MEDIAN	4.35	
		MAXIMUM	5.30	
	EOS/ET	Change from Baseline	N	109
			MEAN	4.634
			SD	0.406
			MINIMUM	3.60
			MEDIAN	4.60
			MAXIMUM	5.60
			N	109
			MEAN	0.278
			SD	0.434
MINIMUM	-0.90			
MEDIAN	0.30			
MAXIMUM	1.20			

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Protein	Screening	N	112
		MEAN	7.419
		SD	0.424
		MINIMUM	6.51
		MEDIAN	7.43
		MAXIMUM	8.44
	EOS/ET	N	109
		MEAN	7.433
		SD	0.422
		MINIMUM	6.44
		MEDIAN	7.48
		MAXIMUM	8.41
	Change from Baseline	N	109
		MEAN	0.004
		SD	0.353
		MINIMUM	-0.90
		MEDIAN	0.03
		MAXIMUM	1.00
Source: Listing 16.2.8.2			

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.4. Clinical Laboratory Summary and Change from Baseline - Serum Chemistry, Safety Analysis Set

Test	Visit	Statistics	Value
Sodium	Screening	N	112
		MEAN	137.1
		SD	1.839
		MINIMUM	132.0
		MEDIAN	137.0
		MAXIMUM	141.0
	EOS/ET	N	109
		MEAN	136.6
		SD	1.797
		MINIMUM	130.0
		MEDIAN	137.0
		MAXIMUM	142.0
	Change from Baseline	N	109
		MEAN	-.578
		SD	2.366
		MINIMUM	-6.00
		MEDIAN	-1.00
		MAXIMUM	4.00

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 2:12 PM by Table 14.3.4.4.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Basophils	Screening	N	112
		MEAN	0.022
		SD	0.048
		MINIMUM	0.00
		MEDIAN	0.00
		MAXIMUM	0.30
	EOS/ET	N	109
		MEAN	0.027
		SD	0.048
		MINIMUM	0.00
		MEDIAN	0.00
		MAXIMUM	0.20
	Change from Baseline	N	109
		MEAN	0.005
		SD	0.071
		MINIMUM	-0.30
		MEDIAN	0.00
		MAXIMUM	0.20

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Eosinophils	Screening	N	112
		MEAN	3.785
		SD	2.062
		MINIMUM	0.80
		MEDIAN	3.40
		MAXIMUM	9.80
	EOS/ET	N	109
		MEAN	3.758
		SD	2.557
		MINIMUM	0.90
Change from Baseline	Change from Baseline	MEDIAN	3.00
		MAXIMUM	18.00
		N	109
		MEAN	0.001
		SD	2.125
		MINIMUM	-5.00
		MEDIAN	-0.10
		MAXIMUM	16.10

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Hematocrit	Screening	N	112
		MEAN	41.04
		SD	3.963
		MINIMUM	32.40
		MEDIAN	41.10
		MAXIMUM	50.00
	EOS/ET	N	109
		MEAN	42.53
		SD	4.581
		MINIMUM	32.10
		MEDIAN	43.30
		MAXIMUM	52.10
	Change from Baseline	N	109
		MEAN	1.449
		SD	2.163
		MINIMUM	-3.40
		MEDIAN	1.40
		MAXIMUM	6.10

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Hemoglobin	Screening	N	112
		MEAN	13.58
		SD	1.509
		MINIMUM	10.80
		MEDIAN	13.60
		MAXIMUM	17.00
	EOS/ET	N	109
		MEAN	14.00
		SD	1.726
		MINIMUM	10.00
Change from Baseline		MEDIAN	14.00
		MAXIMUM	17.50
		N	109
		MEAN	0.401
		SD	0.744
		MINIMUM	-1.50
		MEDIAN	0.40
		MAXIMUM	2.00

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Leukocytes	Screening	N	112
		MEAN	7.033
		SD	1.419
		MINIMUM	4.00
		MEDIAN	6.95
		MAXIMUM	10.50
	EOS/ET	N	109
		MEAN	6.541
		SD	1.894
		MINIMUM	3.50
		MEDIAN	6.30
		MAXIMUM	17.40
	Change from Baseline	N	109
		MEAN	-482
		SD	1.591
		MINIMUM	-4.70
		MEDIAN	-0.60
		MAXIMUM	9.00

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Lymphocytes	Screening	N	112
		MEAN	37.21
		SD	6.675
		MINIMUM	19.80
		MEDIAN	37.15
		MAXIMUM	49.90
	EOS/ET	N	109
		MEAN	34.57
		SD	8.488
		MINIMUM	15.00
		MEDIAN	34.40
		MAXIMUM	54.10
	Change from Baseline	N	109
		MEAN	-2.74
		SD	7.665
		MINIMUM	-22.6
		MEDIAN	-2.90
		MAXIMUM	24.40

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Monocytes	Screening	N	112
		MEAN	6.791
		SD	1.759
		MINIMUM	3.60
		MEDIAN	6.50
		MAXIMUM	17.00
	EOS/ET	N	109
		MEAN	5.782
		SD	1.829
		MINIMUM	1.90
		MEDIAN	5.40
		MAXIMUM	13.60
	Change from Baseline	N	109
		MEAN	-1.01
		SD	2.225
		MINIMUM	-13.0
		MEDIAN	-1.10
		MAXIMUM	8.00

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
Neutrophils	Screening	N	112
		MEAN	51.85
		SD	8.861
		MINIMUM	1.51
		MEDIAN	52.35
		MAXIMUM	72.90
	EOS/ET	N	109
		MEAN	55.87
		SD	9.470
		MINIMUM	36.90
		MEDIAN	55.20
		MAXIMUM	79.90
	Change from Baseline	N	109
		MEAN	4.108
		SD	8.992
		MINIMUM	-26.2
		MEDIAN	4.20
		MAXIMUM	41.59

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value	
Platelets	Screening	N	112	
		MEAN	281.8	
		SD	66.29	
		MINIMUM	145.0	
		MEDIAN	279.5	
		MAXIMUM	526.0	
	EOS/ET	Change from Baseline	N	109
			MEAN	312.5
			SD	79.48
			MINIMUM	114.0
			MEDIAN	306.0
			MAXIMUM	531.0
			N	109
			MEAN	31.12
			SD	53.47
MINIMUM	-170			
MEDIAN	28.00			
MAXIMUM	281.0			

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.5. Clinical Laboratory Summary and Change from Baseline - Hematology, Safety Analysis Set

Test	Visit	Statistics	Value
RBC	Screening	N	112
		MEAN	4.808
		SD	0.563
		MINIMUM	3.20
		MEDIAN	4.79
		MAXIMUM	6.38
	EOS/ET	N	109
		MEAN	4.984
		SD	0.583
		MINIMUM	3.36
		MEDIAN	4.91
		MAXIMUM	6.54
	Change from Baseline	N	109
		MEAN	0.173
		SD	0.262
		MINIMUM	-0.53
		MEDIAN	0.19
		MAXIMUM	0.76

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:17 AM by Table 14.3.4.5.sas
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Table 14.3.4.6 Clinical Laboratory Shift from Baseline - Serum Chemistry, Safety Analysis Set

Parameter	Screening	EOS/ET		
	Range	NORMAL	ABNORMAL	Total
ALT(SGPT)	ABNORMAL	1	2	3
	NORMAL	94	12	106
	TOTAL	95	14	109
AST(SGOT)	ABNORMAL	0	1	1
	NORMAL	103	5	108
	TOTAL	103	6	109
Albumin	ABNORMAL	0	0	0
	NORMAL	109	0	109
	TOTAL	109	0	109
Alkaline Phosphatase	ABNORMAL	0	5	5
	NORMAL	93	11	104
	TOTAL	93	16	109
Bicarbonate	ABNORMAL	4	1	5
	NORMAL	100	4	104
	TOTAL	104	5	109
Bilirubin	ABNORMAL	9	2	11
	NORMAL	96	2	98
	TOTAL	105	4	109

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 1:08 PM by Table 14.3.4.6.sas
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Table 14.3.4.6 Clinical Laboratory Shift from Baseline - Serum Chemistry, Safety Analysis Set

Parameter	Screening	EOS/ET		
	Range	NORMAL	ABNORMAL	Total
Calcium	ABNORMAL	3	2	5
	NORMAL	101	3	104
	TOTAL	104	5	109
Chloride	ABNORMAL	12	13	25
	NORMAL	68	16	84
	TOTAL	80	29	109
Cholesterol	ABNORMAL	10	3	13
	NORMAL	93	3	96
	TOTAL	103	6	109
Creatinine	ABNORMAL	11	8	19
	NORMAL	87	3	90
	TOTAL	98	11	109
Potassium	ABNORMAL	0	1	1
	NORMAL	98	10	108
	TOTAL	98	11	109
Protein	ABNORMAL	4	2	6
	NORMAL	98	5	103
	TOTAL	102	7	109

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 1:08 PM by Table 14.3.4.6.sas
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Table 14.3.4.6 Clinical Laboratory Shift from Baseline - Serum Chemistry, Safety Analysis Set

Parameter	Screening	EOS/ET		
	Range	NORMAL	ABNORMAL	Total
Sodium	ABNORMAL	11	3	14
	NORMAL	72	23	95
	TOTAL	83	26	109
Urea Nitrogen	ABNORMAL	2	29	31
	NORMAL	34	44	78
	TOTAL	36	73	109

Source: Listing 16.2.8.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 14FEB2020 at 1:08 PM by Table 14.3.4.6.sas
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Table 14.3.4.7 Clinical Laboratory Shift from Baseline - Hematology, Safety Analysis Set

Parameter	Screening	EOS/ET		
	Range	NORMAL	ABNORMAL	Total
Basophils	ABNORMAL	0	0	0
	NORMAL	109	0	109
	TOTAL	109	0	109
Eosinophils	ABNORMAL	12	8	20
	NORMAL	81	8	89
	TOTAL	93	16	109
Erythrocytes	ABNORMAL	19	19	38
	NORMAL	58	13	71
	TOTAL	77	32	109
Hematocrit	ABNORMAL	16	8	24
	NORMAL	79	6	85
	TOTAL	95	14	109
Hemoglobin	ABNORMAL	14	18	32
	NORMAL	73	4	77
	TOTAL	87	22	109
Leukocytes	ABNORMAL	0	0	0
	NORMAL	103	6	109
	TOTAL	103	6	109

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 17FEB2020 at 9:51 AM by Table 14.3.4.7.sas
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Table 14.3.4.7 Clinical Laboratory Shift from Baseline - Hematology, Safety Analysis Set

Parameter	Screening	EOS/ET		
	Range	NORMAL	ABNORMAL	Total
Lymphocytes	ABNORMAL	26	18	44
	NORMAL	52	13	65
	TOTAL	78	31	109
Monocytes	ABNORMAL	3	0	3
	NORMAL	103	3	106
	TOTAL	106	3	109
Neutrophils	ABNORMAL	5	0	5
	NORMAL	97	7	104
	TOTAL	102	7	109
Platelets	ABNORMAL	2	2	4
	NORMAL	91	14	105
	TOTAL	93	16	109

Source: Listing 16.2.8.3

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 17FEB2020 at 9:51 AM by Table 14.3.4.7.sas
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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

				Treatment				Change From Baseline				
Vital Test Parameter	Visit	Statistic	Overall	A	B	C	D	A	B	C	D	
Diastolic Blood Pressure	Screening	N	112									
		Mean	72.1									
		SD	3.65									
		Minimum	64									
		Median	72									
		Maximum	80									
	check-In	N			107	107	109	112				
		Mean			72.2	71.5	72.3	71.7
		SD			4.1	4.3	4.6	4.8
		Minimum			61	64	64	55
0-Hr (Baseline)	N	Mean		72	70	72	70	
		SD		82	88	83	83	
		Minimum		107	106	108	109					
		Maximum		72.2	72.3	72.4	72.1	
0-Hr (Baseline)	N	Mean		3.1	3.4	3.4	3.3	
		SD		66	64	62	64	
		Minimum		72	72	72	72	
		Maximum		80	80	80	80	

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 23DEC2019 at 5:40 PM by Table 14.3.5.sas
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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

				Treatment				Change From Baseline			
Vital Test Parameter	Visit	Statistic	Overall	A	B	C	D	A	B	C	D
	2-Hr	N		107	106	108	109	107	106	108	109
		Mean		71.7	72.2	72.2	72.5	-0.5	-0.1	-0.2	0.4
		SD		3.7	4.0	3.7	3.9	4.1	4.3	4.3	3.9
		Minimum		64	64	64	64	-10	-12	-8	-8
		Median		70	72	72	72	-2	-1	-2	2
		Maximum		80	80	80	80	10	12	10	10
	4-Hr	N		107	106	108	109	107	106	108	109
		Mean		71.3	72.4	72.4	72.1	-0.8	0.1	0.0	-0.1
		SD		3.8	4.0	3.2	4.0	3.9	4.1	3.6	4.7
		Minimum		64	64	66	64	-10	-12	-10	-12
		Median		72	72	72	72	0	0	0	0
		Maximum		80	80	80	80	10	12	10	12
	6-Hr	N		107	106	108	109	107	106	108	109
		Mean		71.9	72.3	72.5	72.8	-0.2	0.1	0.2	0.6
		SD		3.9	4.2	3.9	3.9	4.3	5.0	4.4	4.2
		Minimum		64	64	64	64	-12	-14	-10	-8
		Median		72	72	72	72	0	0	0	0
		Maximum		80	80	80	80	10	12	10	10

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

				Treatment				Change From Baseline			
Vital Test Parameter	Visit	Statistic	Overall	A	B	C	D	A	B	C	D
	12-Hr	N		107	106	108	109	107	106	108	109
		Mean		71.7	71.8	72.5	72.3	-0.5	-0.5	0.1	0.1
		SD		3.9	4.1	3.7	3.7	4.5	5.0	4.3	4.7
		Minimum		64	64	64	64	-12	-12	-10	-14
		Median		72	70	72	72	0	0	0	0
		Maximum		80	80	80	80	12	12	10	10
	24-Hr	N		106	106	108	109	106	106	108	109
		Mean		71.7	72.4	71.9	71.6	-0.5	0.1	-0.4	-0.6
		SD		4.3	3.6	3.9	4.2	4.2	4.8	4.6	5.0
		Minimum		64	66	64	64	-12	-12	-12	-14
		Median		71	72	72	70	0	0	0	-2
		Maximum		80	80	80	80	10	16	10	10
	36-Hr	N		106	106	108	109	106	106	108	109
		Mean		72.1	72.0	72.5	72.0	-0.1	-0.2	0.2	-0.2
		SD		4.2	4.2	3.9	3.7	4.2	4.9	4.8	4.8
		Minimum		62	64	64	64	-10	-12	-14	-14
		Median		72	72	72	72	0	0	0	0
		Maximum		80	80	80	80	14	10	14	12

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

Vital Test Parameter	Visit	Statistic	Overall	Treatment				Change From Baseline			
				A	B	C	D	A	B	C	D
Pulse Rate	Screening	N	112								
		Mean	75.1								
		SD	4.32								
		Minimum	64								
		Median	75								
		Maximum	88								
	check-In	N		107	107	109	112				
		Mean		75.4	75.7	75.2	75.0
		SD		5.6	6.5	6.6	6.0
		Minimum		64	60	64	62
		Median		76	76	74	74
		Maximum		91	96	108	93
	0-Hr (Baseline)	N		107	106	108	109				
		Mean		74.2	74.7	74.8	74.5
		SD		3.7	3.9	3.7	3.8
		Minimum		64	64	66	66
		Median		74	76	74	74
		Maximum		88	82	86	92

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 23DEC2019 at 5:40 PM by Table 14.3.5.sas
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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

Vital Test Parameter	Visit	Statistic	Overall	Treatment				Change From Baseline			
				A	B	C	D	A	B	C	D
	2-Hr	N		107	106	108	109	107	106	108	109
		Mean		73.3	73.5	73.2	73.2	-0.9	-1.2	-1.6	-1.3
		SD		4.6	5.1	4.6	4.5	4.8	5.2	4.9	4.8
		Minimum		64	64	62	64	-16	-12	-14	-14
		Median		72	74	74	74	-2	-2	-2	-2
		Maximum		86	86	82	88	12	12	12	10
	4-Hr	N		107	106	108	109	107	106	108	109
		Mean		73.9	74.8	74.3	74.6	-0.3	0.1	-0.5	0.1
		SD		4.6	5.0	4.7	4.9	4.8	5.4	5.3	5.4
		Minimum		62	64	62	64	-16	-14	-10	-10
		Median		74	75	74	74	0	0	-2	0
		Maximum		88	88	86	90	10	10	14	12
	6-Hr	N		107	106	108	109	107	106	108	109
		Mean		76.9	77.0	76.4	76.6	2.8	2.3	1.6	2.1
		SD		5.4	4.9	4.9	5.5	5.9	5.3	5.6	5.8
		Minimum		66	66	66	66	-14	-14	-10	-10
		Median		78	76	76	76	2	2	2	2
		Maximum		90	92	90	94	20	18	20	16

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

Vital Test Parameter	Visit	Statistic	Overall	Treatment				Change From Baseline			
				A	B	C	D	A	B	C	D
	12-Hr	N		107	106	108	109	107	106	108	109
		Mean		75.6	76.1	75.7	75.2	1.4	1.4	0.9	0.7
		SD		4.6	4.3	4.4	5.2	5.5	5.4	5.2	5.5
		Minimum		62	64	66	64	-12	-10	-10	-14
		Median		76	76	76	76	2	0	0	2
		Maximum		88	88	88	94	16	16	16	16
	24-Hr	N		106	106	108	109	106	106	108	109
		Mean		74.3	75.3	74.1	74.4	0.1	0.6	-0.7	-0.1
		SD		4.8	4.6	5.2	4.8	5.3	5.5	5.7	5.4
		Minimum		64	62	62	64	-10	-10	-12	-14
		Median		74	76	74	74	0	0	0	0
		Maximum		92	88	88	92	18	14	18	14
	36-Hr	N		106	106	108	109	106	106	108	109
		Mean		74.4	74.8	74.9	74.8	0.2	0.1	0.1	0.2
		SD		4.7	4.3	4.9	4.7	4.8	4.8	5.4	5.3
		Minimum		62	64	62	64	-14	-14	-12	-10
		Median		74	74	74	76	0	0	0	0
		Maximum		84	84	88	86	12	12	14	12

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

Vital Test Parameter	Visit	Statistic	Overall	Treatment				Change From Baseline				
				A	B	C	D	A	B	C	D	
Systolic Blood Pressure	Screening	N	112									
		Mean	114.4									
		SD	5.12									
		Minimum	104									
		Median	114									
		Maximum	128									
	check-In	N			107	107	109	112				
		Mean			113.4	113.2	113.4	113.4
		SD			4.4	5.2	5.2	5.4
		Minimum			104	104	106	94
0-Hr (Baseline)	0-Hr (Baseline)	N										
		Mean										
		SD										
		Minimum										
		Median										
		Maximum										

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

Vital Test Parameter	Visit	Statistic	Overall	Treatment				Change From Baseline			
				A	B	C	D	A	B	C	D
	2-Hr	N		107	106	108	109	107	106	108	109
		Mean		112.3	112.5	112.6	112.6	-0.9	-0.8	-1.1	-0.5
		SD		4.7	4.2	4.1	4.3	4.7	4.5	4.2	4.5
		Minimum		104	104	104	104	-12	-12	-8	-10
		Median		112	112	112	112	-2	-2	-2	-2
		Maximum		124	124	120	128	12	12	12	10
	4-Hr	N		107	106	108	109	107	106	108	109
		Mean		112.0	112.8	112.5	112.9	-1.2	-0.5	-1.2	-0.3
		SD		4.3	4.5	3.9	4.4	4.4	4.7	4.6	4.9
		Minimum		104	104	104	104	-14	-12	-10	-14
		Median		112	112	112	112	-2	-2	-2	0
		Maximum		124	124	124	124	14	10	10	14
	6-Hr	N		107	106	108	109	107	106	108	109
		Mean		113.1	113.7	113.1	113.2	-0.1	0.4	-0.7	0.1
		SD		4.4	4.7	4.5	4.4	4.7	5.7	5.4	5.2
		Minimum		104	106	104	104	-10	-12	-14	-14
		Median		112	114	113	112	0	0	0	0
		Maximum		124	126	124	124	10	18	10	14

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

Vital Test Parameter	Visit	Statistic	Overall	Treatment				Change From Baseline			
				A	B	C	D	A	B	C	D
	12-Hr	N		107	106	108	109	107	106	108	109
		Mean		112.4	113.2	113.8	113.4	-0.7	-0.2	0.0	0.3
		SD		4.4	4.7	4.7	4.6	4.5	5.6	5.1	5.3
		Minimum		104	104	104	104	-12	-14	-16	-12
		Median		112	112	114	112	0	0	0	0
		Maximum		122	126	128	126	10	12	14	16
	24-Hr	N		106	106	108	109	106	106	108	109
		Mean		112.8	113.0	112.6	112.5	-0.4	-0.3	-1.2	-0.6
		SD		4.4	4.4	4.5	4.4	4.6	5.2	5.4	4.9
		Minimum		104	104	104	104	-12	-12	-12	-12
		Median		112	112	112	112	0	0	-2	0
		Maximum		126	122	126	124	12	16	14	10
	36-Hr	N		106	106	108	109	106	106	108	109
		Mean		113.7	112.8	113.6	113.0	0.5	-0.5	-0.1	-0.1
		SD		4.8	4.1	4.4	4.8	4.9	5.2	5.2	5.7
		Minimum		106	104	104	104	-14	-14	-14	-14
		Median		114	112	114	112	0	0	0	0

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.5. Vital Signs Summary and Change from Baseline, Safety Analysis Set

				Treatment				Change From Baseline			
Vital Test Parameter	Visit	Statistic	Overall	A	B	C	D	A	B	C	D
		Maximum		128	122	126	126	10	12	10	14
Source: Listing 16.2.8.9.2											

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
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Table 14.3.6.1 ECG Summary and Change from Baseline, Safety Analysis Set

Test	Visit	Statistics	Value
HR	Screening	N	112
		Mean	69.3
		SD	9.4
		Minimum	50
		Median	68
		Maximum	94
	EOS/ET	N	110
		Mean	67.3
		SD	11.0
		Minimum	45
		Median	64
		Maximum	107
	Change from Baseline	N	110
		Mean	-2.0
		SD	9.7
		Minimum	-29
		Median	-2
		Maximum	30

Source: Listing 16.2.10.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:33 AM by Table 14.3.6.1.sas
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Table 14.3.6.1 ECG Summary and Change from Baseline, Safety Analysis Set

Test	Visit	Statistics	Value
PR Interval	Screening	N	112
		Mean	142.8
		SD	15.9
		Minimum	110
		Median	141
		Maximum	189
	EOS/ET	N	110
		Mean	141.9
		SD	16.2
		Minimum	102
		Median	141
		Maximum	183
	Change from Baseline	N	110
		Mean	-1.2
		SD	9.5
		Minimum	-26
		Median	-1
		Maximum	22

Source: Listing 16.2.10.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:33 AM by Table 14.3.6.1.sas
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Table 14.3.6.1 ECG Summary and Change from Baseline, Safety Analysis Set

Test	Visit	Statistics	Value
QRS Duration	Screening	N	112
		Mean	90.9
		SD	8.9
		Minimum	75
		Median	90
		Maximum	116
	EOS/ET	N	110
		Mean	88.9
		SD	8.6
		Minimum	69
		Median	88
		Maximum	113
	Change from Baseline	N	110
		Mean	-2.1
		SD	5.8
		Minimum	-23
		Median	-2
		Maximum	12

Source: Listing 16.2.10.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:33 AM by Table 14.3.6.1.sas
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Table 14.3.6.1 ECG Summary and Change from Baseline, Safety Analysis Set

Test	Visit	Statistics	Value
QT Interval	Screening	N	112
		Mean	370.2
		SD	20.3
		Minimum	329
		Median	367
		Maximum	432
	EOS/ET	N	110
		Mean	370.8
		SD	22.6
		Minimum	311
		Median	369
		Maximum	424
	Change from Baseline	N	110
		Mean	0.6
		SD	19.8
		Minimum	-54
		Median	2
		Maximum	45

Source: Listing 16.2.10.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:33 AM by Table 14.3.6.1.sas
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Table 14.3.6.1 ECG Summary and Change from Baseline, Safety Analysis Set

Test	Visit	Statistics	Value
QTc Interval	Screening	N	112
		Mean	387.8
		SD	16.6
		Minimum	353
		Median	388
		Maximum	439
	EOS/ET	N	110
		Mean	384.1
		SD	17.9
		Minimum	350
		Median	383
		Maximum	424
	Change from Baseline	N	110
		Mean	-3.9
		SD	11.9
		Minimum	-38
		Median	-5
		Maximum	28

Source: Listing 16.2.10.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:33 AM by Table 14.3.6.1.sas
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Table 14.3.6.2 ECG Finding Shift from Baseline, Safety Analysis Set

Parameter	Screening	EOS/ET		
	Range	NORMAL	ABNORMAL NCS/ ABNORMAL CS	Total
Interpretation	NORMAL	107	2	109
	ABNORMAL(NCS)/ABNORMAL(CS)	0	0	0
	TOTAL	107	2	109

Source: Listing 16.2.10.2

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 23DEC2019 at 5:00 PM by Table 14.3.6.2.sas
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Table 14.3.7 Physical Examination Findings Shifts from Baseline to End of Study, Safety Analysis Set

All physical exam findings at baseline and end of study are normal.

Table 14.3.8. Summary of Protocol Deviation by Treatment Group, Safety Analysis Set

Deviation Reason n (%), D	Treatment A N=107	Treatment B N=106	Treatment C N=108	Treatment D N=109	Total N=112
Subject with at least 1 deviation	51 (47.7), 94	50 (47.2), 88	52 (48.1), 111	52 (47.7), 110	98 (87.5), 403
BLOOD SAMPLE COLLECTION DEVIATION	34 (31.8), 69	44 (41.5), 81	30 (27.8), 51	42 (38.5), 73	78 (69.6), 274
CHARCOAL ADMINISTRATION DEVIATION	0	0	11 (10.2), 25	8 (7.3), 22	19 (17.0), 47
DRUG ADMINISTRATION DEVIATION	1 (0.9), 1	0	1 (0.9), 1	0	2 (1.8), 2
DRUG ADMINISTRATION OBSERVATIONS	24 (22.4), 24	7 (6.6), 7	33 (30.6), 33	12 (11.0), 12	56 (50.0), 76
PROTOCOL NON-COMPLIANCE	0	0	0	3 (2.8), 3	3 (2.7), 3
SAMPLE PROCESSING DEVIATION	0	0	1 (0.9), 1	0	1 (0.9), 1
Major Protocol Deviations	8 (7.5), 8	0	15 (13.9), 15	8 (7.3), 9	27 (24.1), 32
BLOOD SAMPLE COLLECTION DEVIATION	0	0	0	1 (0.9), 2	1 (0.9), 2
DRUG ADMINISTRATION OBSERVATIONS	8 (7.5), 8	0	15 (13.9), 15	4 (3.7), 4	24 (21.4), 27
PROTOCOL NON-COMPLIANCE	0	0	0	3 (2.8), 3	3 (2.7), 3
D: Deviation Source: Listing 16.2.2 Note: Subjects with Protocol Deviations in more than one treatment are only counted once in total.					

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 04FEB2020 at 11:39 AM by Table 14.3.8.sas
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Table 14.3.10. Summary of Cough Assessment, Safety Analysis Set

Subjects Reporting the Indicated Number of Coughs, n (%)	Treatment A (N=107)	Treatment B (N=106)	Treatment C (N=108)	Treatment D (N=109)	Total (N=112)
Subjects with at least one cough	5 (4.7)	2 (1.9)	15 (13.9)	7 (6.4)	21 (18.8)
Subjects by actual number of coughs Observed					
1	0	1 (0.9)	6 (5.6)	5 (4.6)	7 (6.3)
2	1 (0.9)	1 (0.9)	7 (6.5)	2 (1.8)	9 (8.0)
3	2 (1.9)	0	1 (0.9)	0	2 (1.8)
4	1 (0.9)	0	1 (0.9)	0	2 (1.8)
5	1 (0.9)	0	0	0	1 (0.9)
Source: Listing 16.2.5.6 If subjects experienced coughs in more than one treatment period, the treatment period with the most number of coughs is counted in the Total column					

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations
 Treatment B: FOSTAIR 200/6 mcg- 2 inhalations
 Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations
 Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations
 Table Generation 19FEB2020 at 09:21 AM by Table 14.3.10.sas
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14.4. Summary of Concomitant Medications

This section contains the following table:

Number	Title
14.3.9	Summary of Prior and Concomitant Medication by Therapeutic Class and Preferred Term, Safety Analysis Set

Table 14.3.9. Summary of Prior and Concomitant Medication by Therapeutic class and Preferred term, Safety Analysis Set

Therapeutic Class WHO Version (Sep2019) Preferred Term, n (%)	Total (N=112)
ANTIDIARRHEAL MICROORGANISMS	1(0.9%)
Bacillus coagulans	1(0.9%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	1(0.9%)
Diclofenac sodium	1(0.9%)
CORTICOSTEROIDS, PLAIN	1(0.9%)
Dexamethasone sodium phosphate	1(0.9%)
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1(0.9%)
Ranitidine hydrochloride	1(0.9%)
ELECTROLYTES WITH CARBOHYDRATES	1(0.9%)
Glucose;Potassium chloride;Sodium chloride;Sodium citrate	1(0.9%)
IRON PREPARATIONS	2(1.8%)
Ferrous ascorbate;Folic acid	1(0.9%)
Ferrous ascorbate;Folic acid;Zinc	1(0.9%)
OPIOIDS	1(0.9%)
Tramadol hydrochloride	1(0.9%)
OTHER ANALGESICS AND ANTIPYRETICS	5(4.5%)
Chlorphenamine maleate;Paracetamol;Phenylephrine hydrochloride	1(0.9%)

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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Table 14.3.9. Summary of Prior and Concomitant Medication by Therapeutic class and Preferred term, Safety Analysis Set

Therapeutic Class WHO Version (Sep2019) Preferred Term, n (%)	Total (N=112)
Ibuprofen;Paracetamol	1(0.9%)
Paracetamol	4(3.6%)
QUINOLONE ANTIBACTERIALS	2(1.8%)
NORFLOXACIN	2(1.8%)

Treatment A: Lupin BDP/FF 200/6 mcg- 2 inhalations

Treatment B: FOSTAIR 200/6 mcg- 2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal- 2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal- 2 inhalations

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14.5. Figures

This section contains the following figures:

Number	Title
14.2.2.1.1	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.1.2	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.1.3	Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.1.4	Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.1.5	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.1.6	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.1.7	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (without charcoal)
14.2.2.1.8	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (without charcoal)
14.2.2.1.9	Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (without charcoal)
14.2.2.1.10	Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (without charcoal)
14.2.2.1.11	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), FAS (without charcoal)
14.2.2.1.12	Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), FAS (without charcoal)
14.2.2.2.1	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.2.2	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (without charcoal)

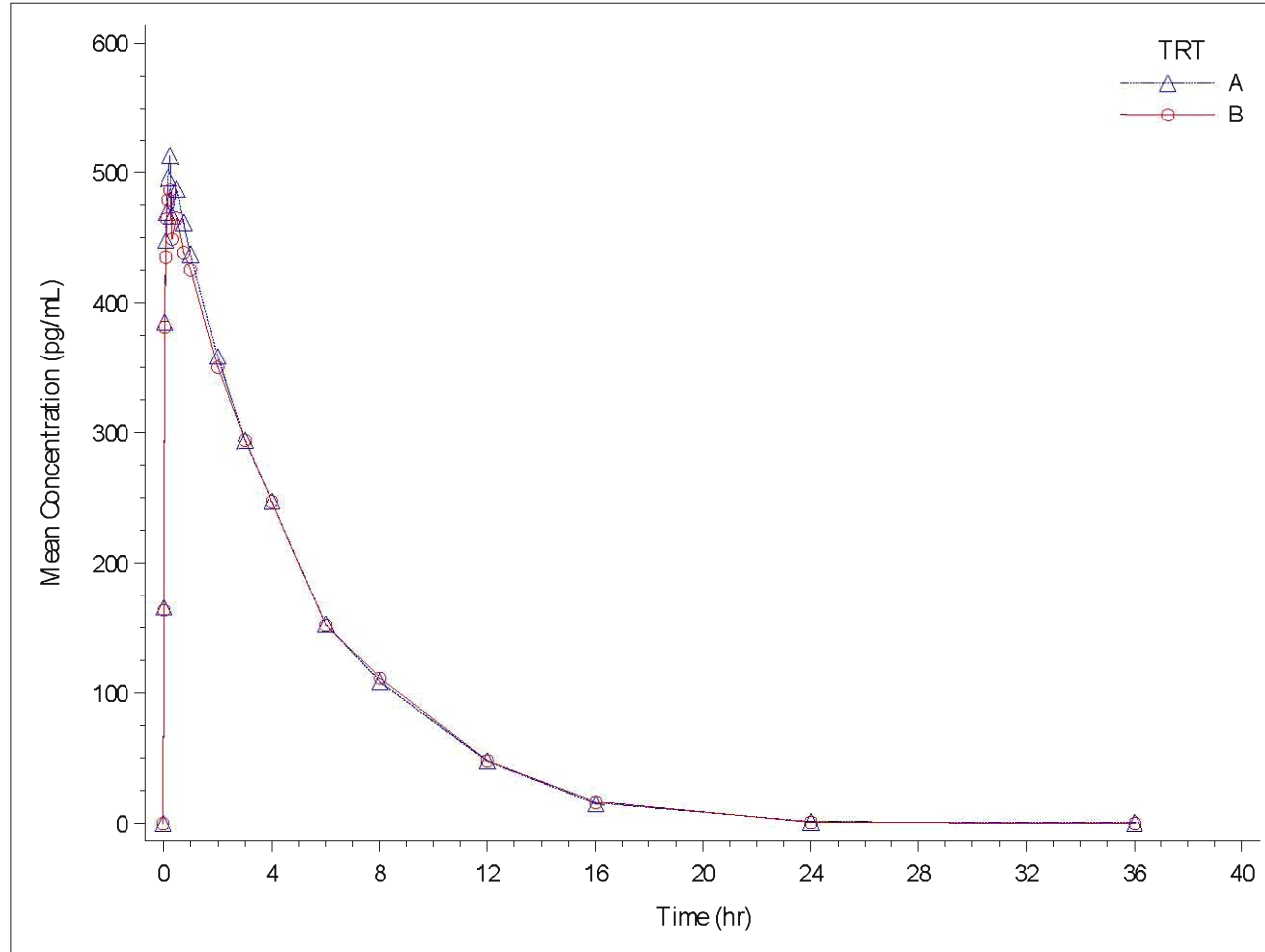
Number	Title
14.2.2.2.3	Arithmetic Mean (\pm SD)Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.2.4	Arithmetic Mean (\pm SD)Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.2.5	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.2.6	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.2.7	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (without charcoal)
14.2.2.2.8	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (without charcoal)
14.2.2.2.9	Arithmetic Mean (\pm SD)Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (without charcoal)
14.2.2.2.10	Arithmetic Mean (\pm SD)Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (without charcoal)
14.2.2.2.11	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), FAS (without charcoal)
14.2.2.2.12	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), FAS (without charcoal)
14.2.2.2.13	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (with charcoal)
14.2.2.2.14	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (with charcoal)
14.2.2.2.15	Arithmetic Mean (\pm SD)Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (with charcoal)
14.2.2.2.16	Arithmetic Mean (\pm SD)Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (with charcoal)
14.2.2.2.17	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), PK Analysis Set (with charcoal)

Number	Title
14.2.2.2.18	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), PK Analysis Set (with charcoal)
14.2.2.2.19	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (with charcoal)
14.2.2.2.20	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (with charcoal)
14.2.2.2.21	Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (with charcoal)
14.2.2.2.22	Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (with charcoal)
14.2.2.2.23	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), FAS (with charcoal)
14.2.2.2.24	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), FAS (with charcoal)
14.2.2.2.25	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (with and without charcoal)
14.2.2.2.26	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (with and without charcoal)
14.2.2.2.27	Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (with and without charcoal)
14.2.2.2.28	Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (with and without charcoal)
14.2.2.2.29	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), PK Analysis Set (with and without charcoal)
14.2.2.2.30	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), PK Analysis Set (with and without charcoal)
14.2.2.2.31	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (with and without charcoal)
14.2.2.2.32	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (with and without charcoal)

Number	Title
14.2.2.2.33	Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (with and without charcoal)
14.2.2.2.34	Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (with and without charcoal)
14.2.2.2.35	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), FAS (with and without charcoal)
14.2.2.2.36	Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), FAS (with and without charcoal)
14.2.2.3.1	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.3.2	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.3.3	Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.3.4	Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.3.5	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), PK Analysis Set (without charcoal)
14.2.2.3.6	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), PK Analysis Set (without charcoal)
14.2.2.3.7	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (without charcoal)
14.2.2.3.8	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (without charcoal)
14.2.2.3.9	Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale), FAS (without charcoal)
14.2.2.3.10	Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale), FAS (without charcoal)
14.2.2.3.11	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale), FAS (without charcoal)

Number	Title
14.2.2.3.12	Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale), FAS (without charcoal)

Figure 14.2.2.1.1 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), PK Analysis Set

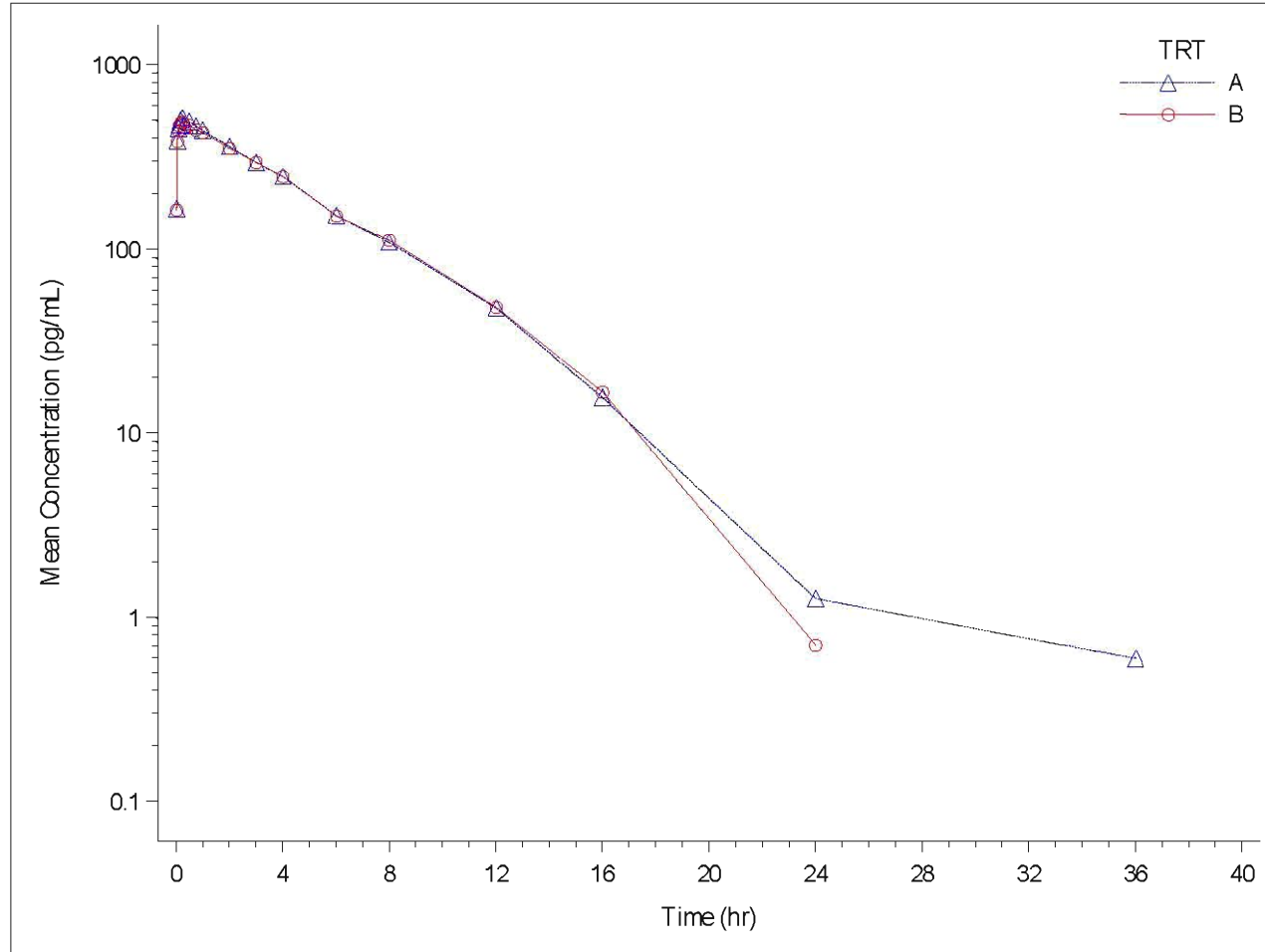


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 9:32 AM by Figure 14.2.2.1.1.sas

Figure 14.2.2.1.2 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), PK Analysis Set

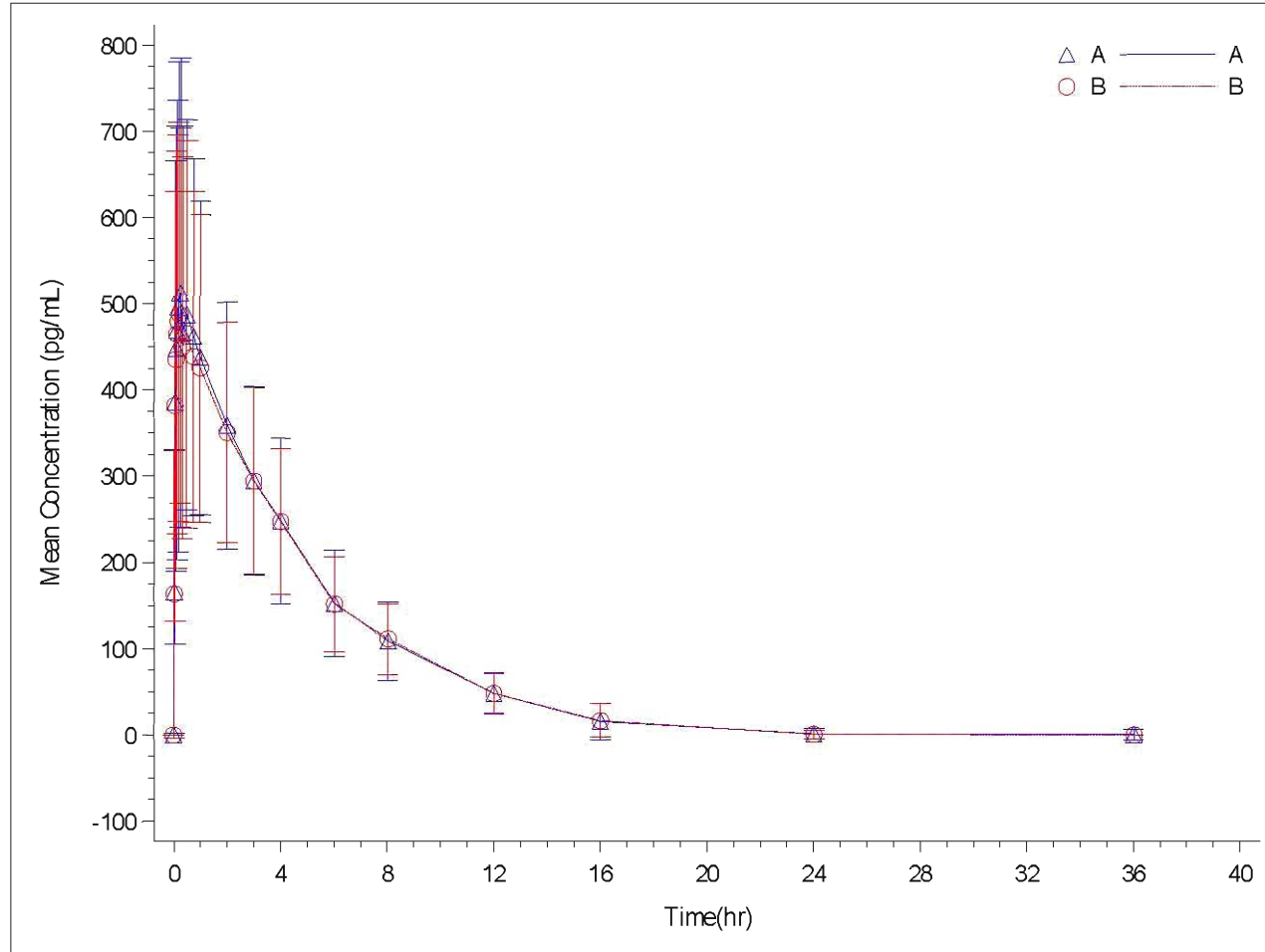


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 9:33 AM by Figure 14.2.2.1.2.sas

Figure 14.2.2.1.3 Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), PK Analysis Set

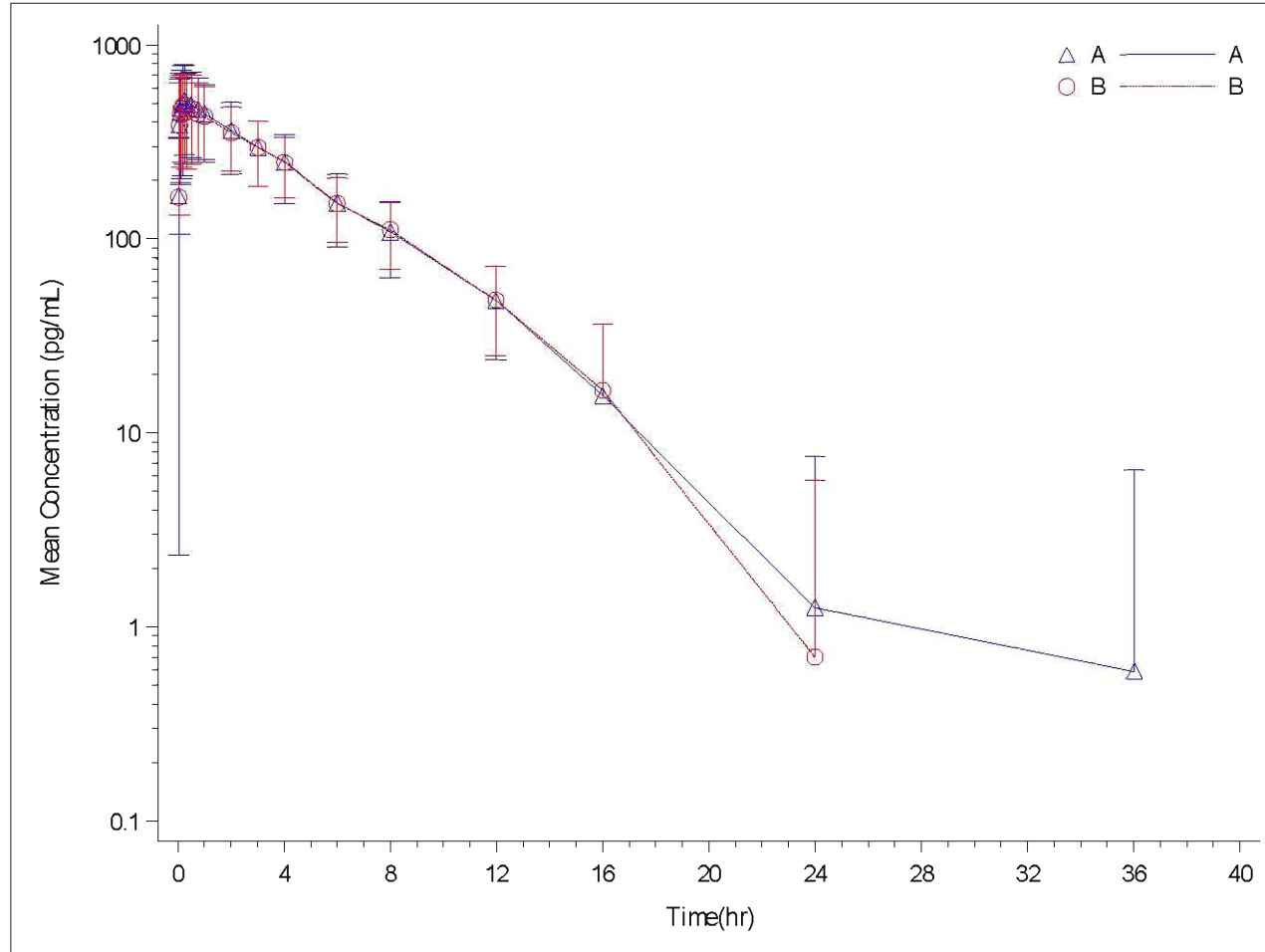


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:18 AM by Figure 14.2.2.1.3.sas

Figure 14.2.2.1.4 Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), PK Analysis Set

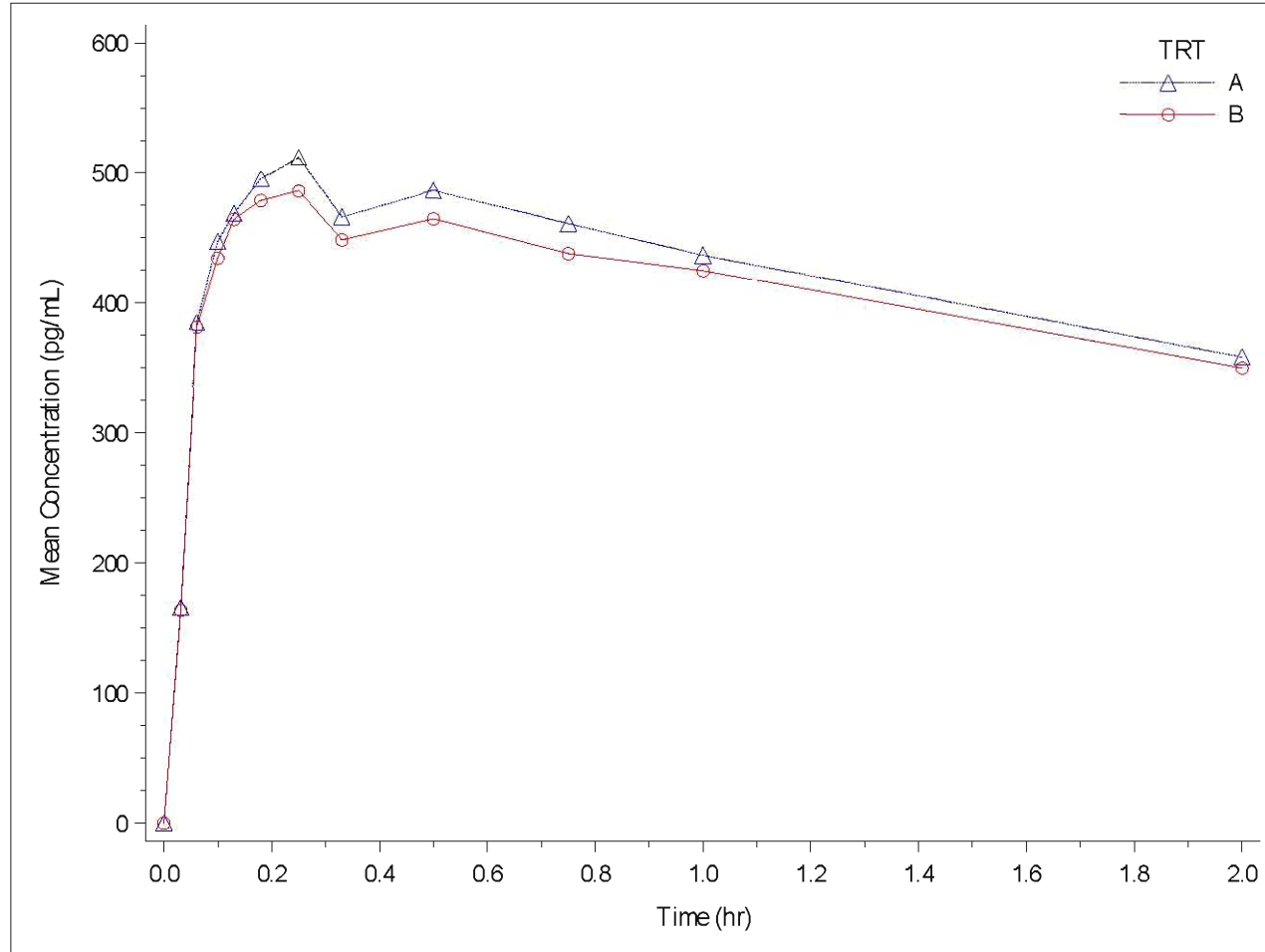


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:25 AM by Figure 14.2.2.1.4.sas

Figure 14.2.2.1.5 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (without charcoal), PK Analysis Set

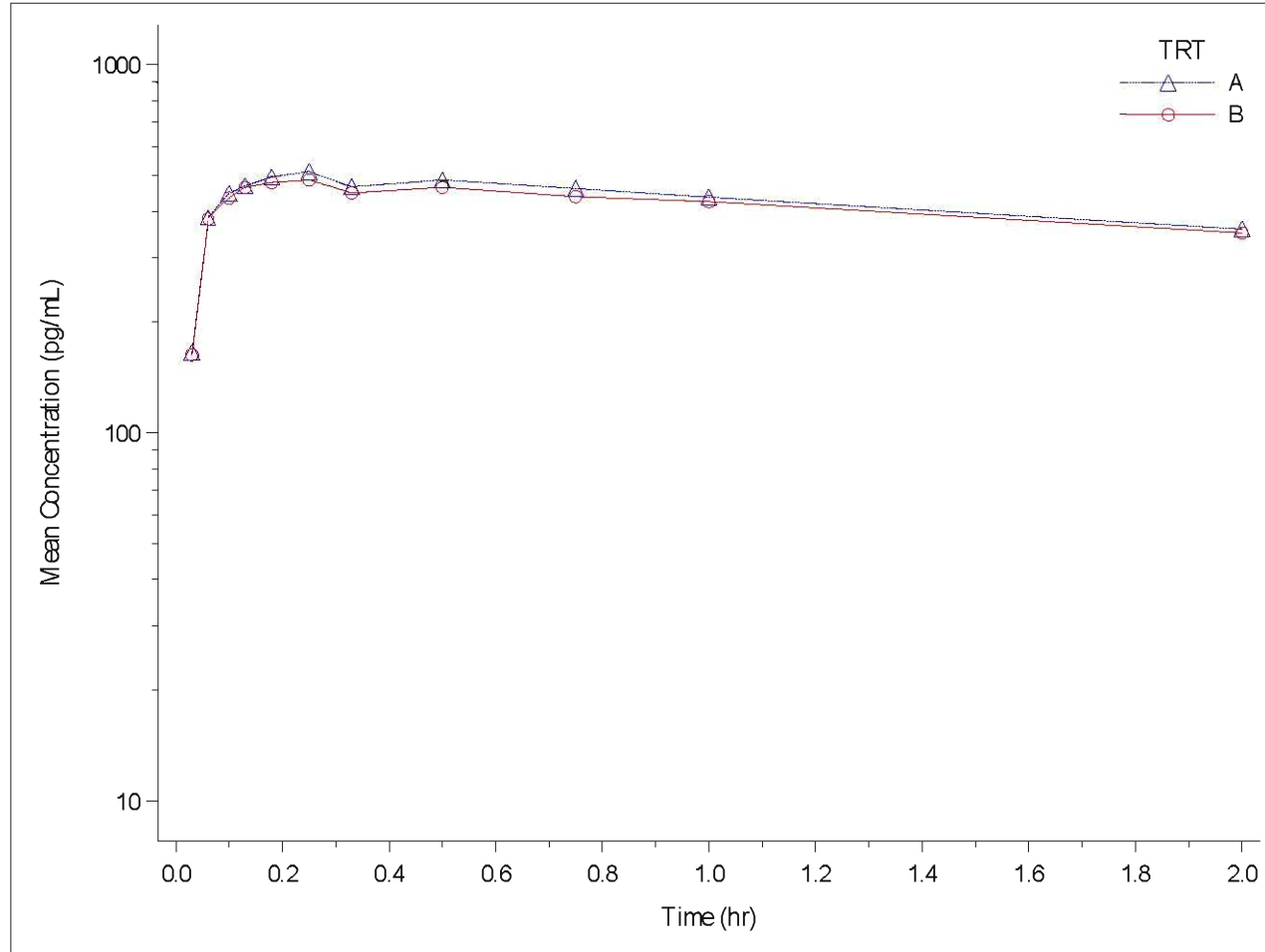


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:09 AM by Figure 14.2.2.1.5.sas

Figure 14.2.2.1.6 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (without charcoal), PK Analysis Set

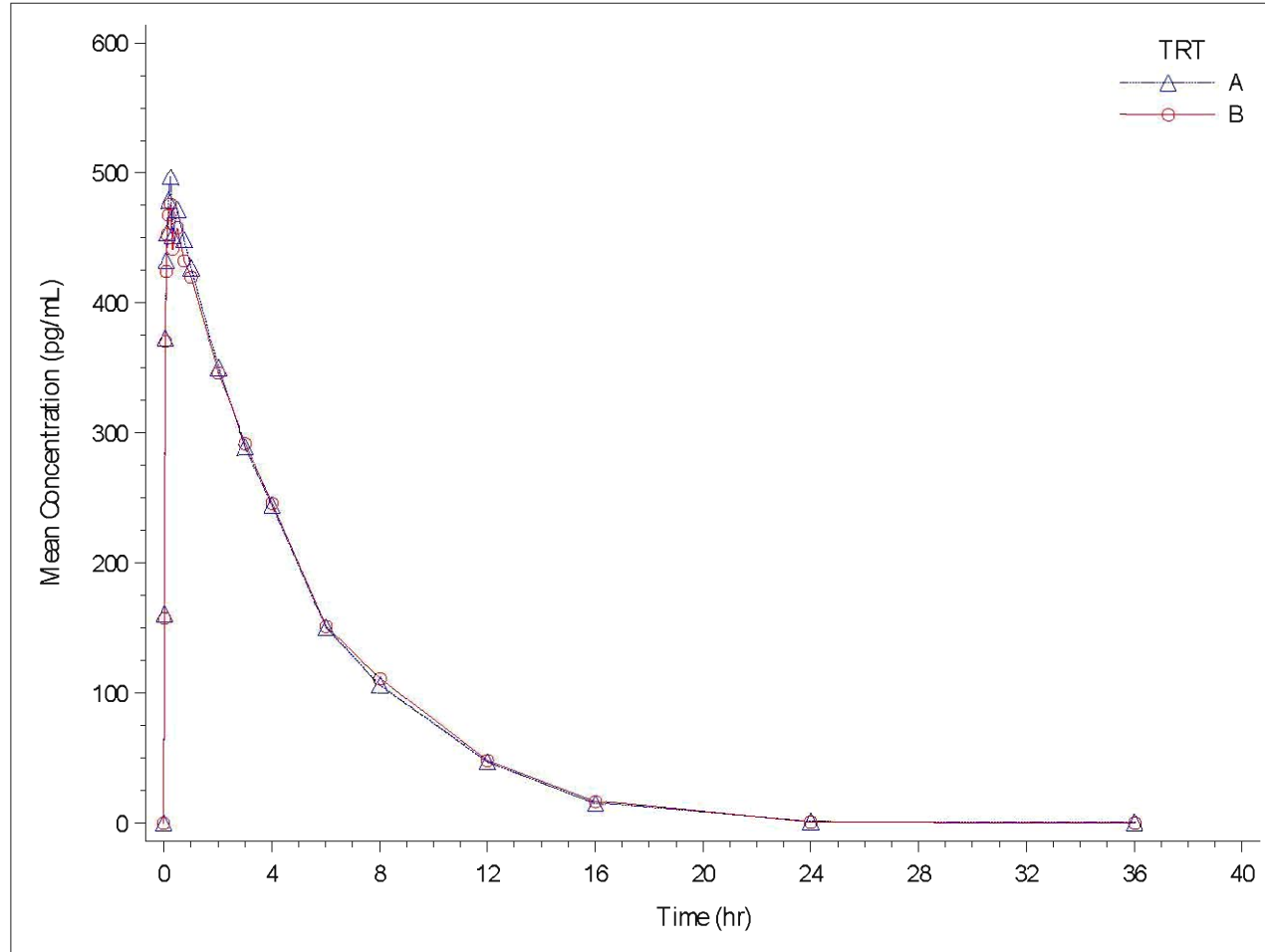


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:11 AM by Figure 14.2.2.1.6.sas

Figure 14.2.2.1.7 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), FAS

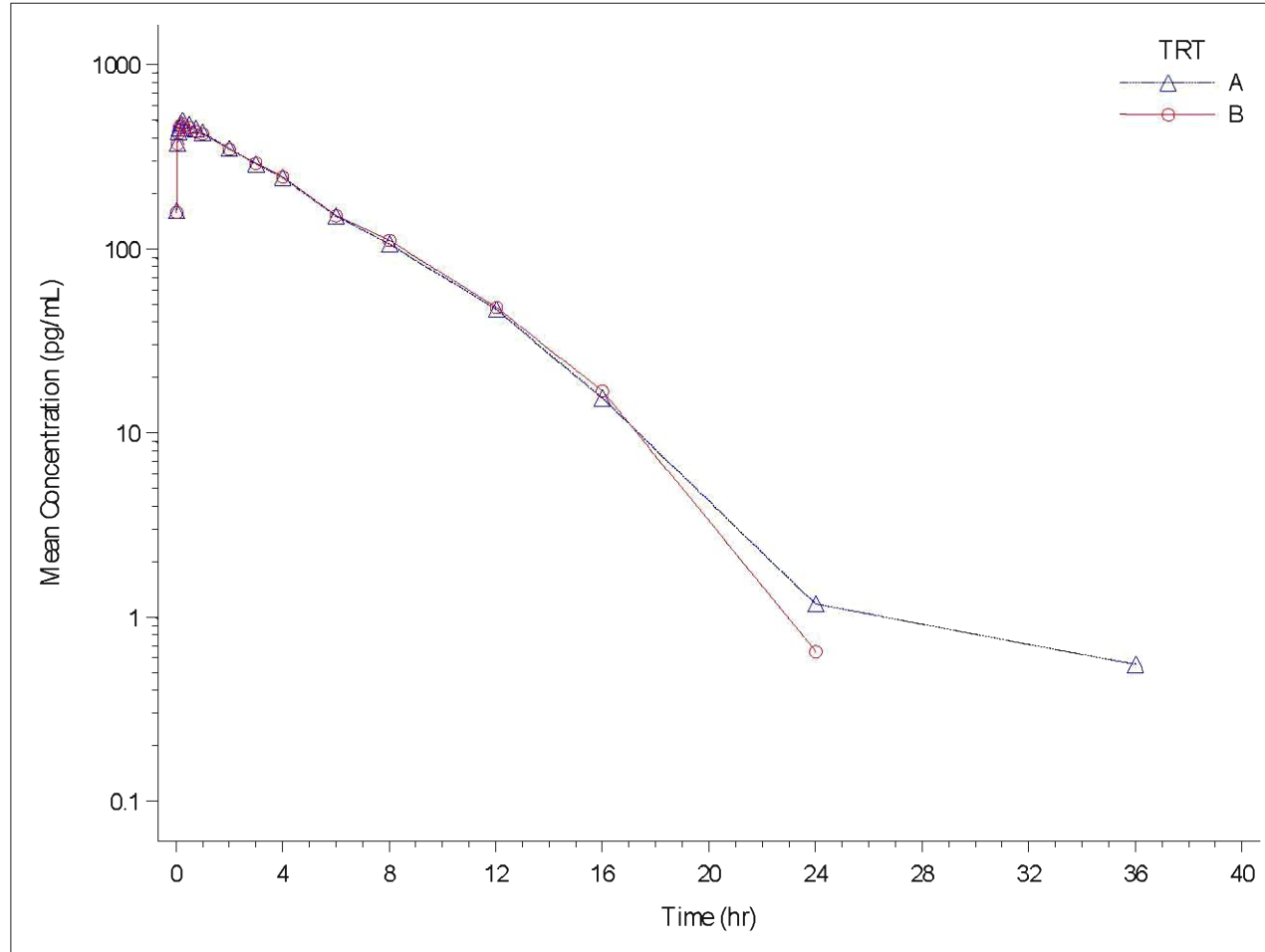


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:13 AM by Figure 14.2.2.1.7.sas

Figure 14.2.2.1.8 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), FAS

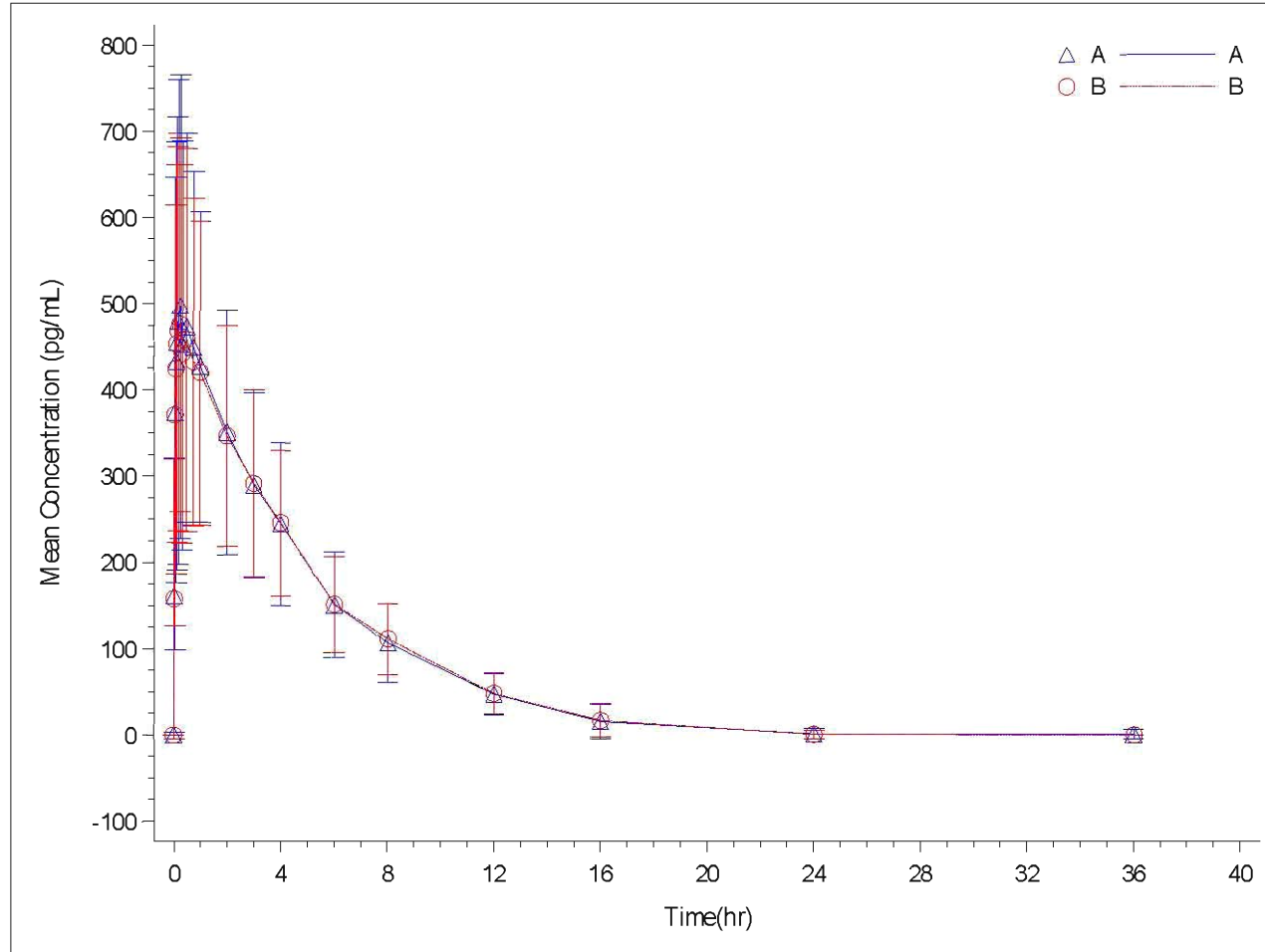


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:15 AM by Figure 14.2.2.1.8.sas

Figure 14.2.2.1.9 Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), FAS

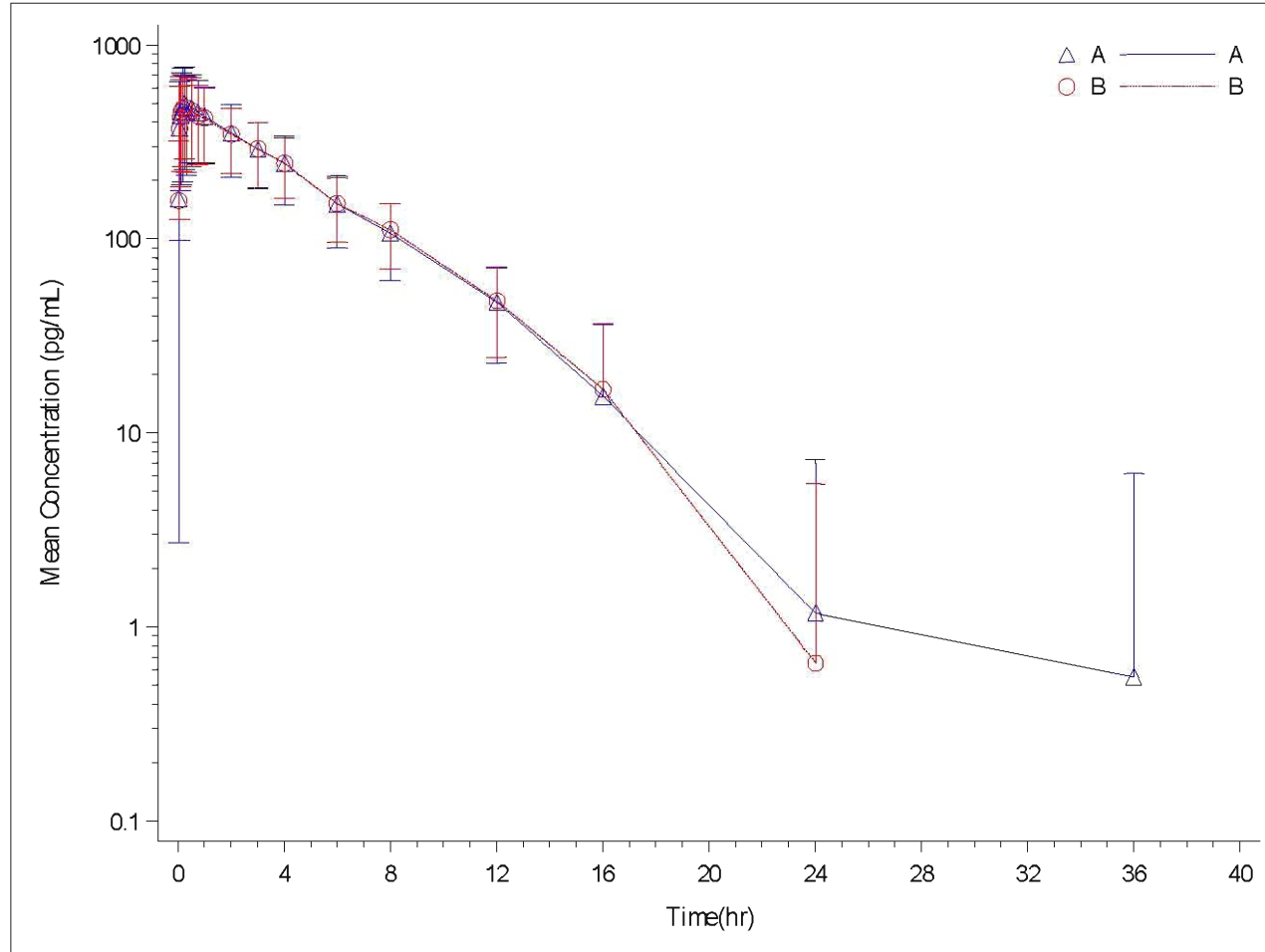


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:27 AM by Figure 14.2.2.1.9.sas

Figure 14.2.2.1.10 Arithmetic Mean (\pm SD) 17-BMP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), FAS

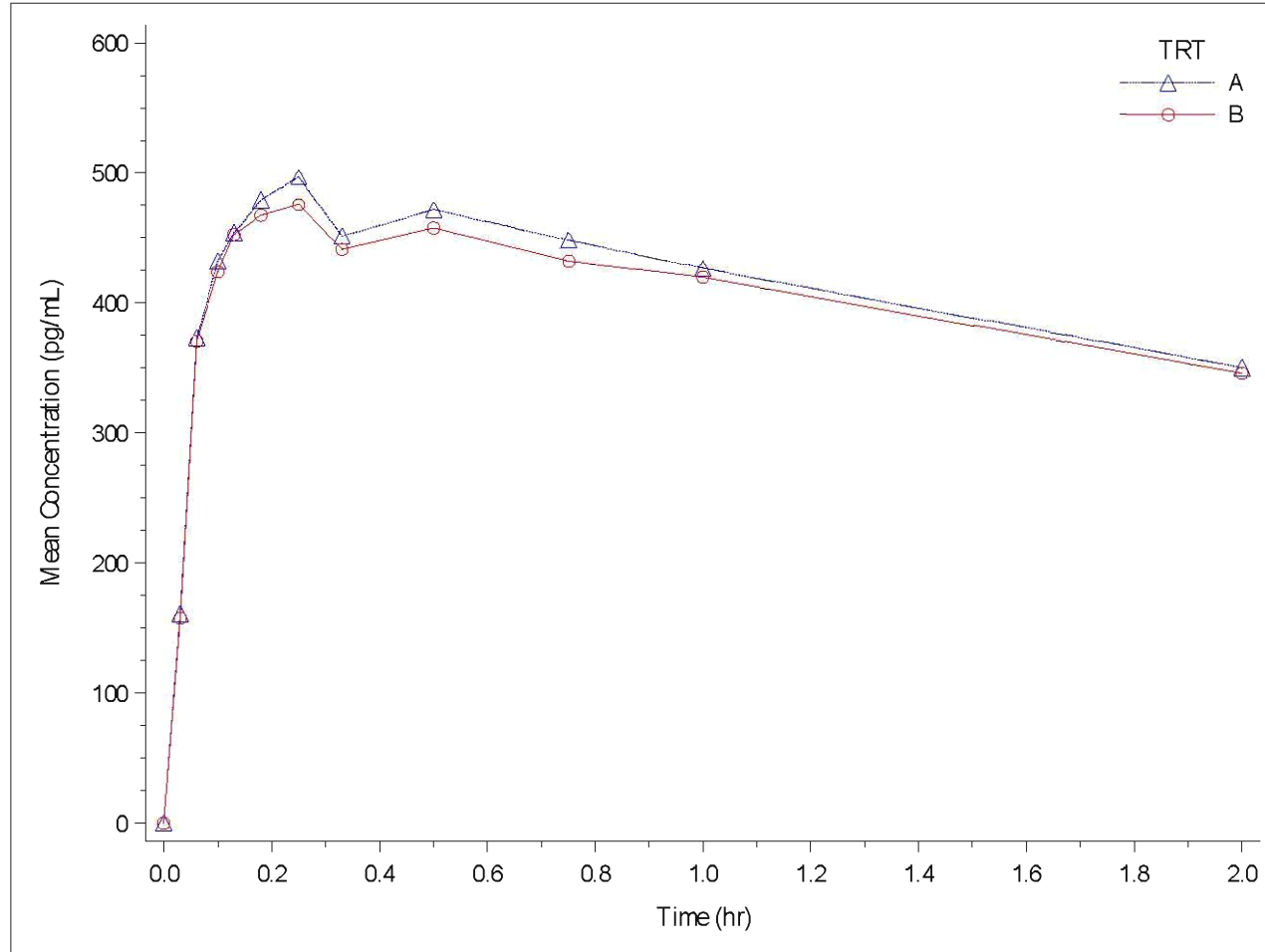


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:28 AM by Figure 14.2.2.1.10.sas

Figure 14.2.2.1.11 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (without charcoal), FAS

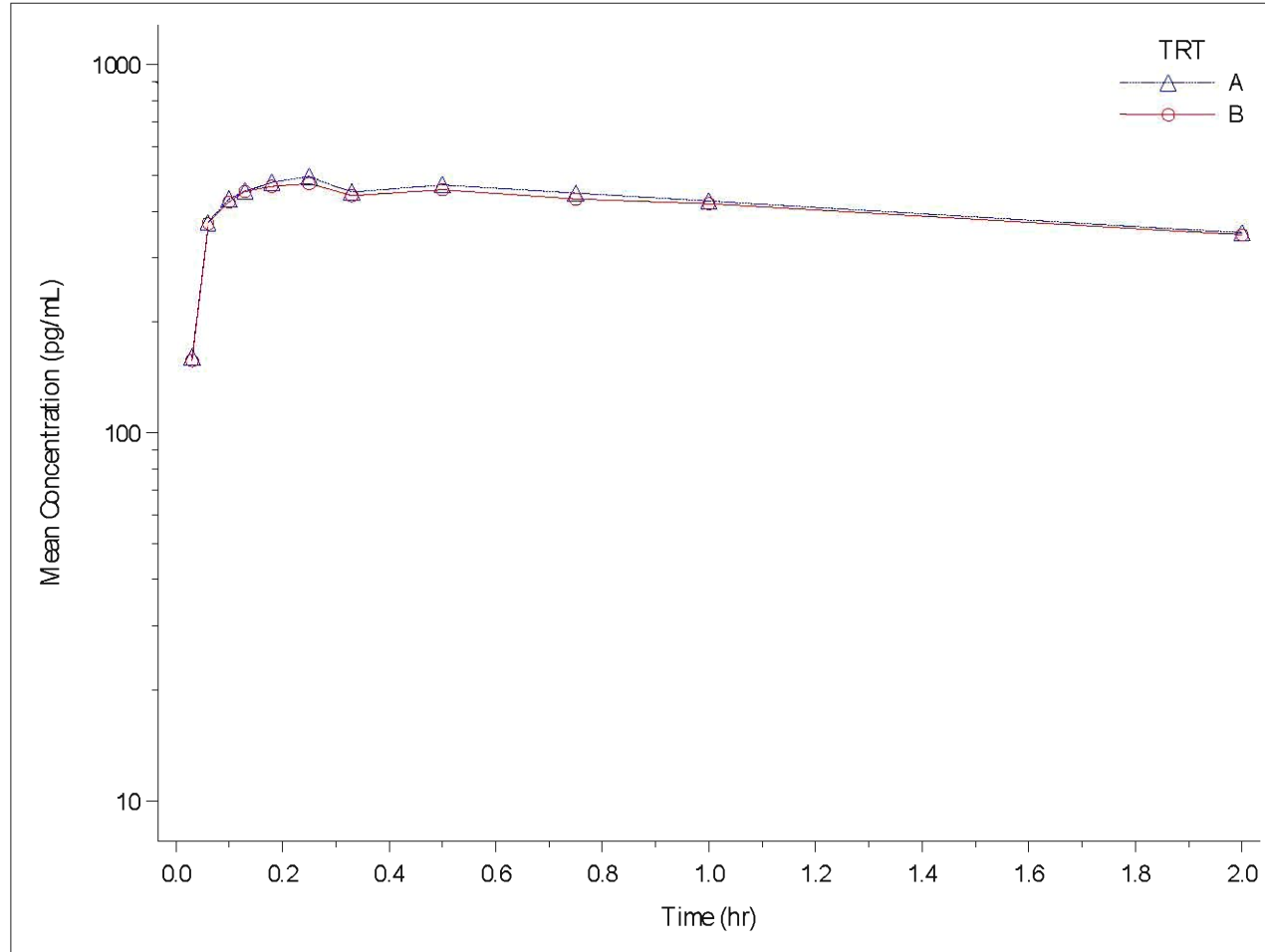


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:24 AM by Figure 14.2.2.1.11.sas

Figure 14.2.2.1.12 Arithmetic Mean 17-BMP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (without charcoal), FAS

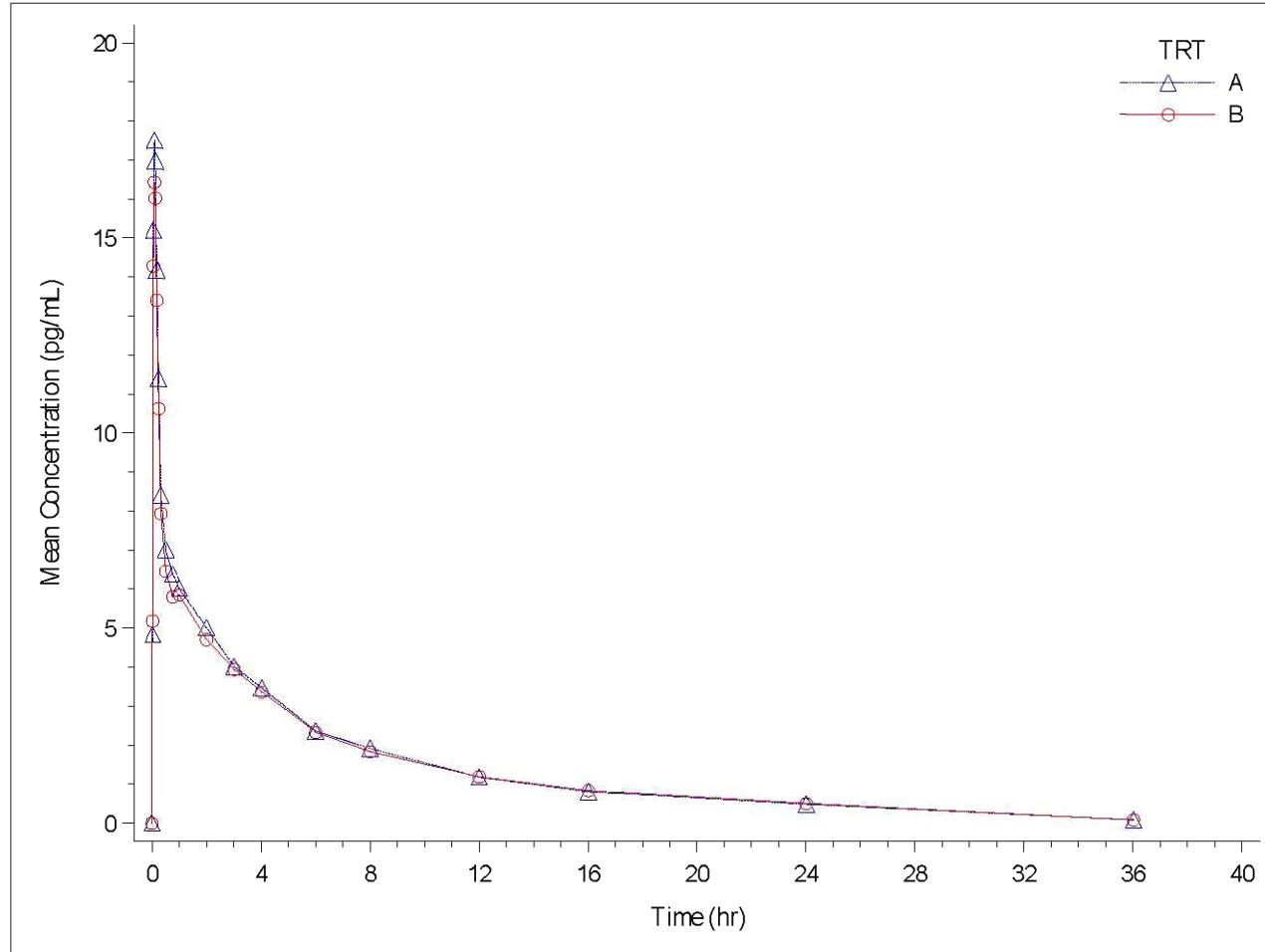


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:27 AM by Figure 14.2.2.1.12.sas

Figure 14.2.2.2.1 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), PK Analysis Set

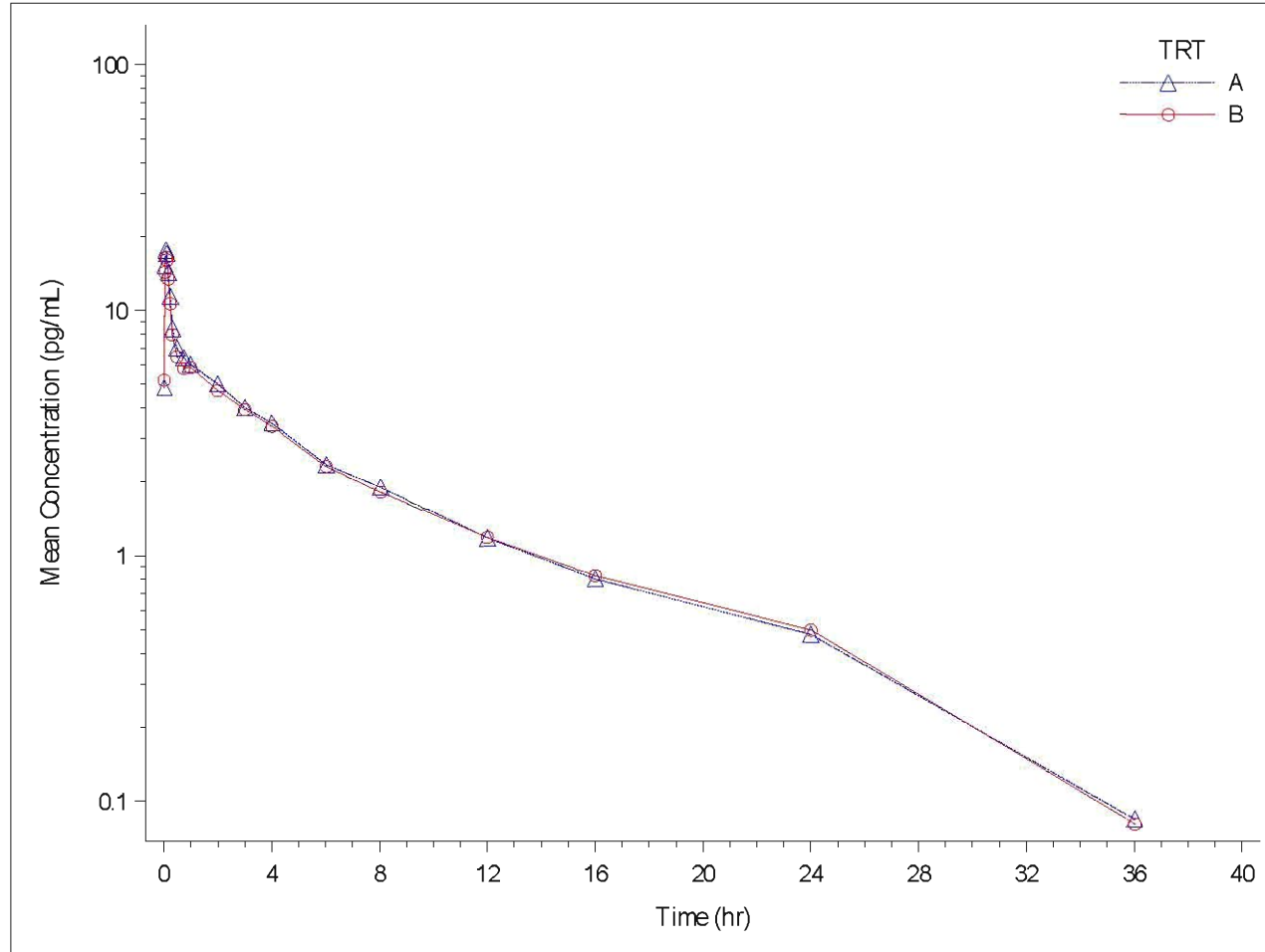


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:28 AM by Figure 14.2.2.2.1.sas

Figure 14.2.2.2.2 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), PK Analysis Set

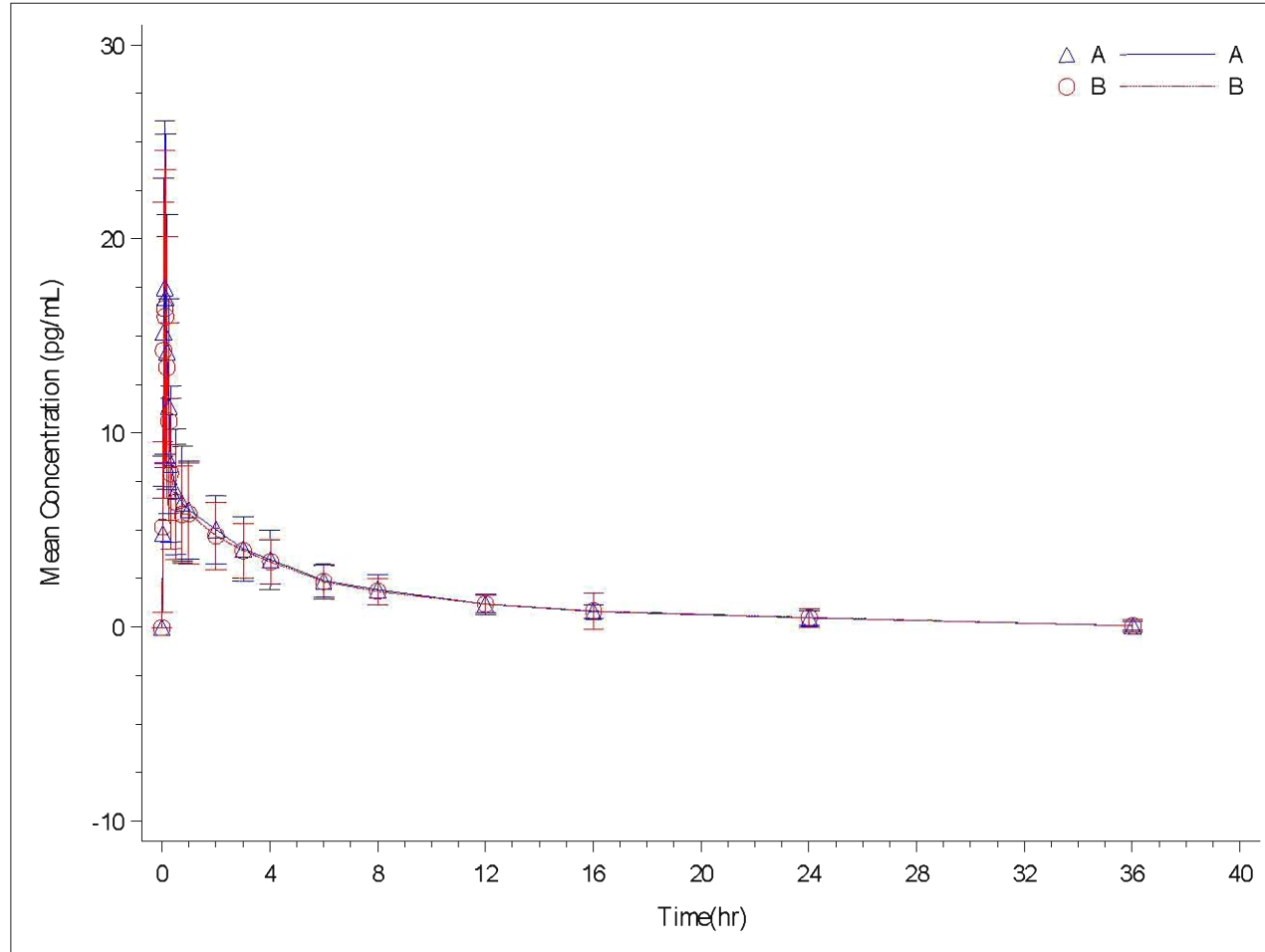


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:29 AM by Figure 14.2.2.2.2.sas

Figure 14.2.2.2.3 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), PK Analysis Set

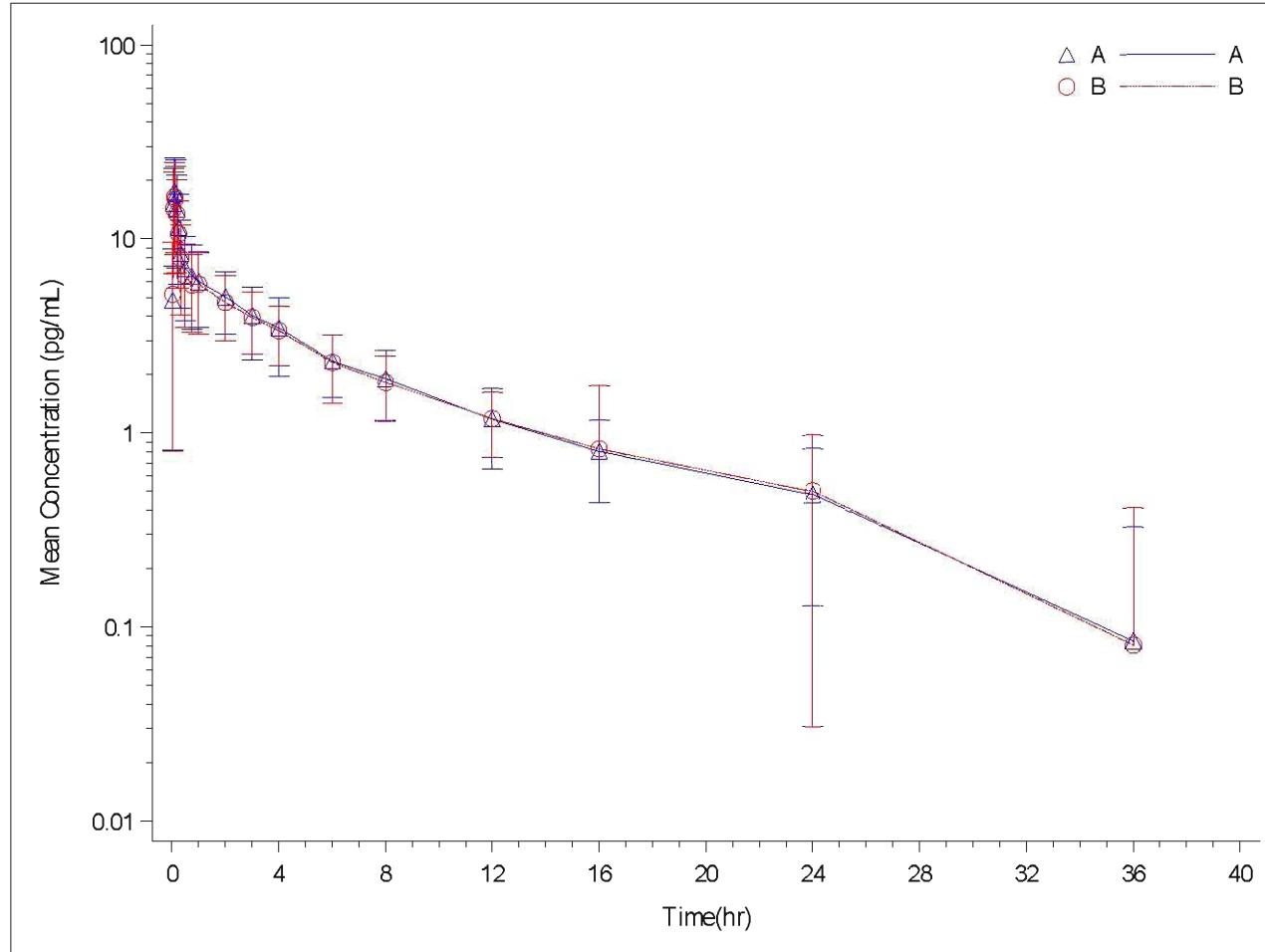


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:30 AM by Figure 14.2.2.2.3.sas

Figure 14.2.2.2.4 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), PK Analysis Set

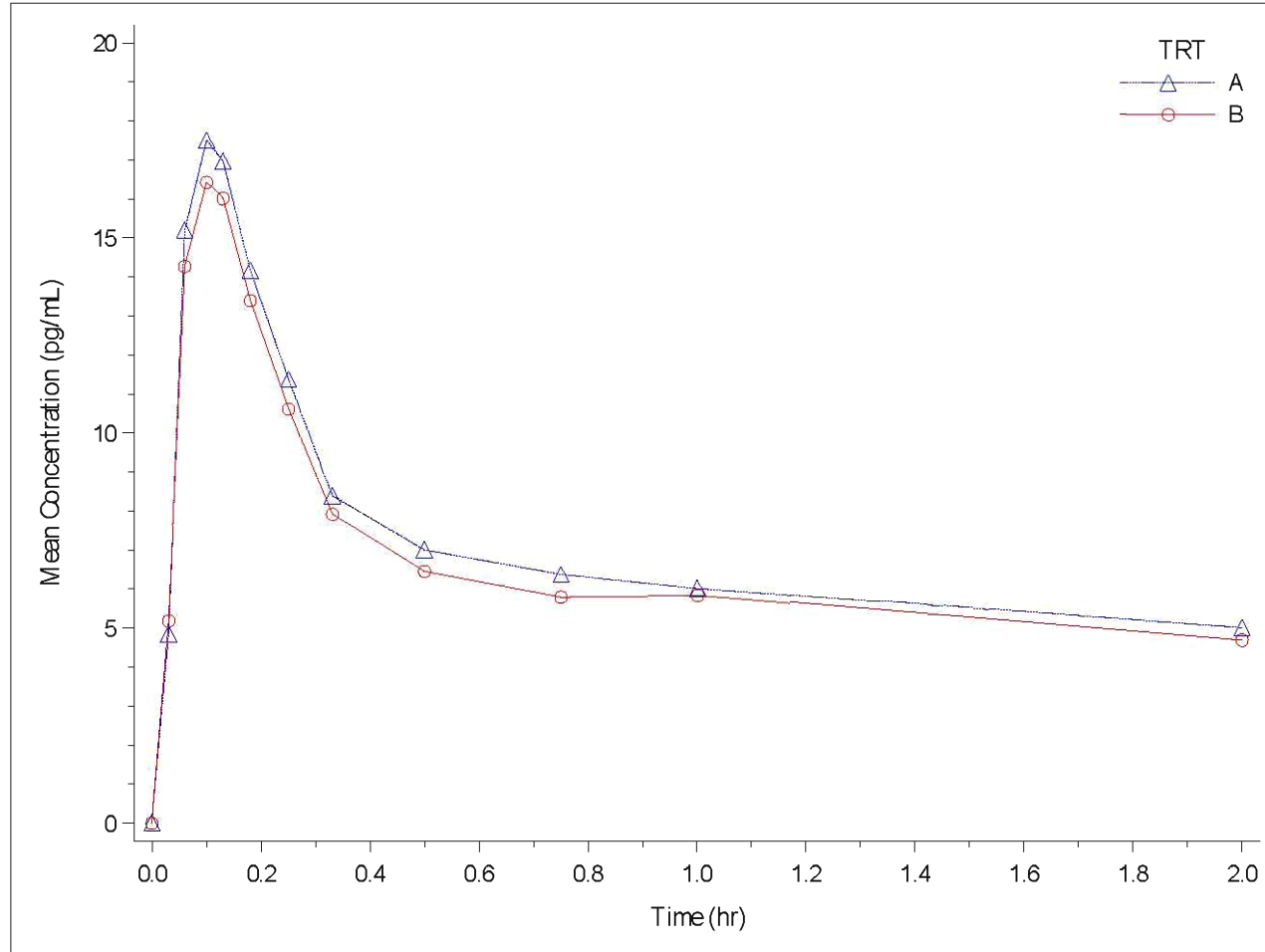


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:32 AM by Figure 14.2.2.2.4.sas

Figure 14.2.2.2.5 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (without charcoal), PK Analysis Set

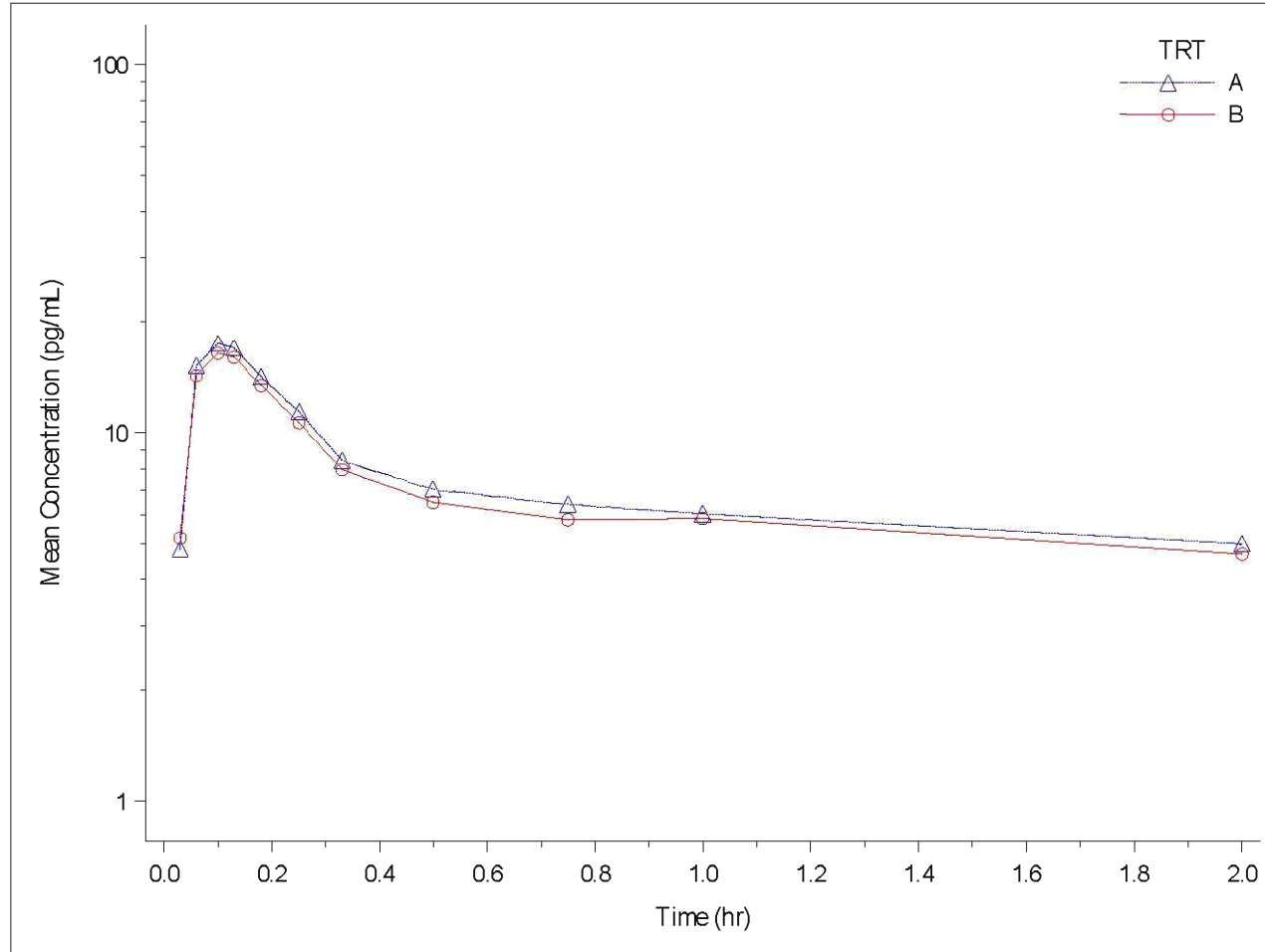


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:32 AM by Figure 14.2.2.2.5.sas

Figure 14.2.2.2.6 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (without charcoal), PK Analysis Set

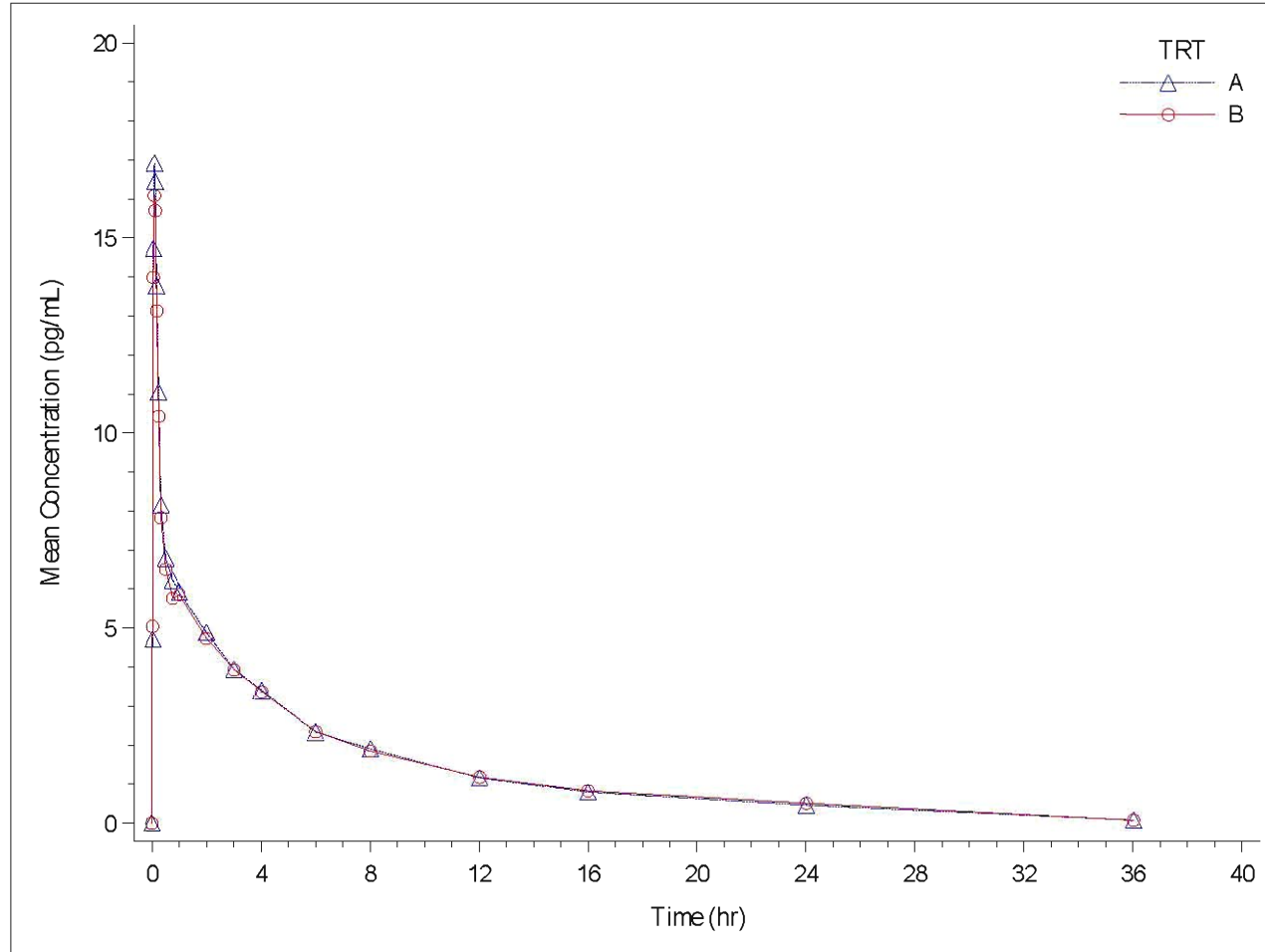


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 10:36 AM by Figure 14.2.2.2.6.sas

Figure 14.2.2.2.7 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), FAS

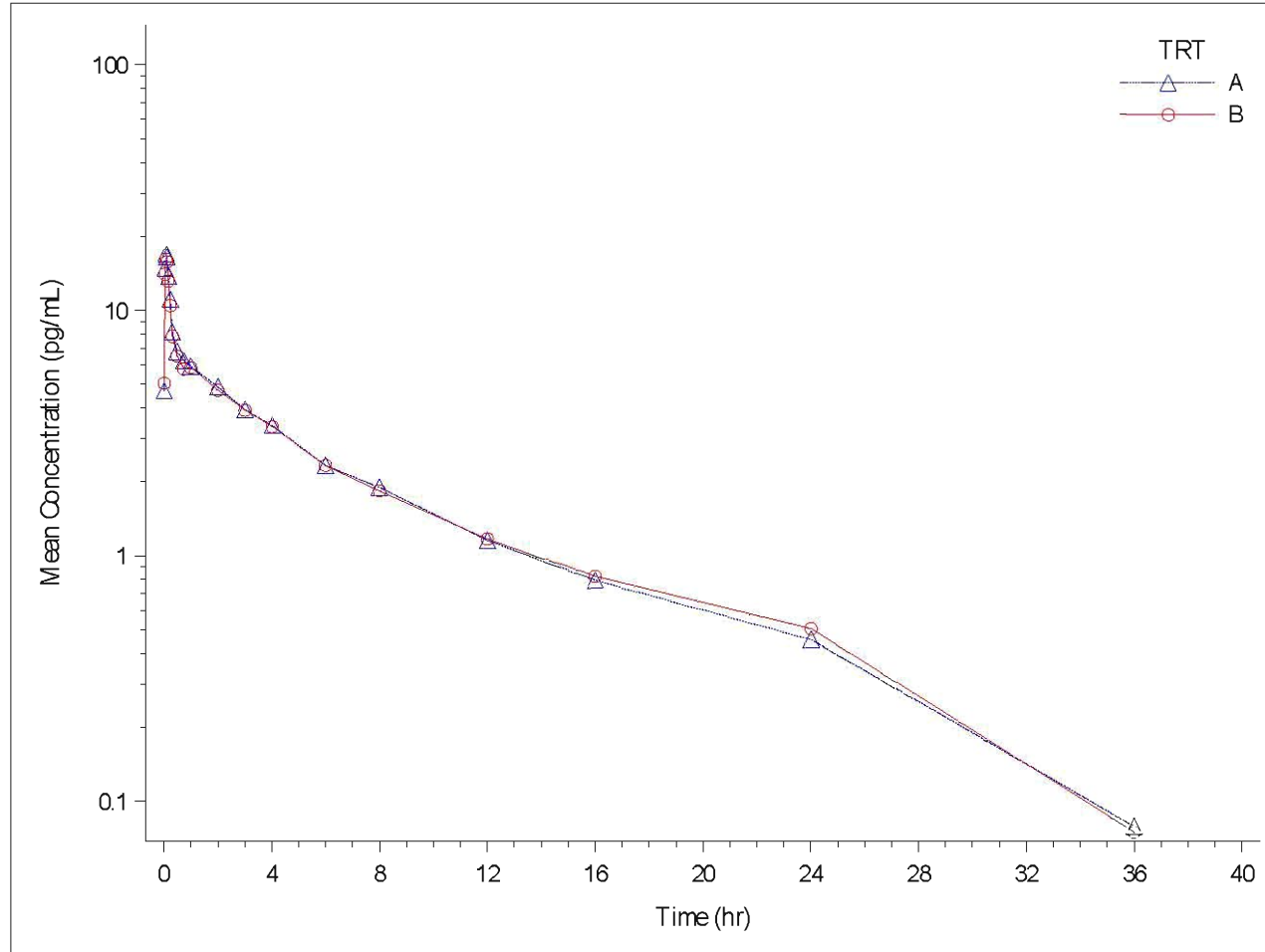


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 11:15 AM by Figure 14.2.2.2.7.sas

Figure 14.2.2.2.8 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), FAS

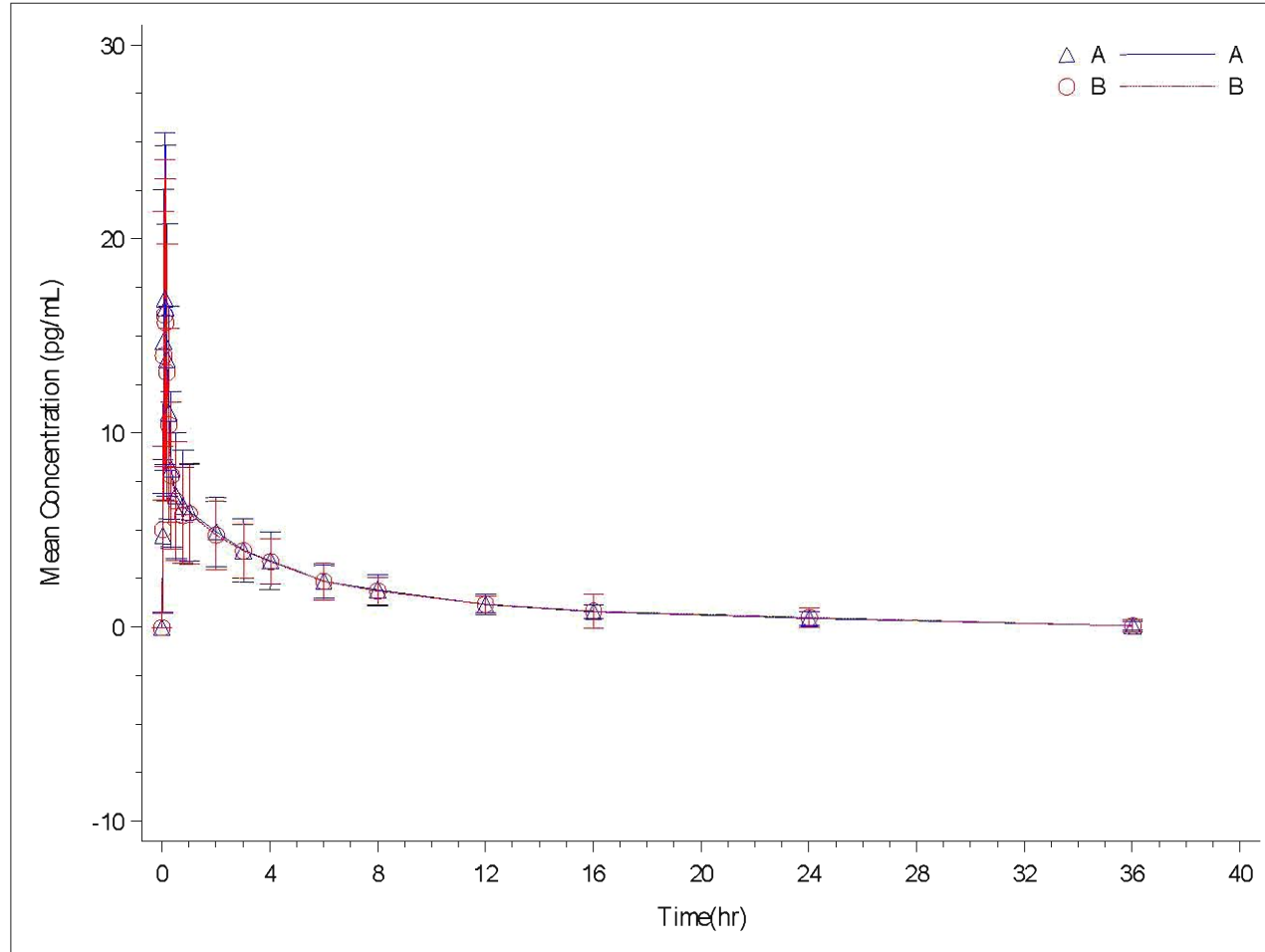


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 11:17 AM by Figure 14.2.2.2.8.sas

Figure 14.2.2.2.9 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), FAS

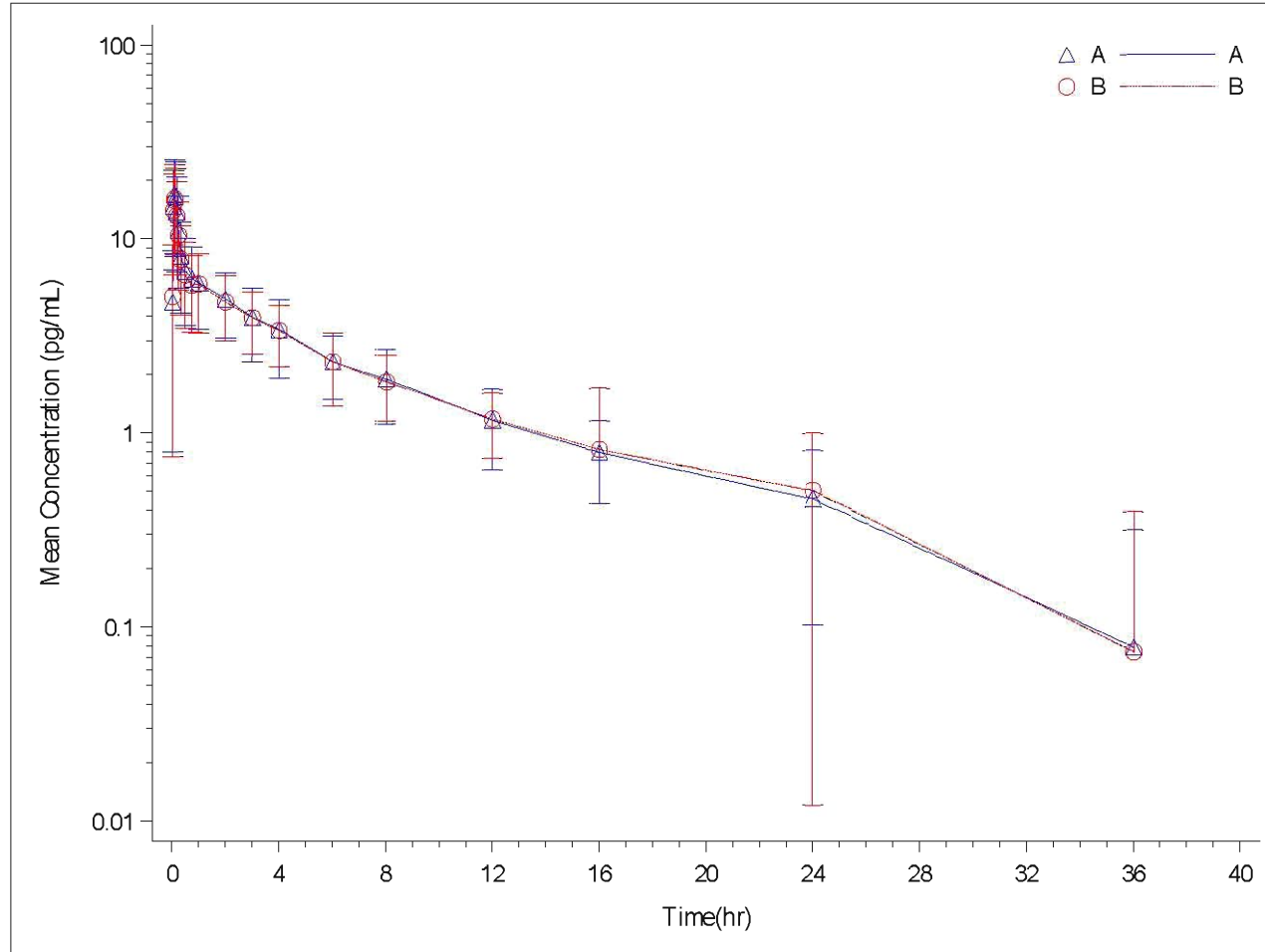


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:33 AM by Figure 14.2.2.2.9.sas

Figure 14.2.2.2.10 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), FAS

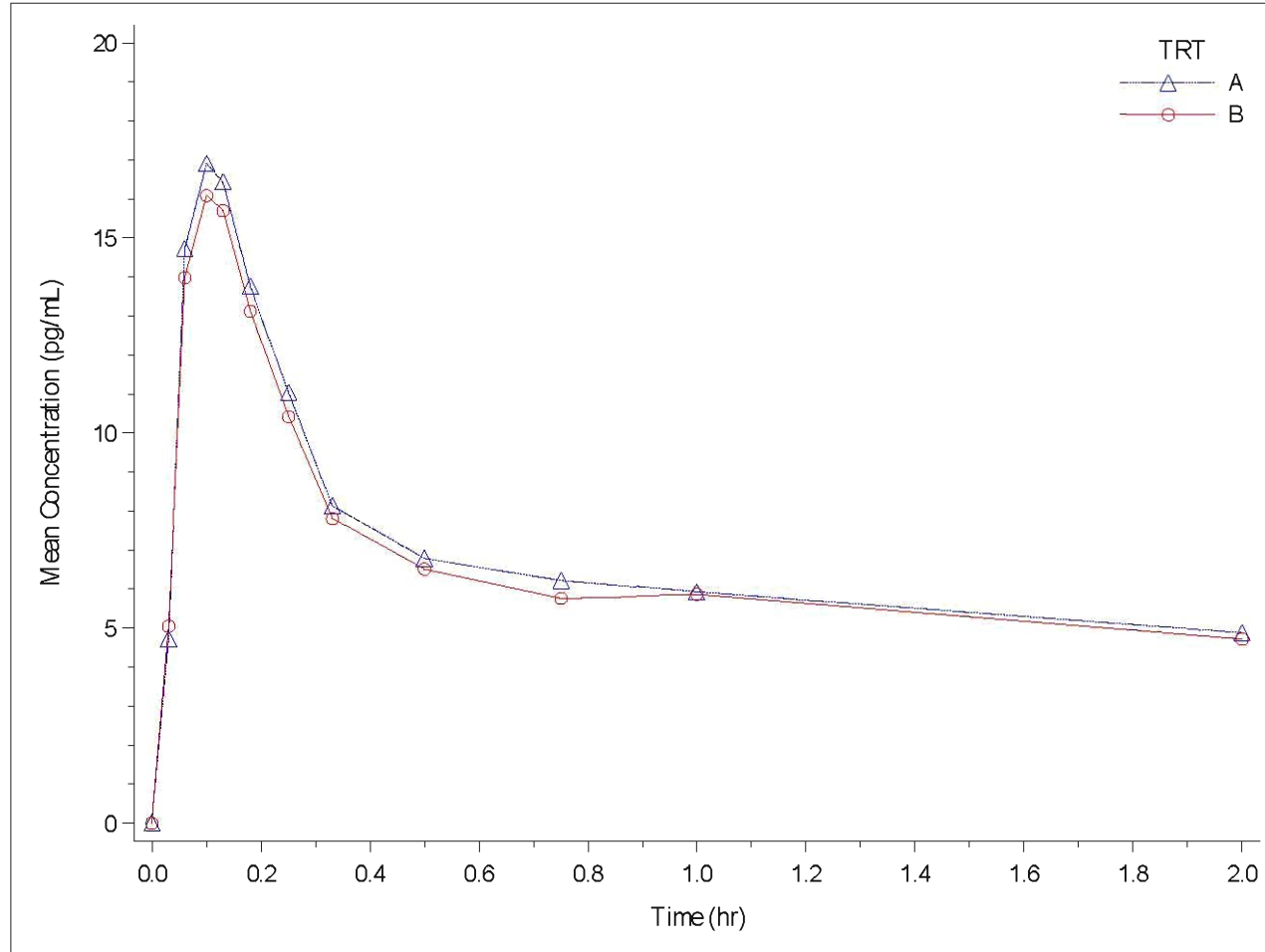


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:33 AM by Figure 14.2.2.2.10.sas

Figure 14.2.2.2.11 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (without charcoal), FAS

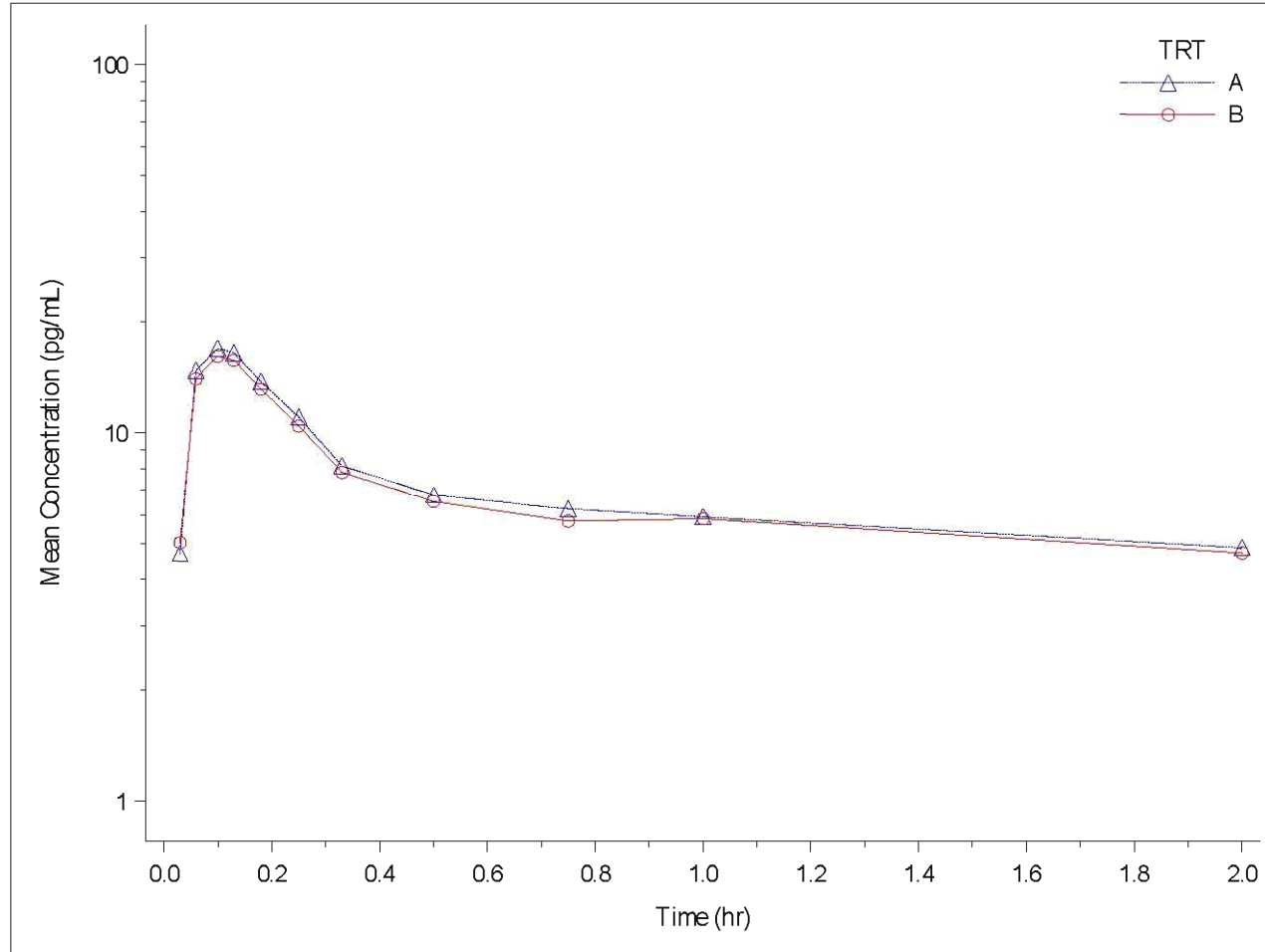


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 11:22 AM by Figure 14.2.2.2.11.sas

Figure 14.2.2.2.12 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (without charcoal), FAS

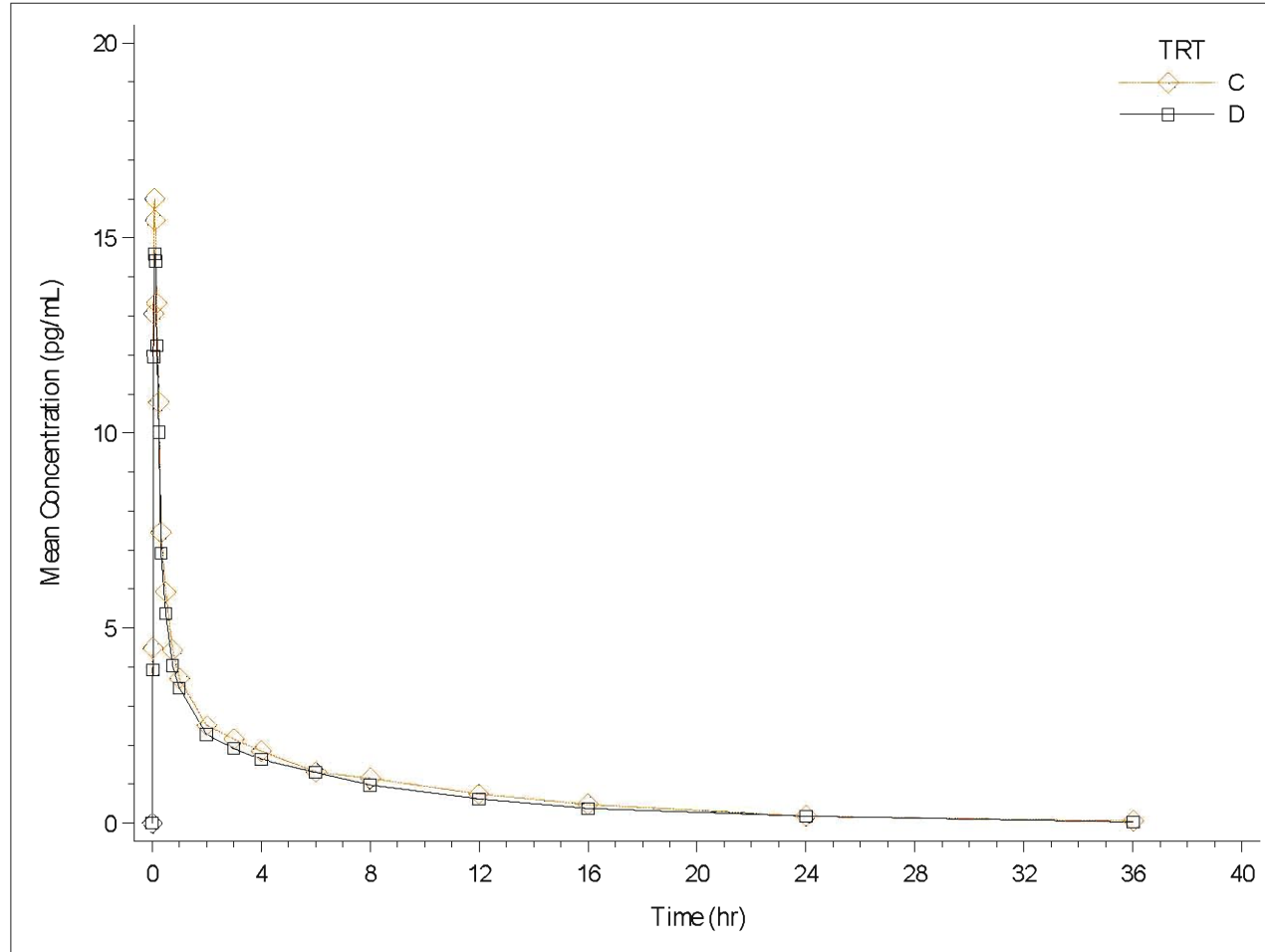


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 11:25 AM by Figure 14.2.2.2.12.sas

Figure 14.2.2.2.13 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with charcoal), PK Analysis Set

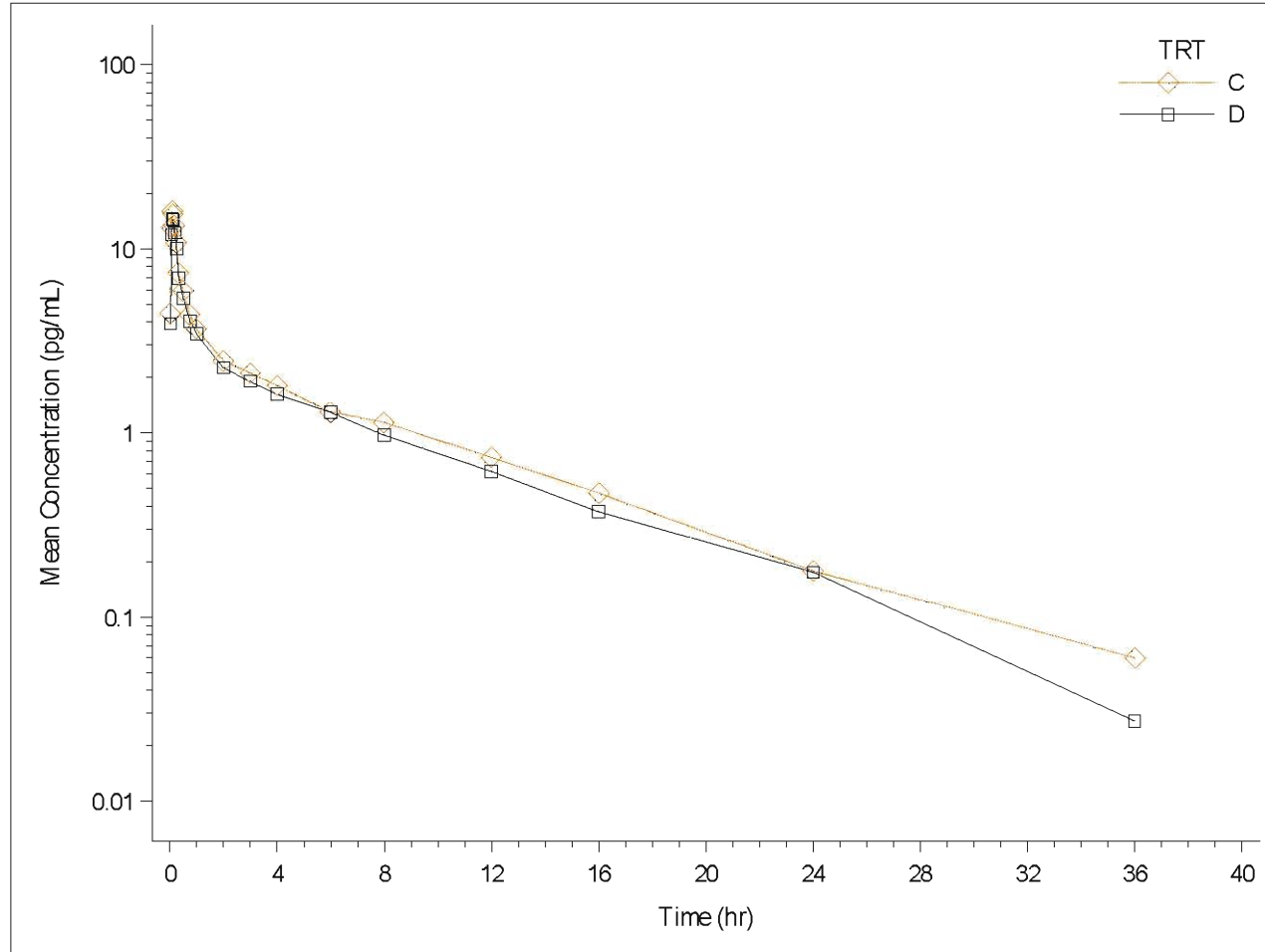


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:38 PM by Figure 14.2.2.2.13.sas

Figure 14.2.2.2.14 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with charcoal), PK Analysis Set

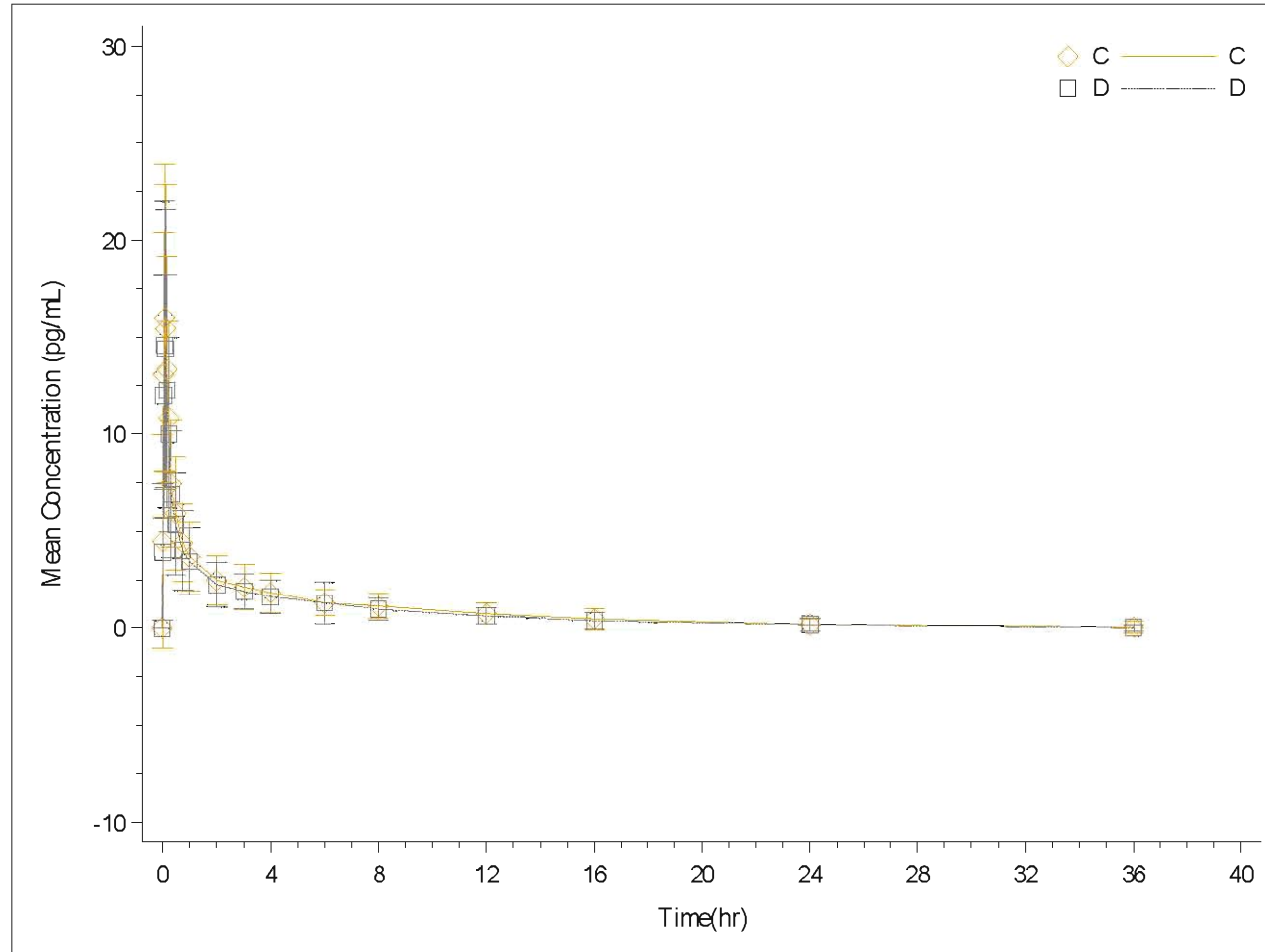


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:39 PM by Figure 14.2.2.2.14.sas

Figure 14.2.2.2.15 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with charcoal), PK Analysis Set

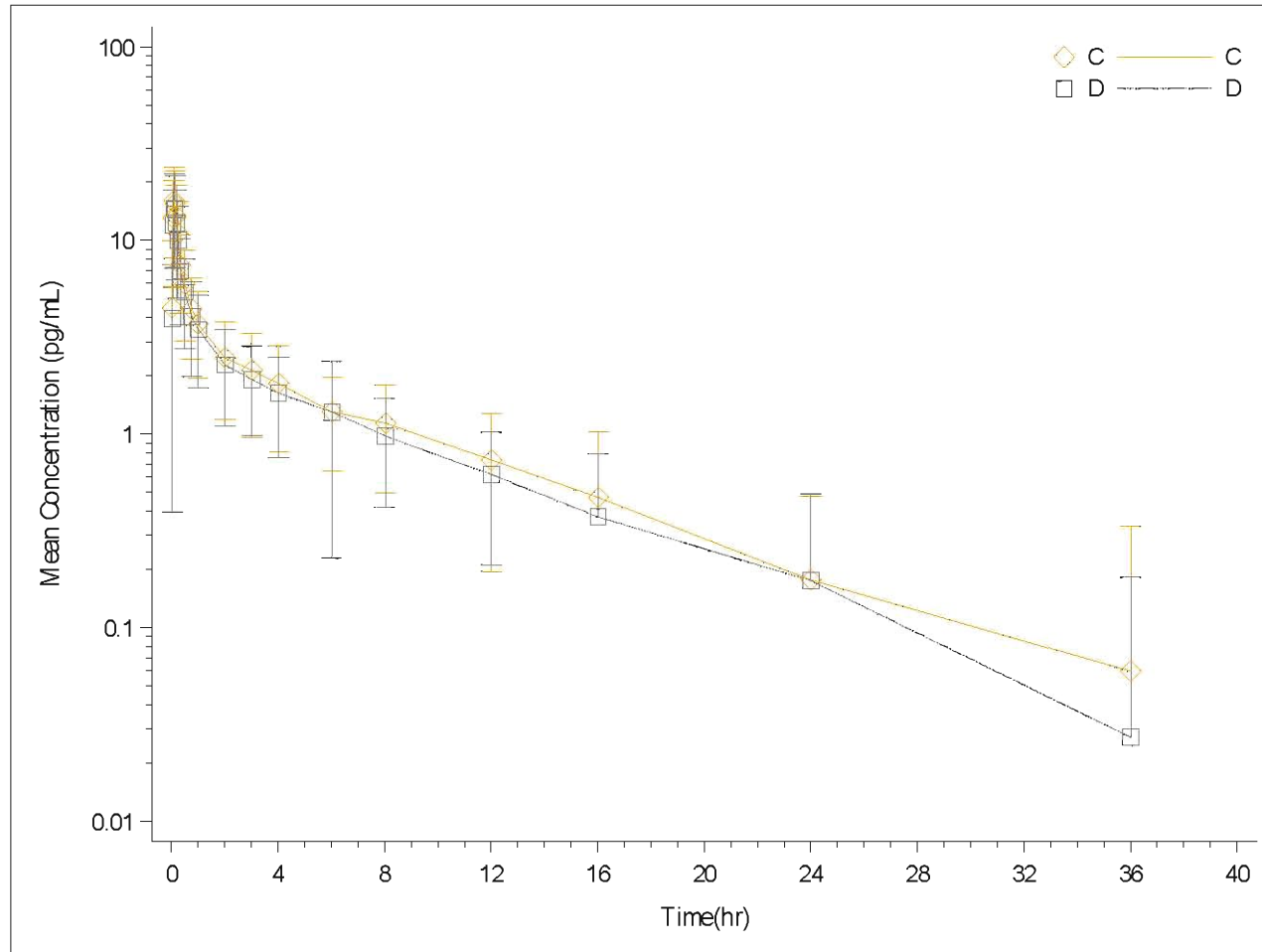


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:39 PM by Figure 14.2.2.2.15.s as

Figure 14.2.2.2.16 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with charcoal), PK Analysis Set

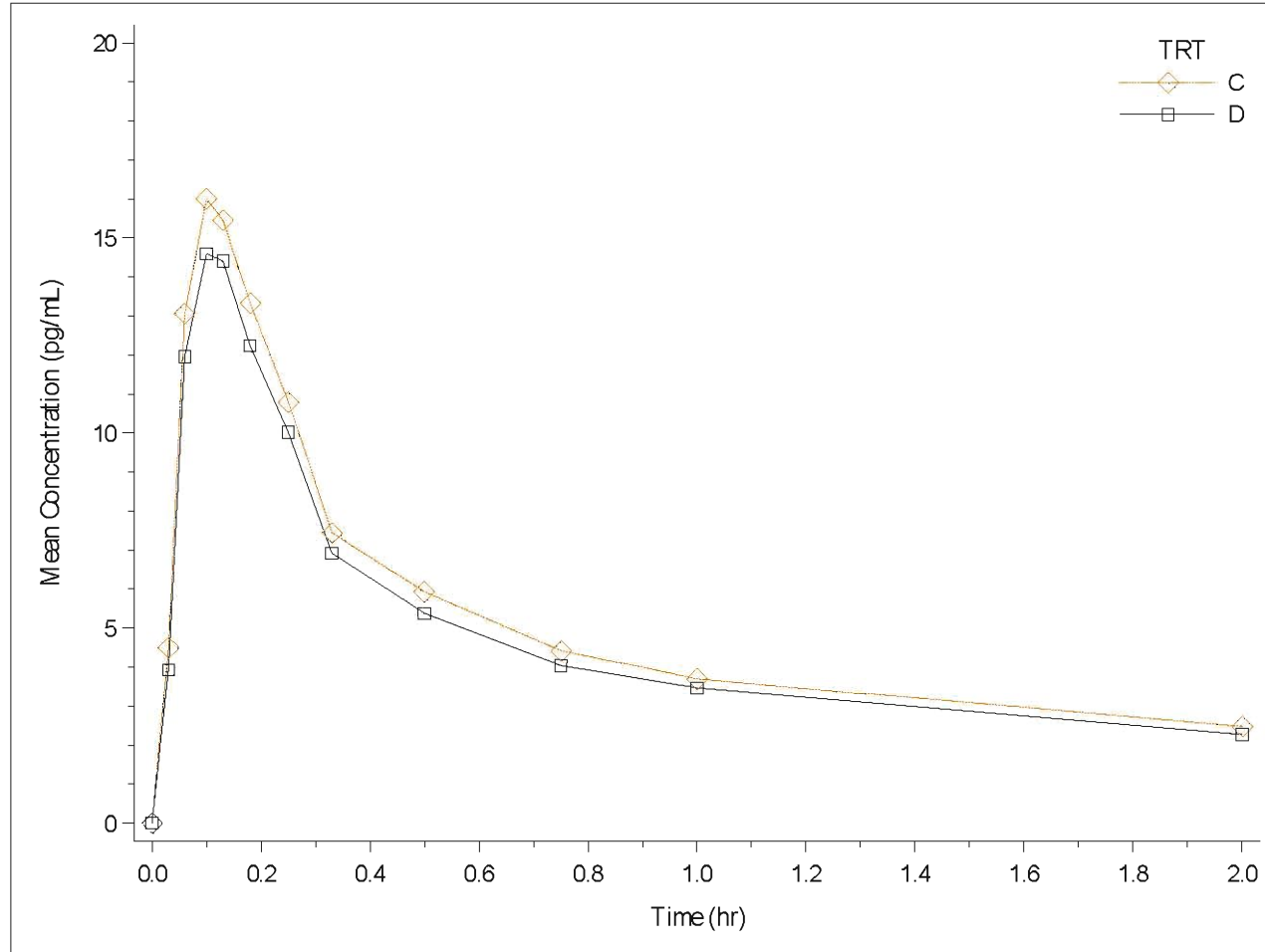


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 15FEB2020 at 11:36 AM by Figure 14.2.2.2.16.sas

Figure 14.2.2.2.17 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (with charcoal), PK Analysis Set

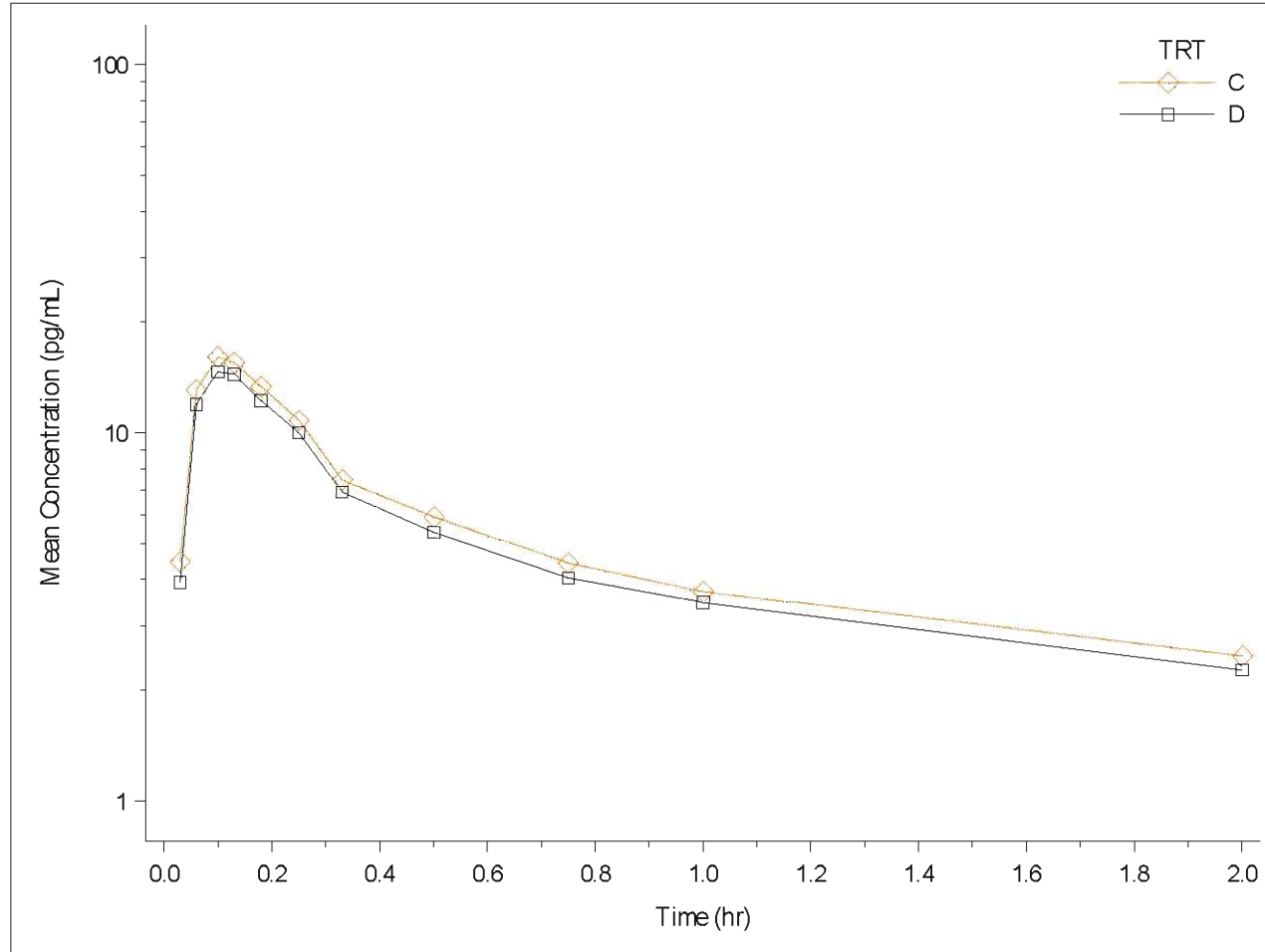


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:41 PM by Figure 14.2.2.2.17.sas

Figure 14.2.2.2.18 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (with charcoal), PK Analysis Set

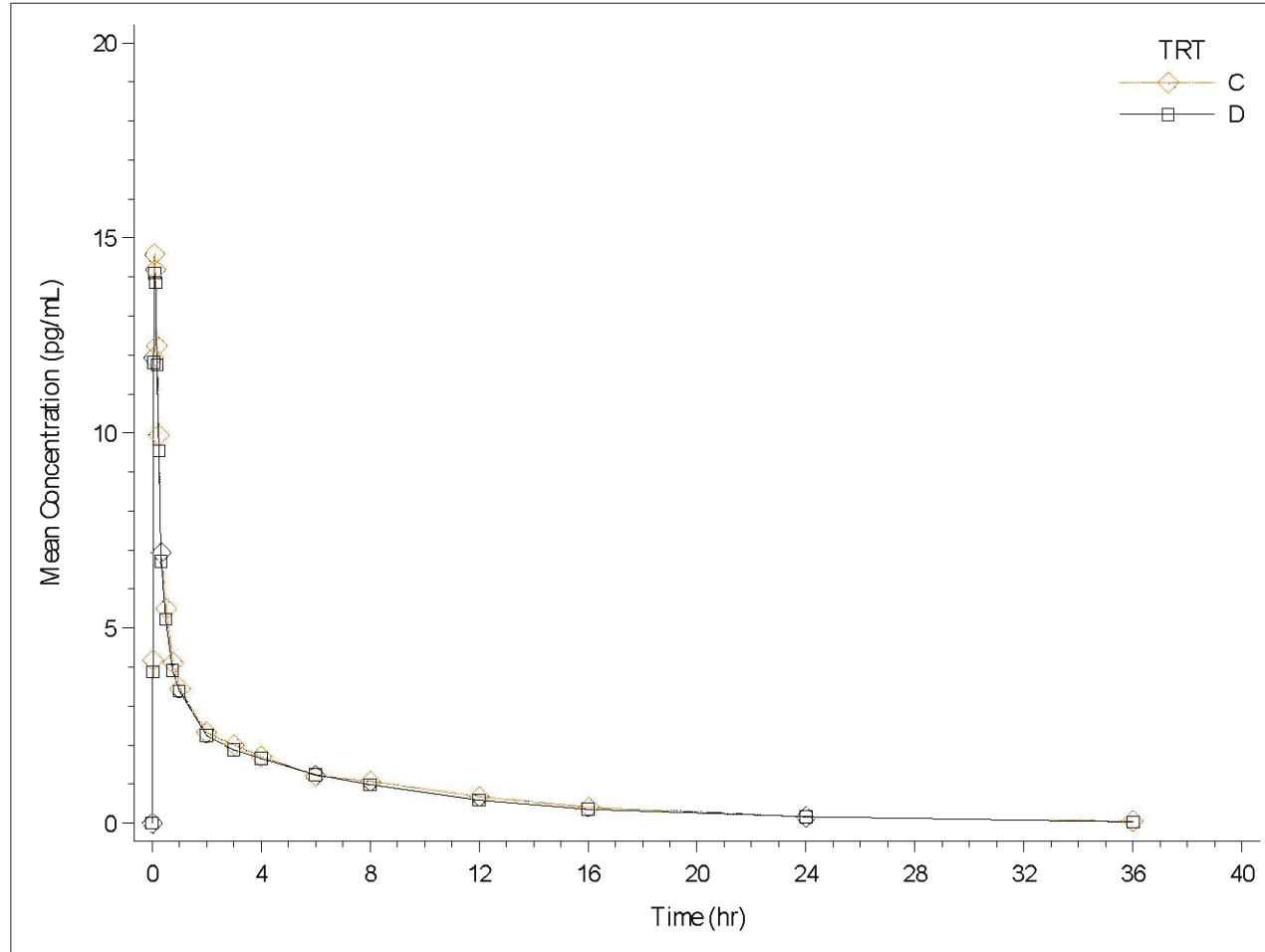


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:41 PM by Figure 14.2.2.2.18.sas

Figure 14.2.2.19 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with charcoal), FAS

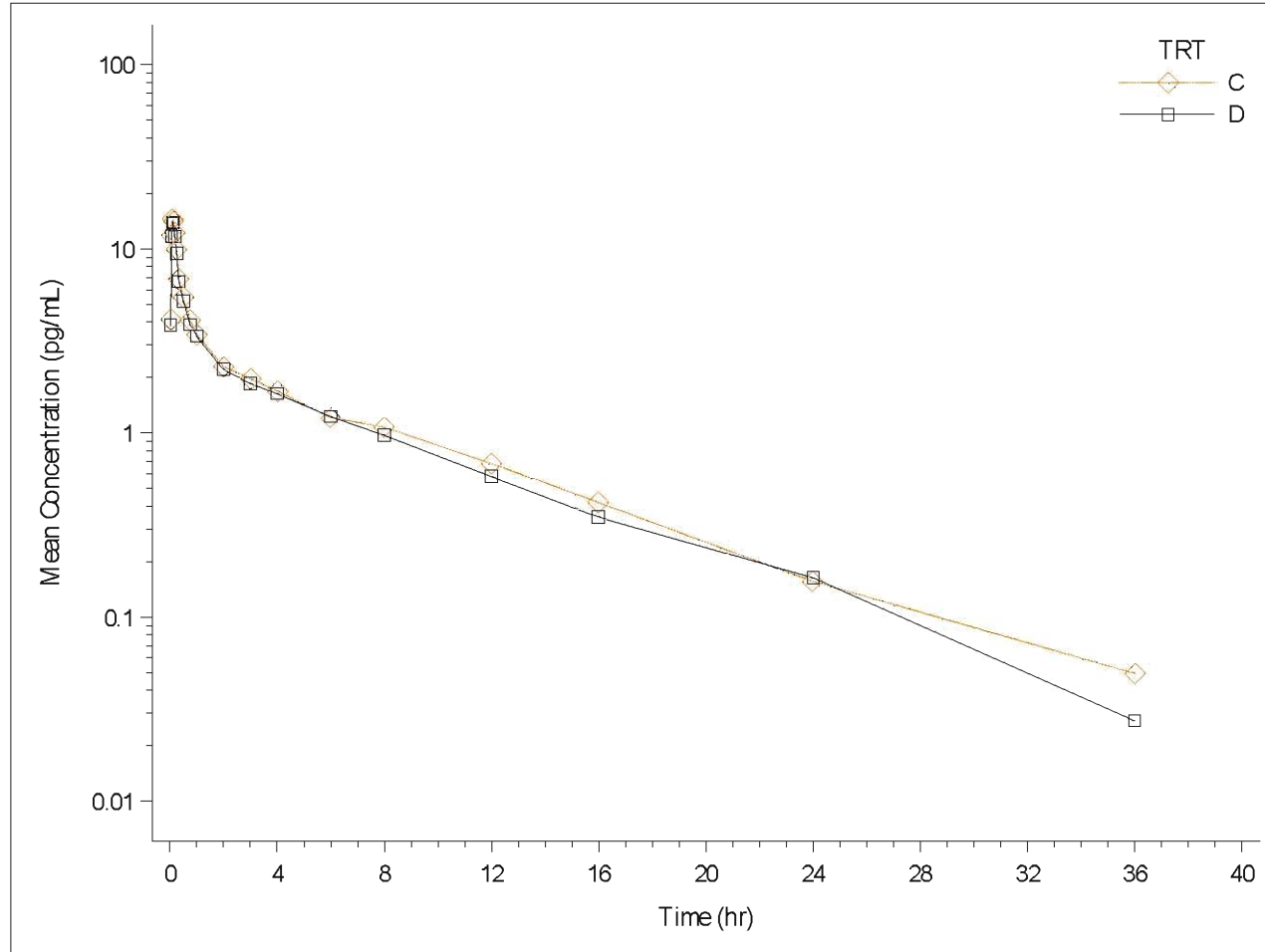


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 15FEB2020 at 11:38 AM by Figure 14.2.2.2.19.sas

Figure 14.2.2.2.20 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with charcoal), FAS

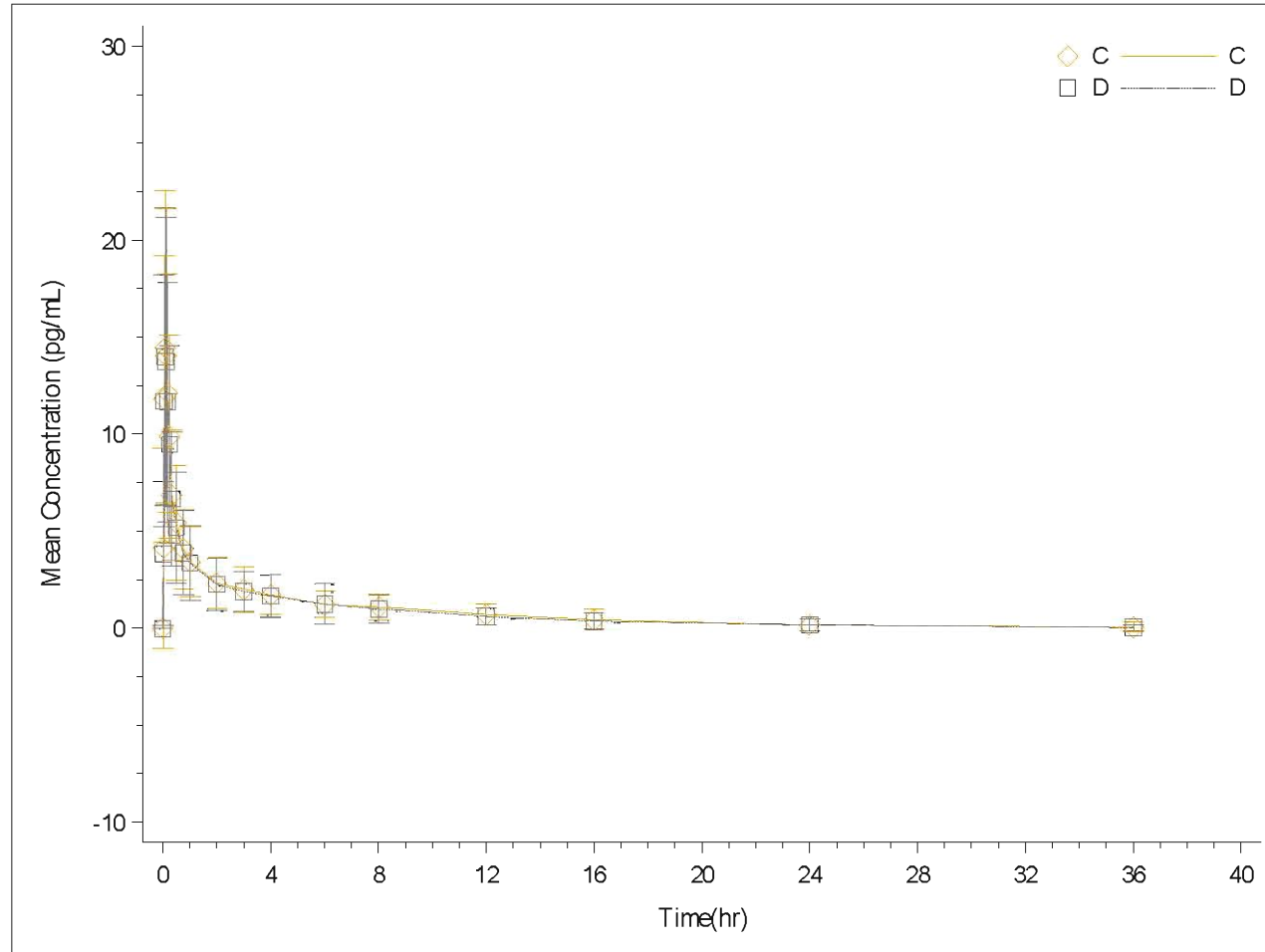


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:43 PM by Figure 14.2.2.2.20.sas

Figure 14.2.2.2.21 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with charcoal), FAS

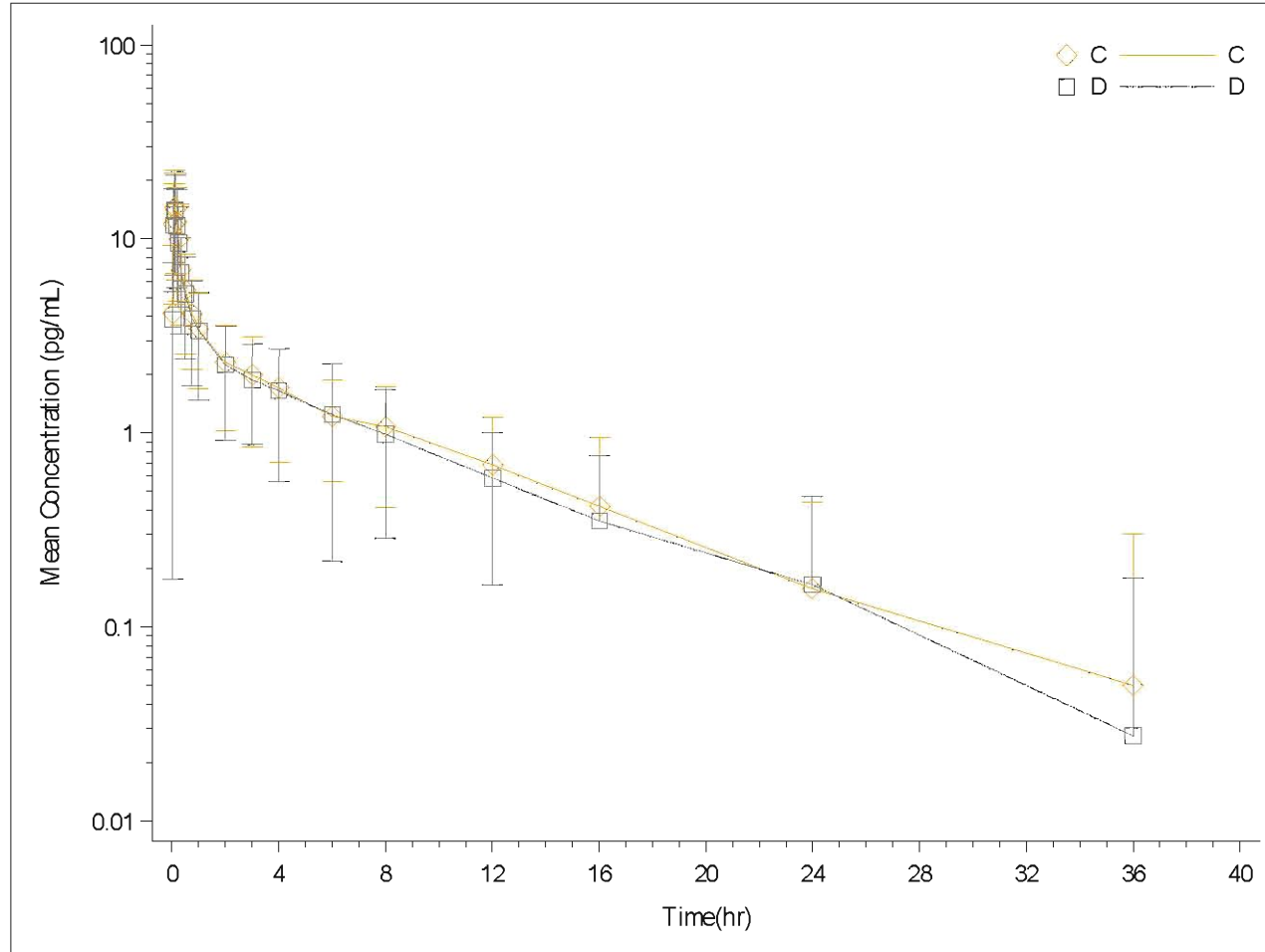


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:44 PM by Figure 14.2.2.2.21.s.as

Figure 14.2.2.2.22 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with charcoal), FAS

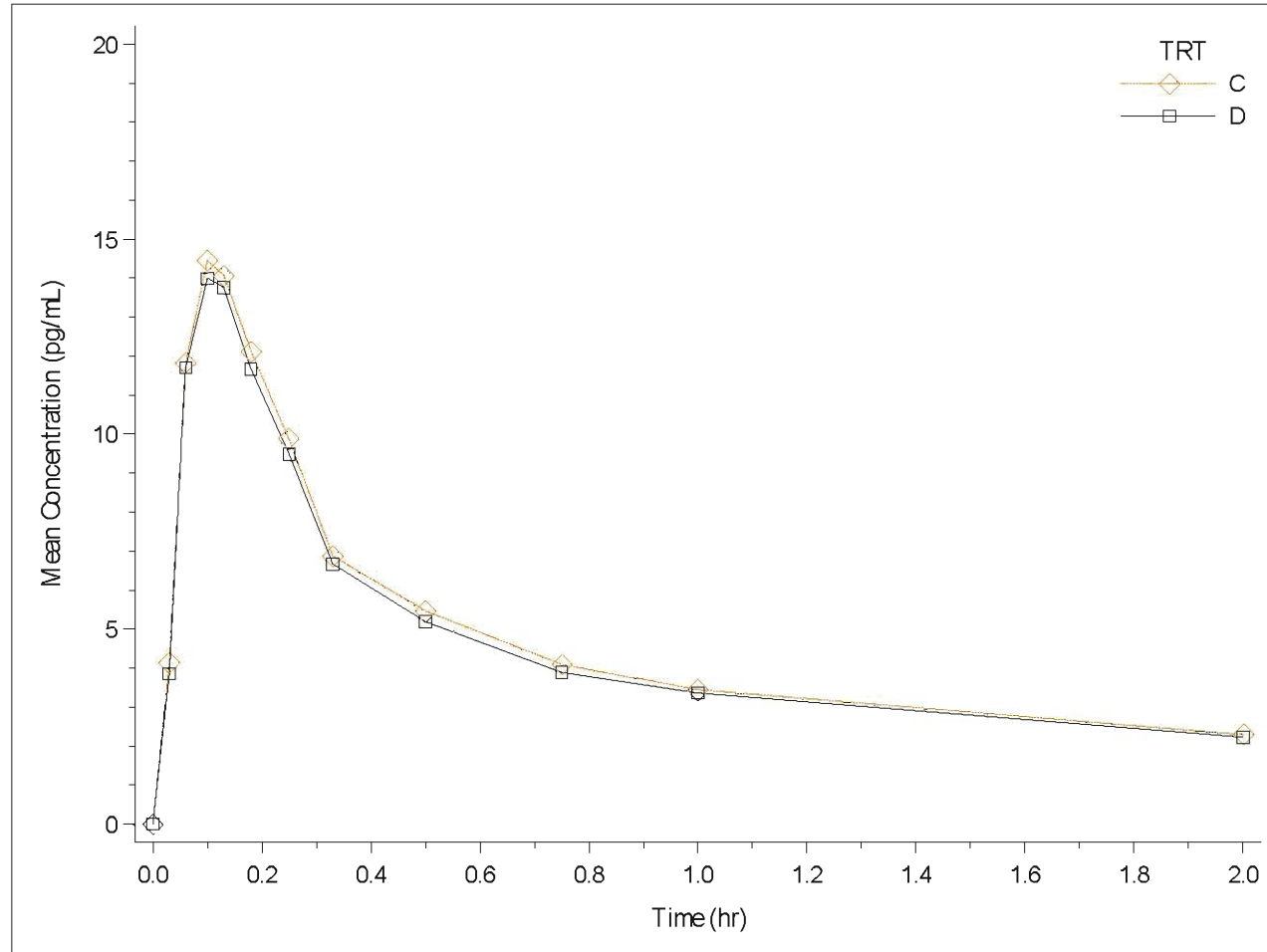


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 15FEB2020 at 11:47 AM by Figure 14.2.2.2.22.sas

Figure 14.2.2.2.23 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (with charcoal), FAS

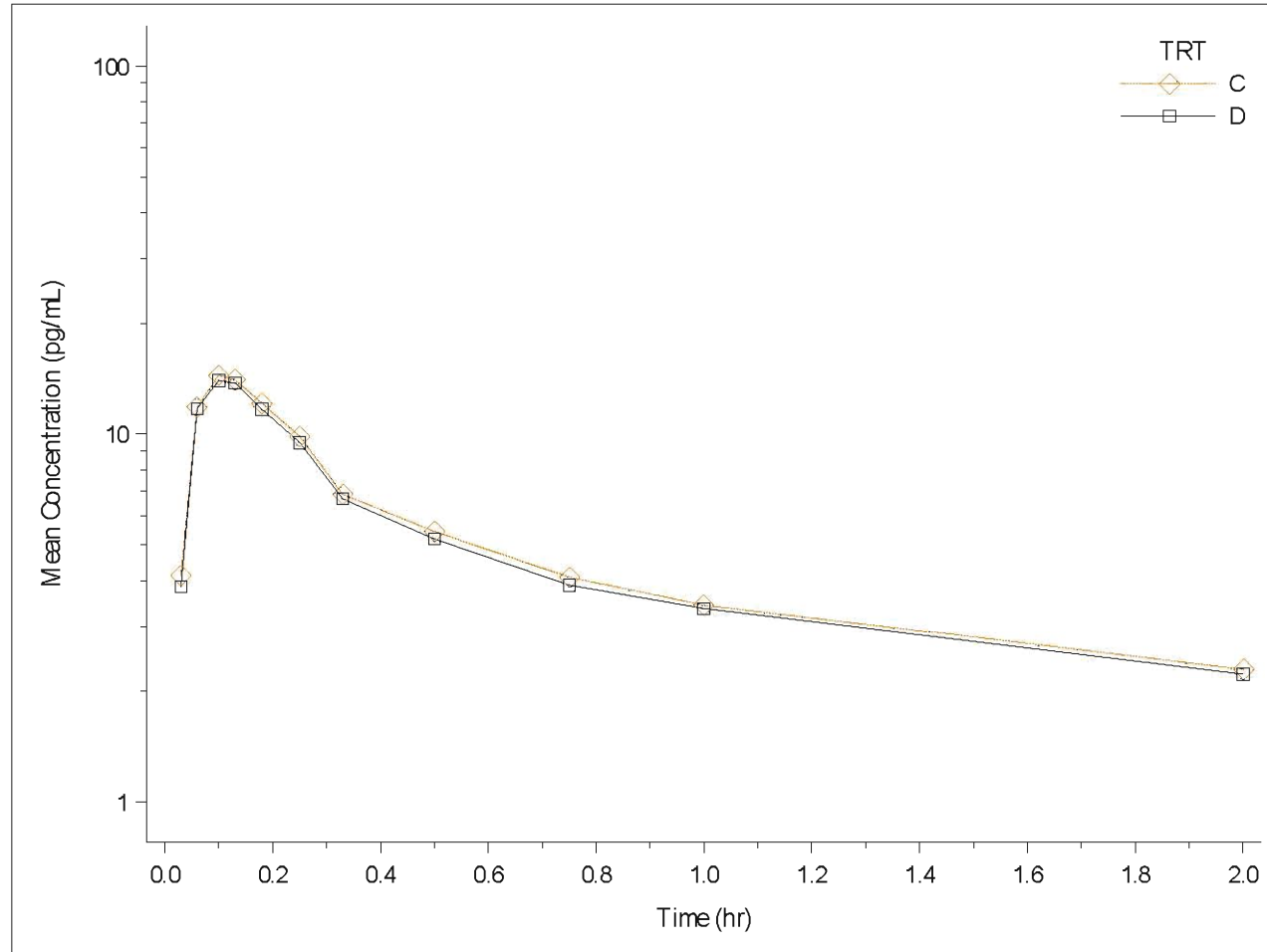


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 31JAN2020 at 7:45 PM by Figure 14.2.2.2.23.s as

Figure 14.2.2.2.24 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-Log Scale) (with charcoal), FAS

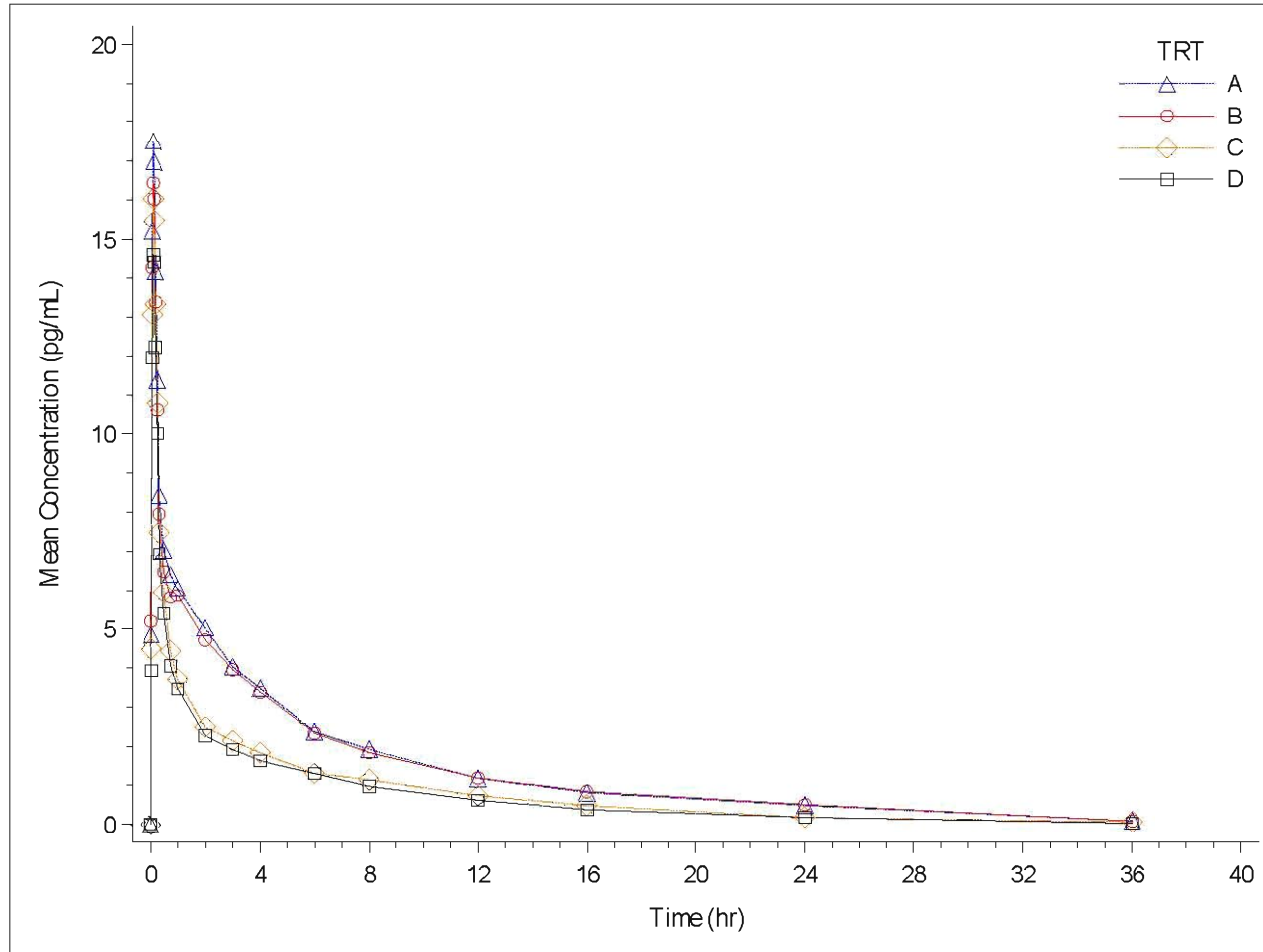


Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

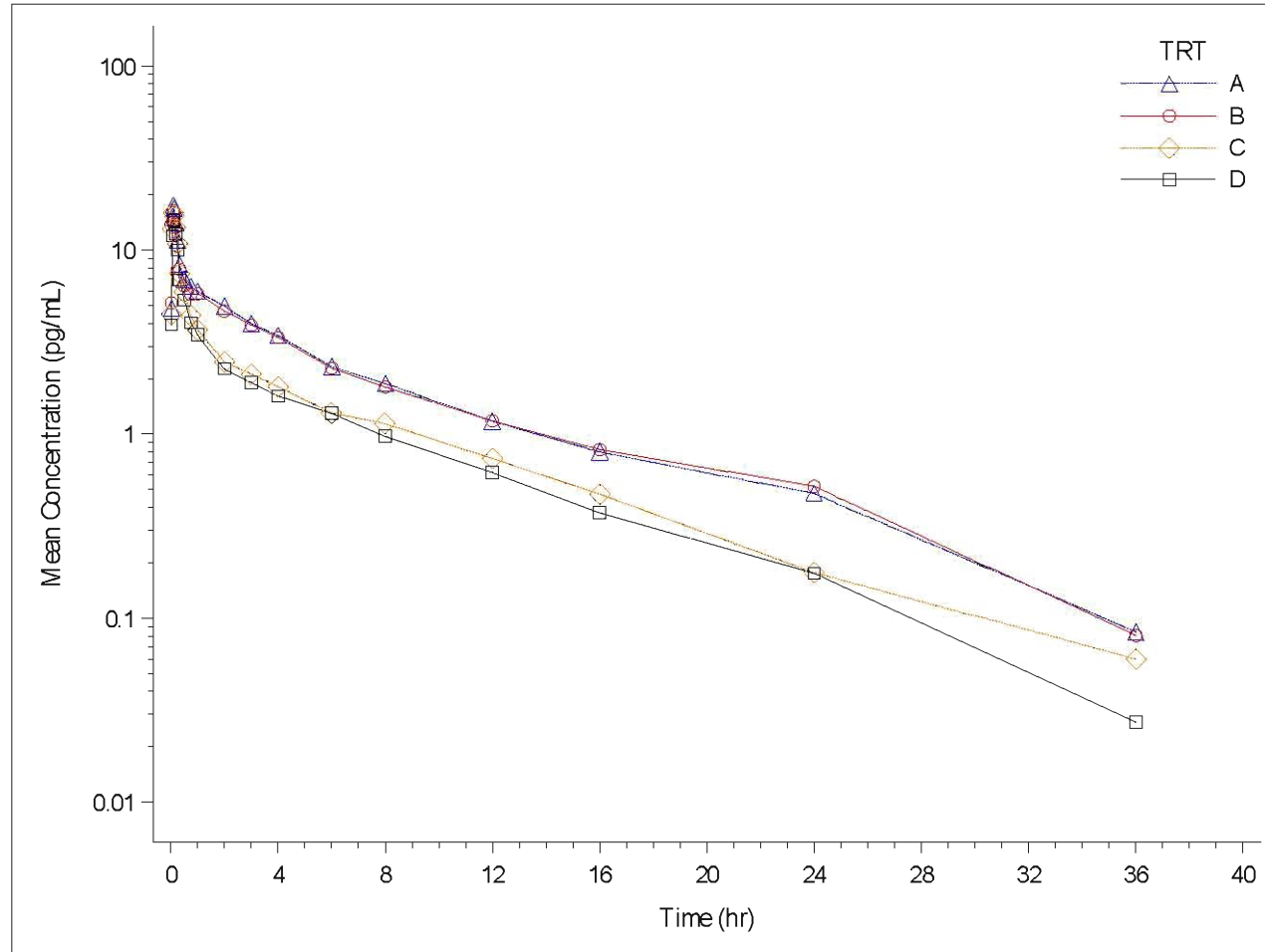
Figure Generation: 31JAN2020 at 7:46 PM by Figure 14.2.2.2.24.s as

Figure 14.2.2.2.25 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with and without charcoal), PK Analysis Set



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations
Treatment B: FOSTAIR 200/6 mcg-2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:46 PM by Figure 14.2.2.2.25.sas

Figure 14.2.2.2.26 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with and without charcoal), PK Analysis Set



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

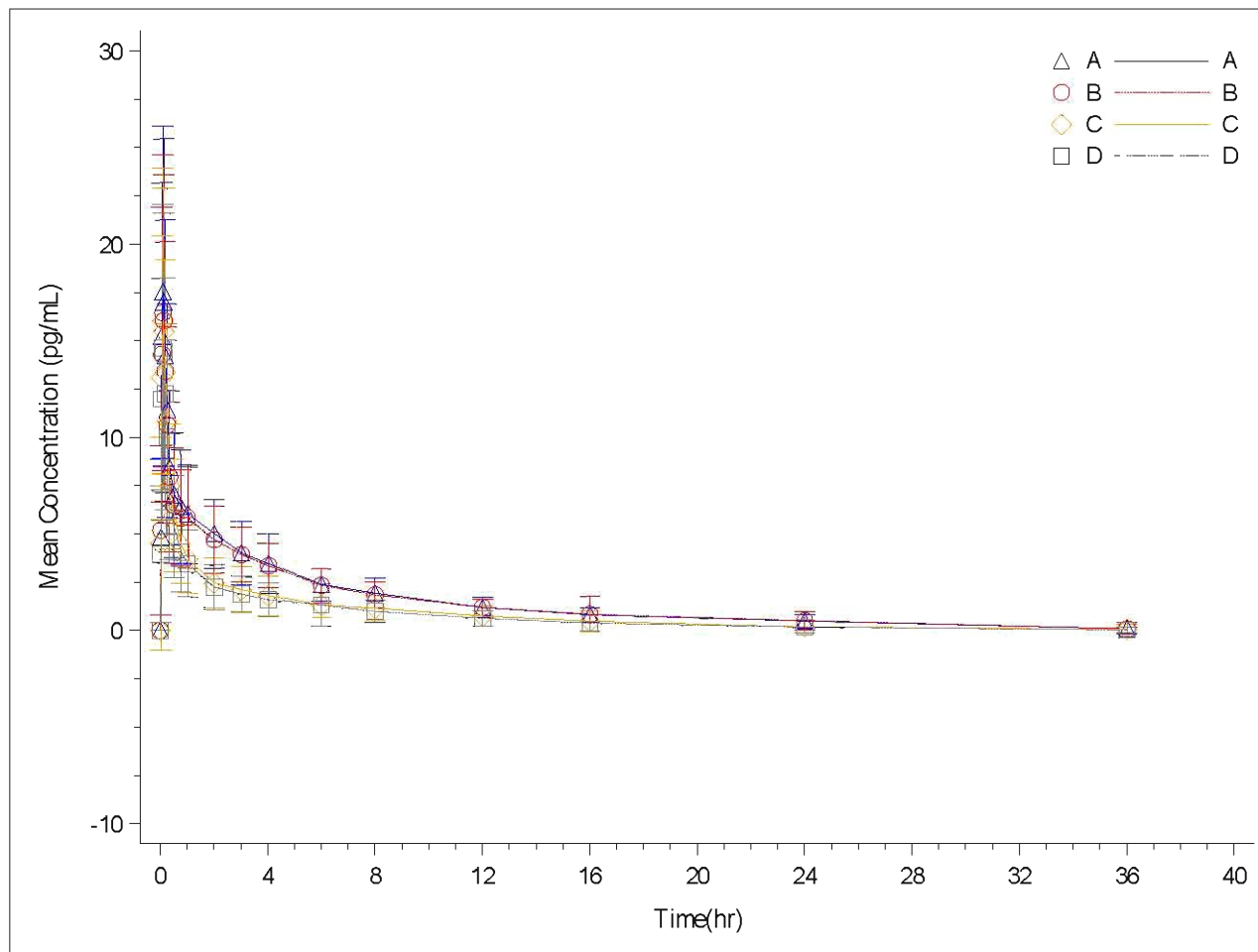
Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

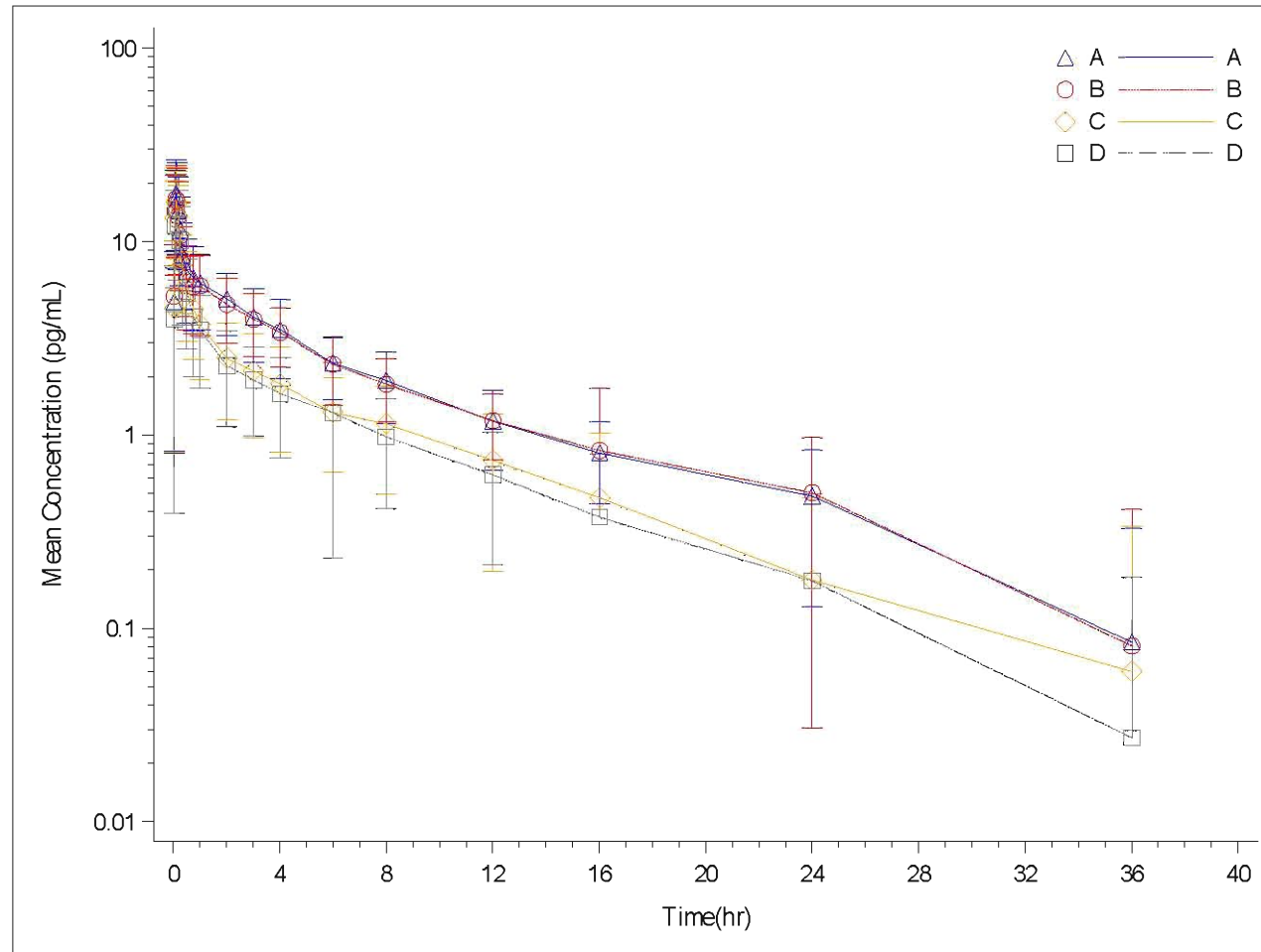
Figure Generation: 31JAN2020 at 7:47 PM by Figure 14.2.2.2.26.sas

Figure 14.2.2.27 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with and without charcoal), PK Analysis Set



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations
Treatment B: FOSTAIR 200/6 mcg-2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:48 PM by Figure 14.2.2.27.sas

Figure 14.2.2.2.28 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with and without charcoal), PK Analysis Set



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

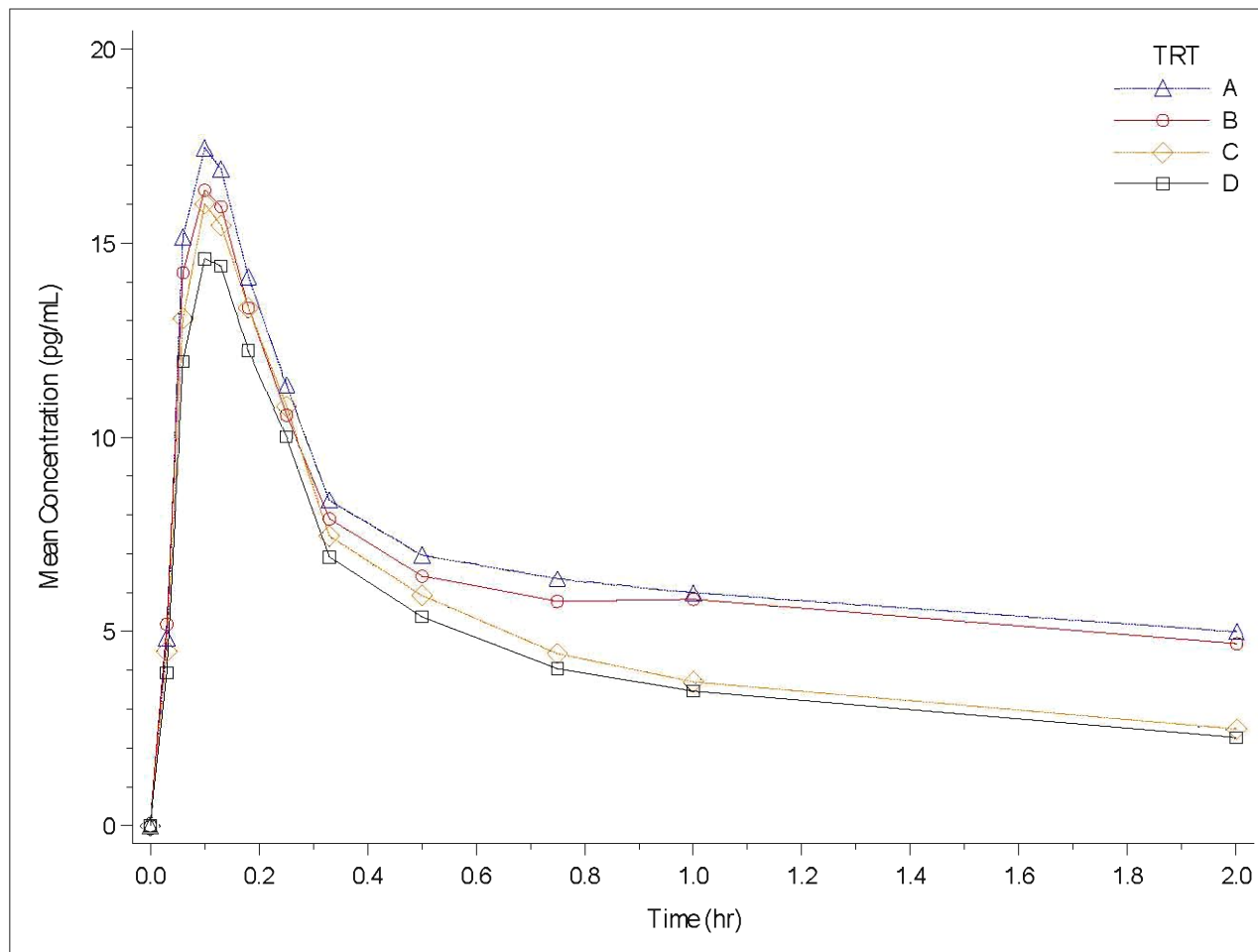
Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

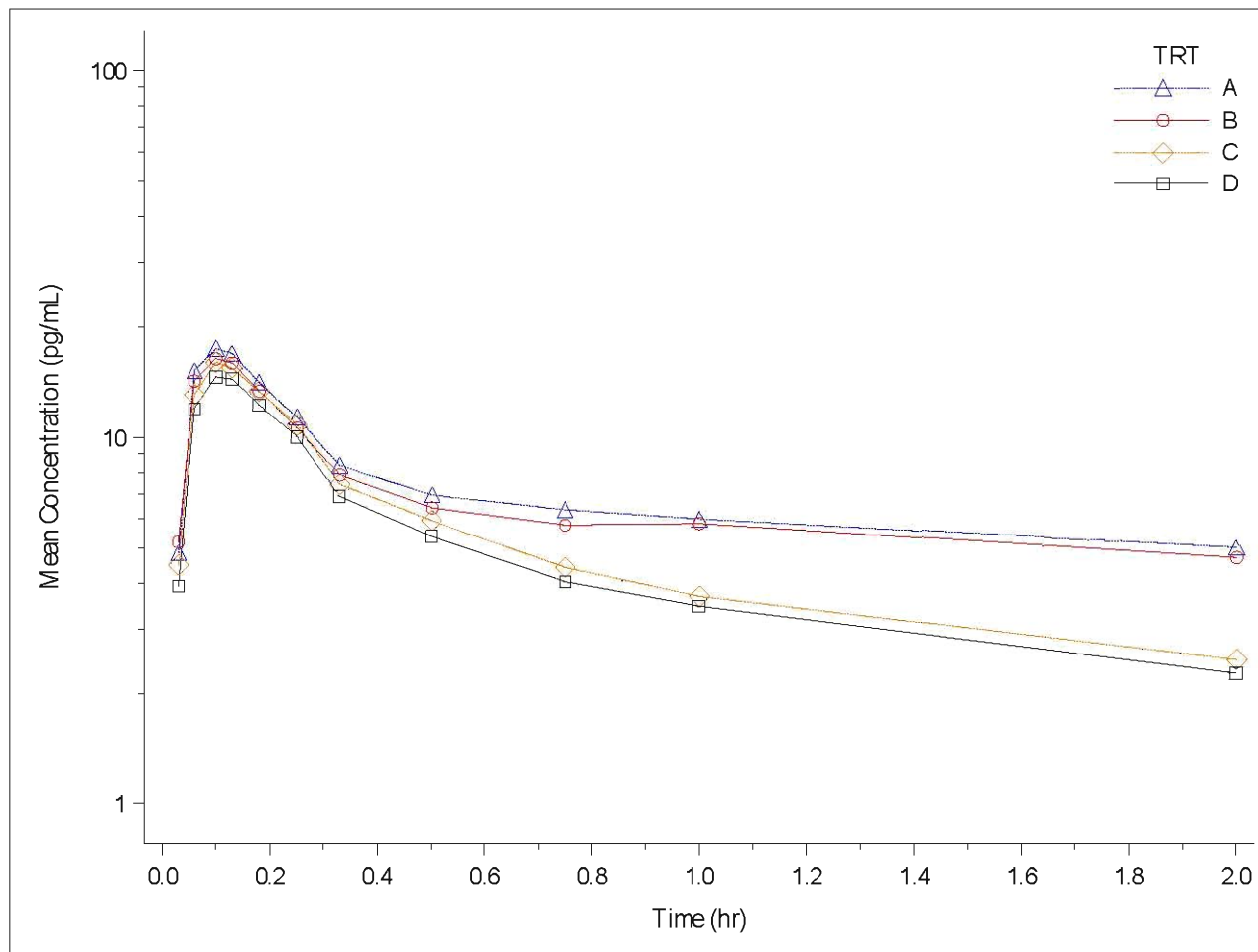
Figure Generation: 15FEB2020 at 11:49 AM by Figure 14.2.2.2.28.sas

Figure 14.2.2.29 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (with and without charcoal), PK Analysis Set



Treatment A: Lupin BDP/FF 200/6 mcg -2 inhalations
Treatment B: FOSTAIR 200/6 mcg -2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:49 PM by Figure 14.2.2.29.sas

Figure 14.2.2.2.30 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (with and without charcoal), PK Analysis Set



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

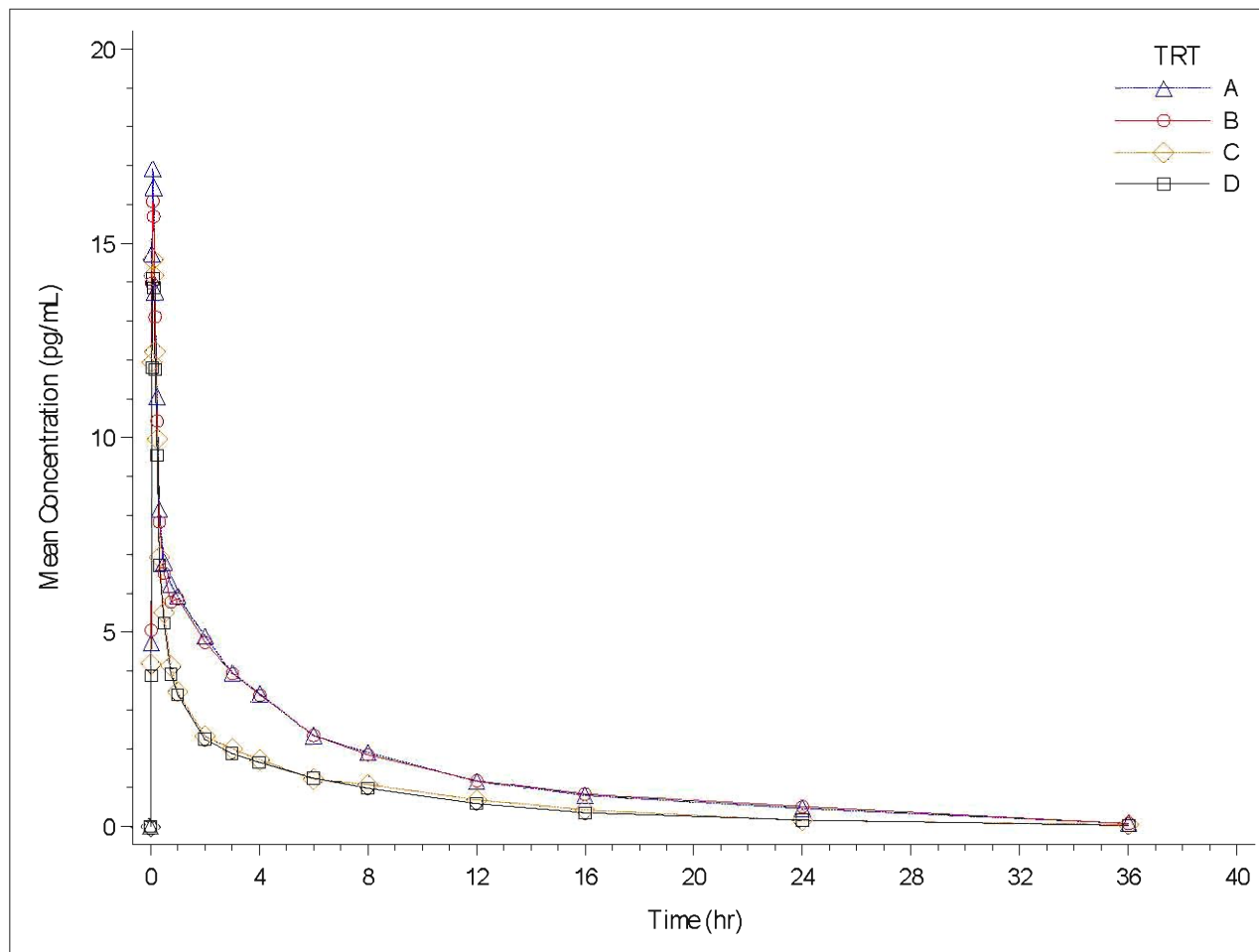
Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

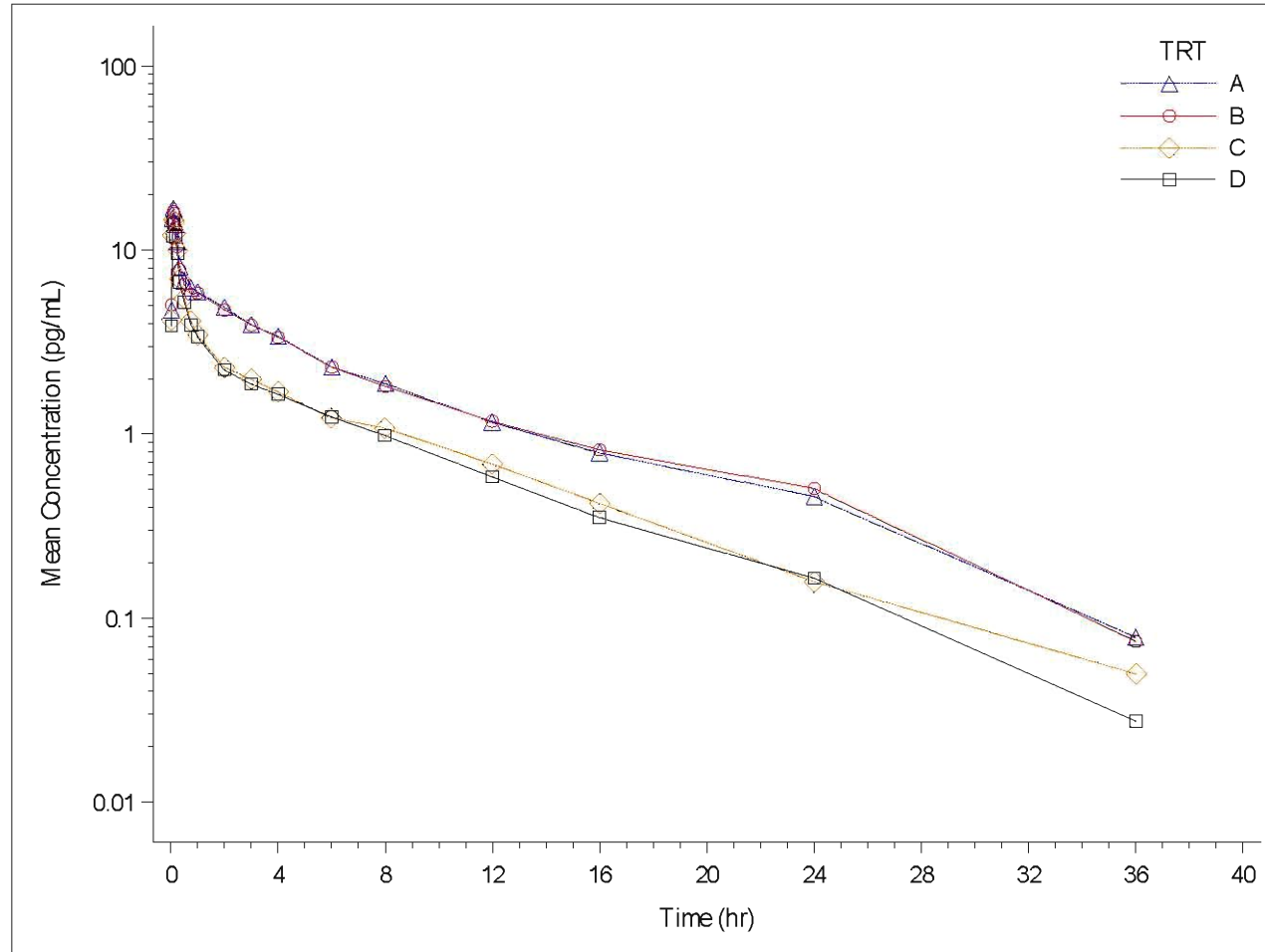
Figure Generation: 31JAN2020 at 7:50 PM by Figure 14.2.2.2.30.sas

Figure 14.2.2.2.31 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with and without charcoal), FAS



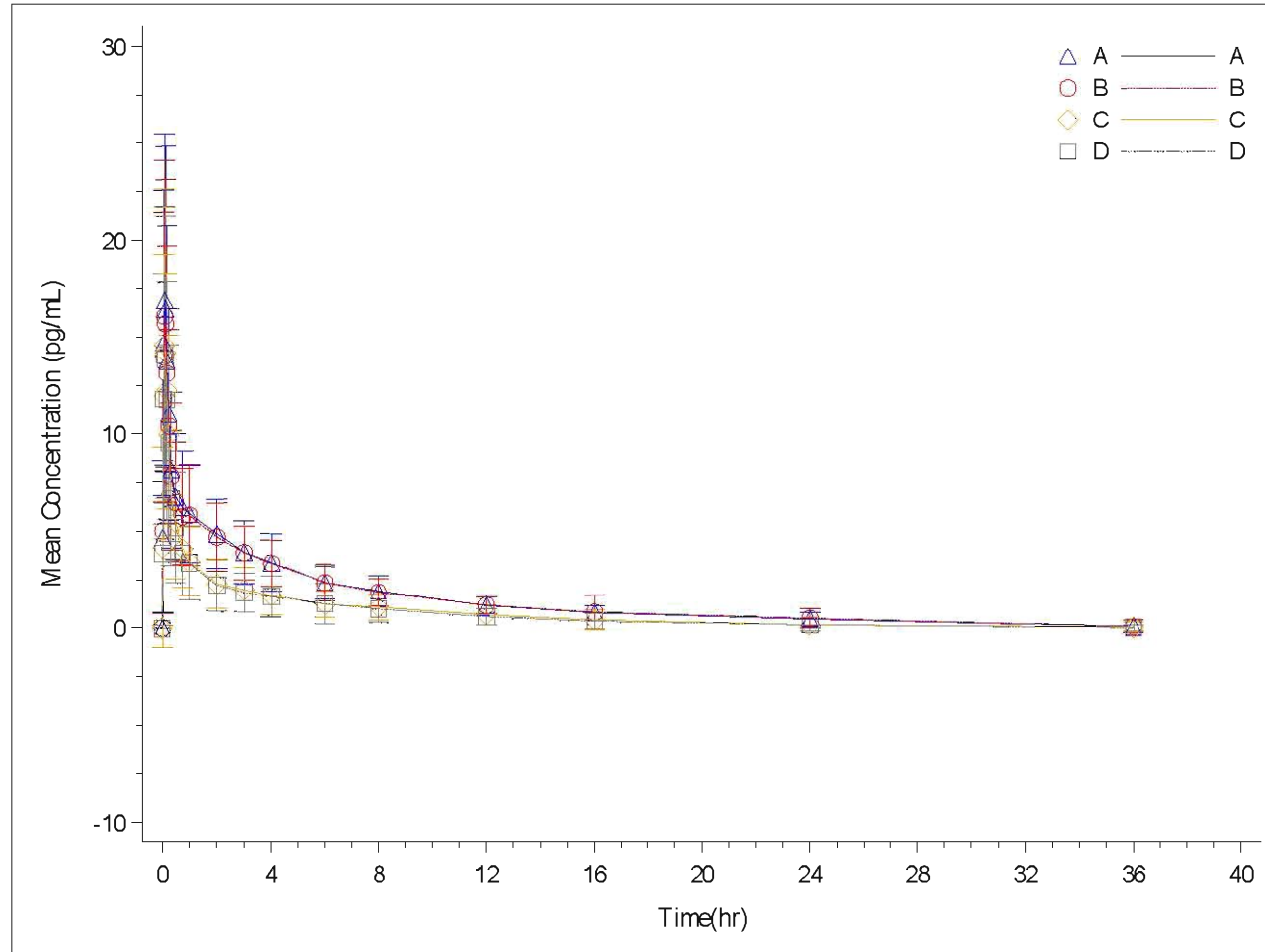
Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations
Treatment B: FOSTAIR 200/6 mcg-2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:51 PM by Figure 14.2.2.2.31.sas

Figure 14.2.2.2.32 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with and without charcoal), FAS



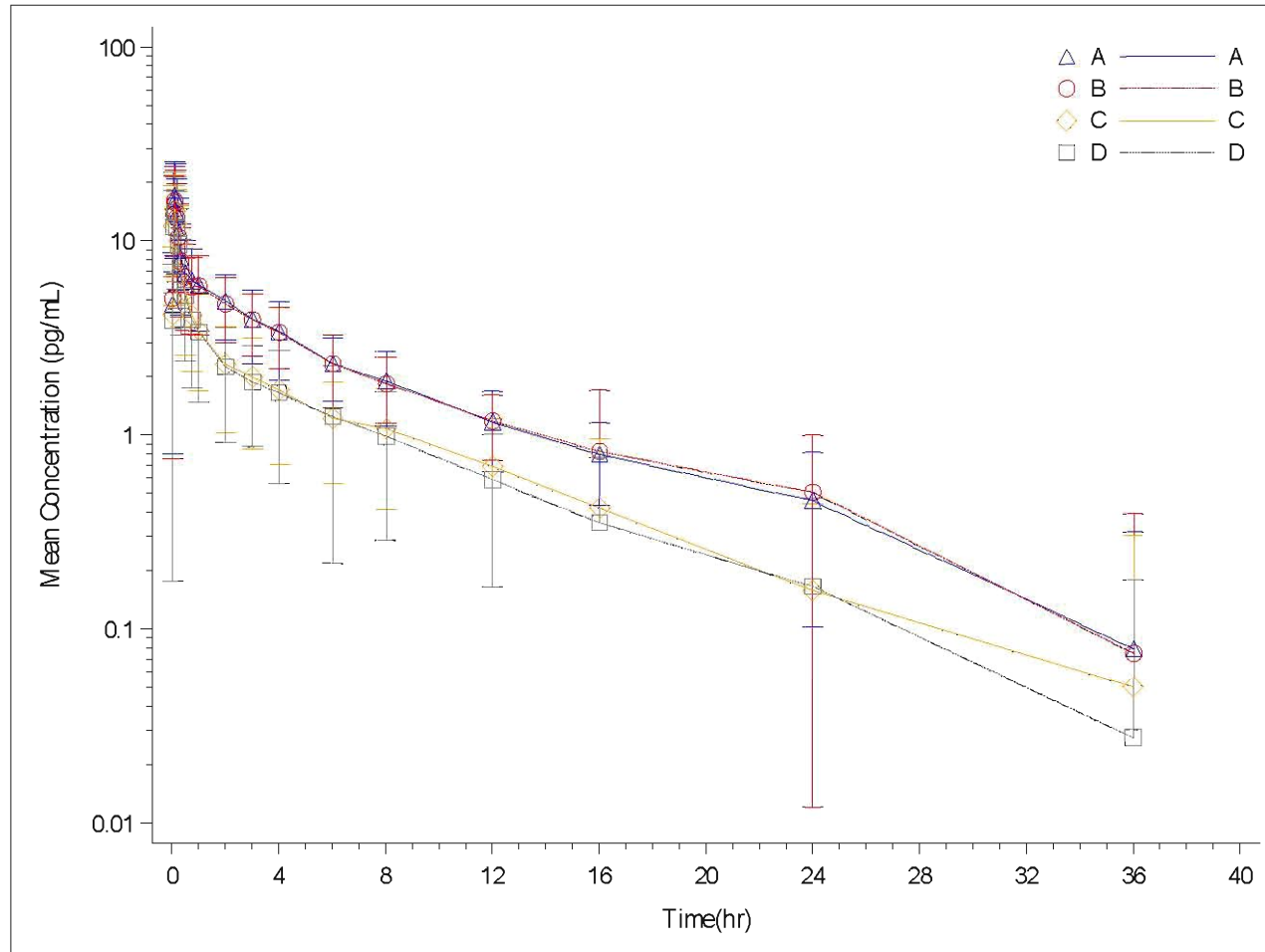
Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations
Treatment B: FOSTAIR 200/6 mcg-2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:51 PM by Figure 14.2.2.2.32.sas

Figure 14.2.2.2.33 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Linear Scale) (with and without charcoal), FAS



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations
Treatment B: FOSTAIR 200/6 mcg-2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:52 PM by Figure 14.2.2.2.33.sas

Figure 14.2.2.2.34 Arithmetic Mean (\pm SD) Formoterol Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (with and without charcoal), FAS



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

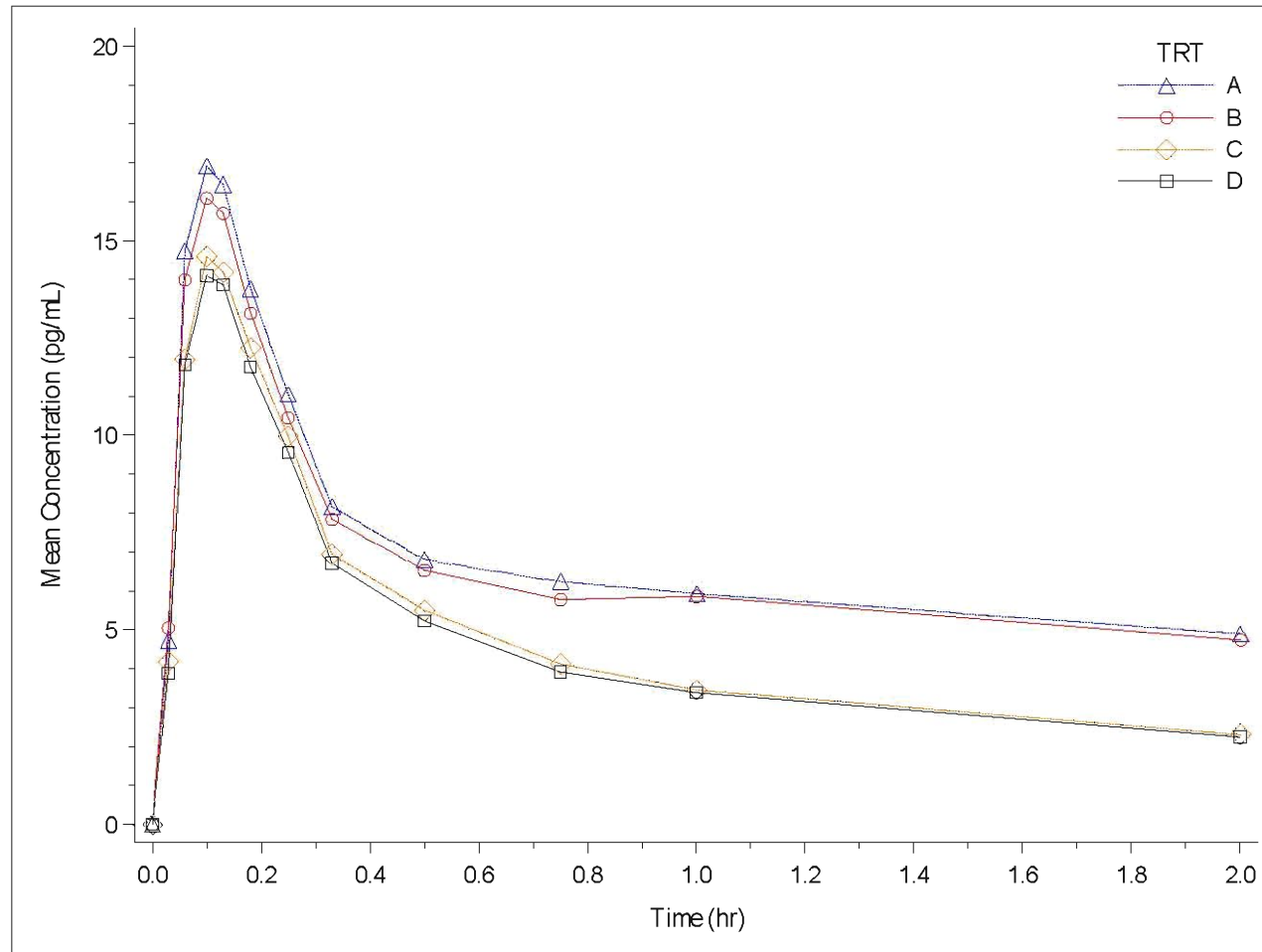
Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

Figure Generation: 15FEB2020 at 11:51 AM by Figure 14.2.2.2.34.sas

Figure 14.2.2.2.35 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (with and without charcoal), FAS



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

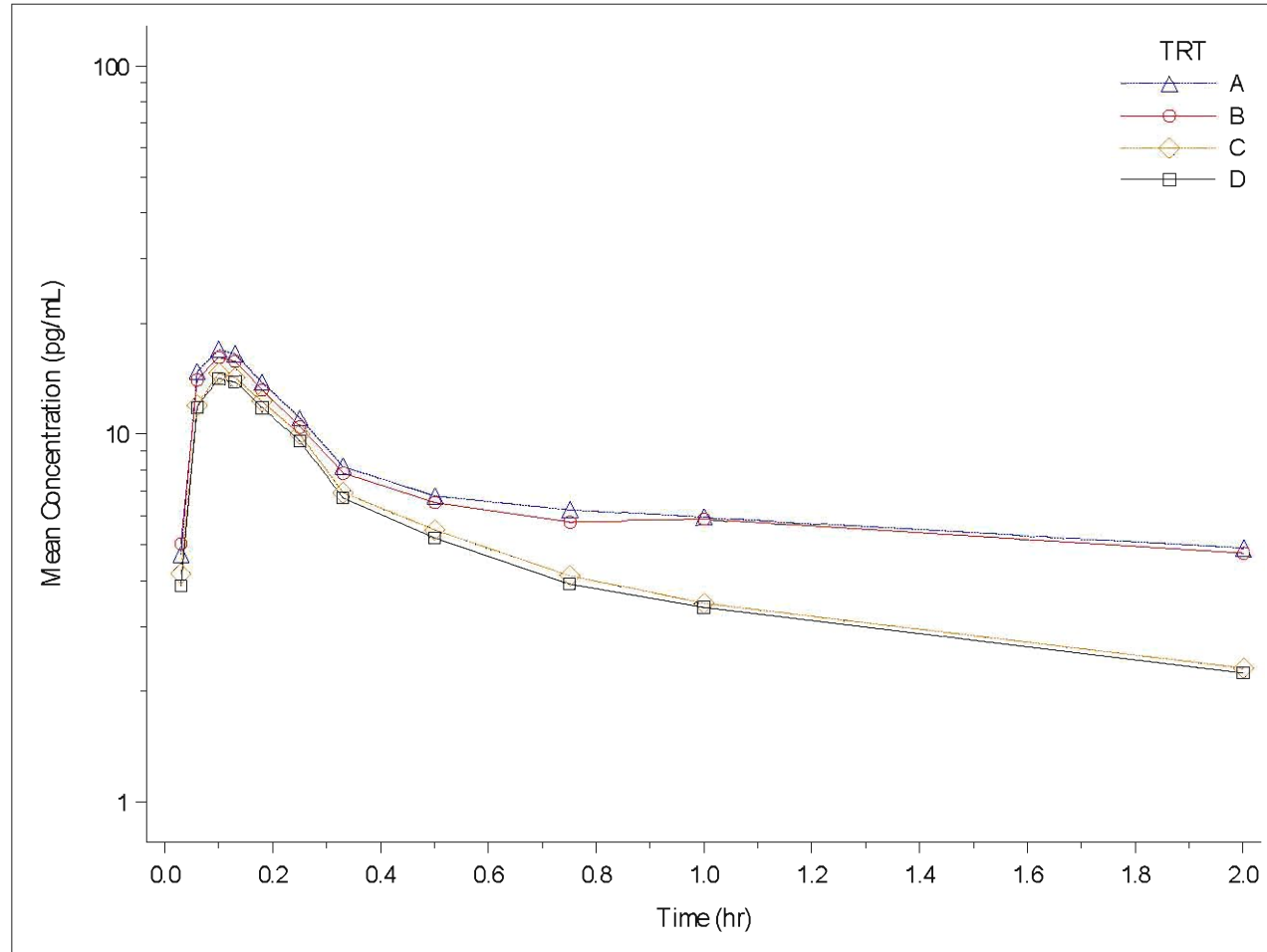
Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations

Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations

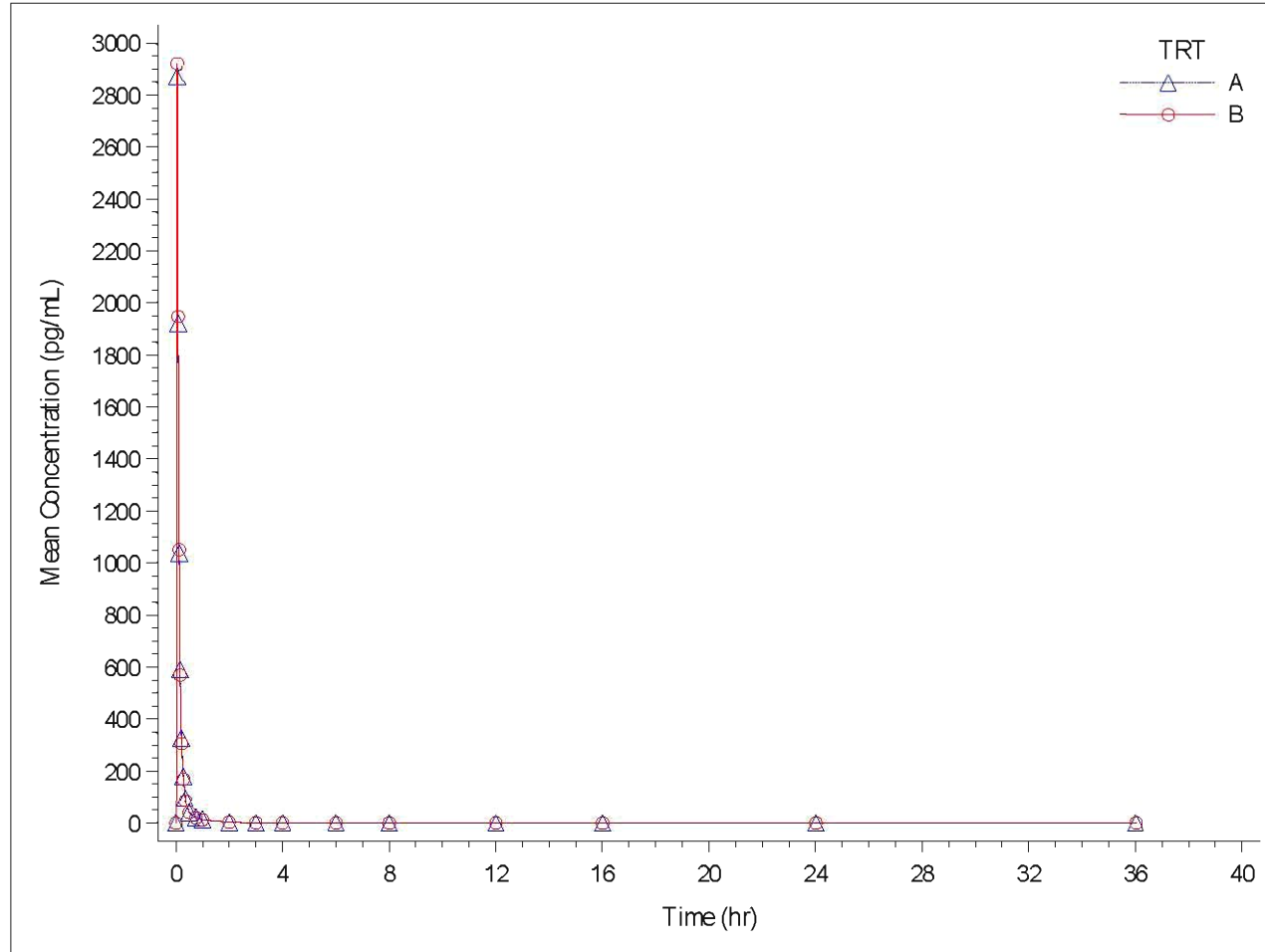
Figure Generation: 31JAN2020 at 7:53 PM by Figure 14.2.2.2.35.sas

Figure 14.2.2.2.36 Arithmetic Mean Formoterol Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-Log Scale) (with and without charcoal), FAS



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations
Treatment B: FOSTAIR 200/6 mcg-2 inhalations
Treatment C: Lupin BDP/FF 200/6 mcg with oral charcoal-2 inhalations
Treatment D: FOSTAIR 200/6 mcg with oral charcoal-2 inhalations
Figure Generation: 31JAN2020 at 7:54 PM by Figure 14.2.2.2.36.sas

Figure 14.2.2.3.1 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), PK Analysis Set

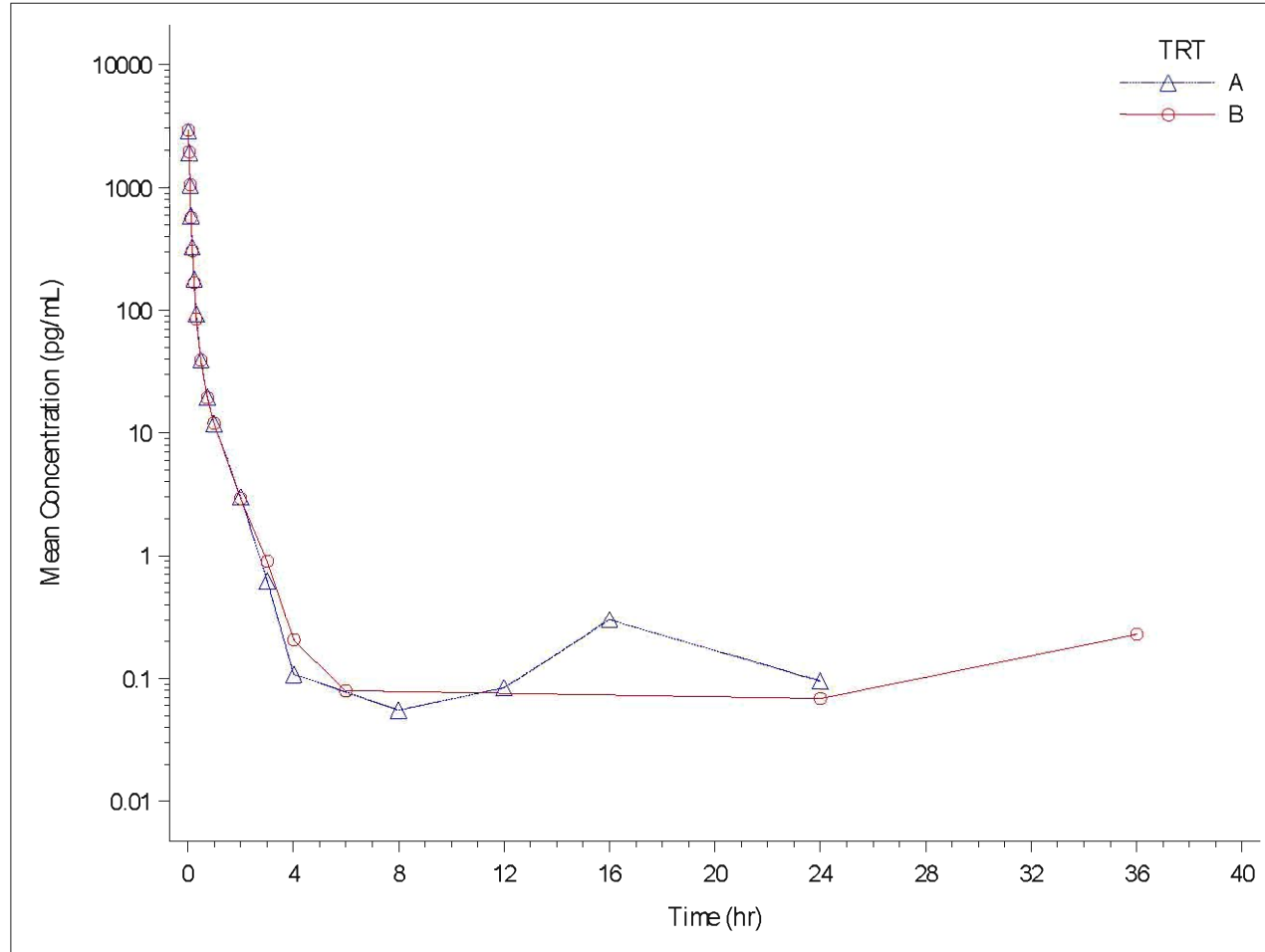


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 1:59 PM by Figure 14.2.2.3.1.sas

Figure 14.2.2.3.2 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), PK Analysis Set

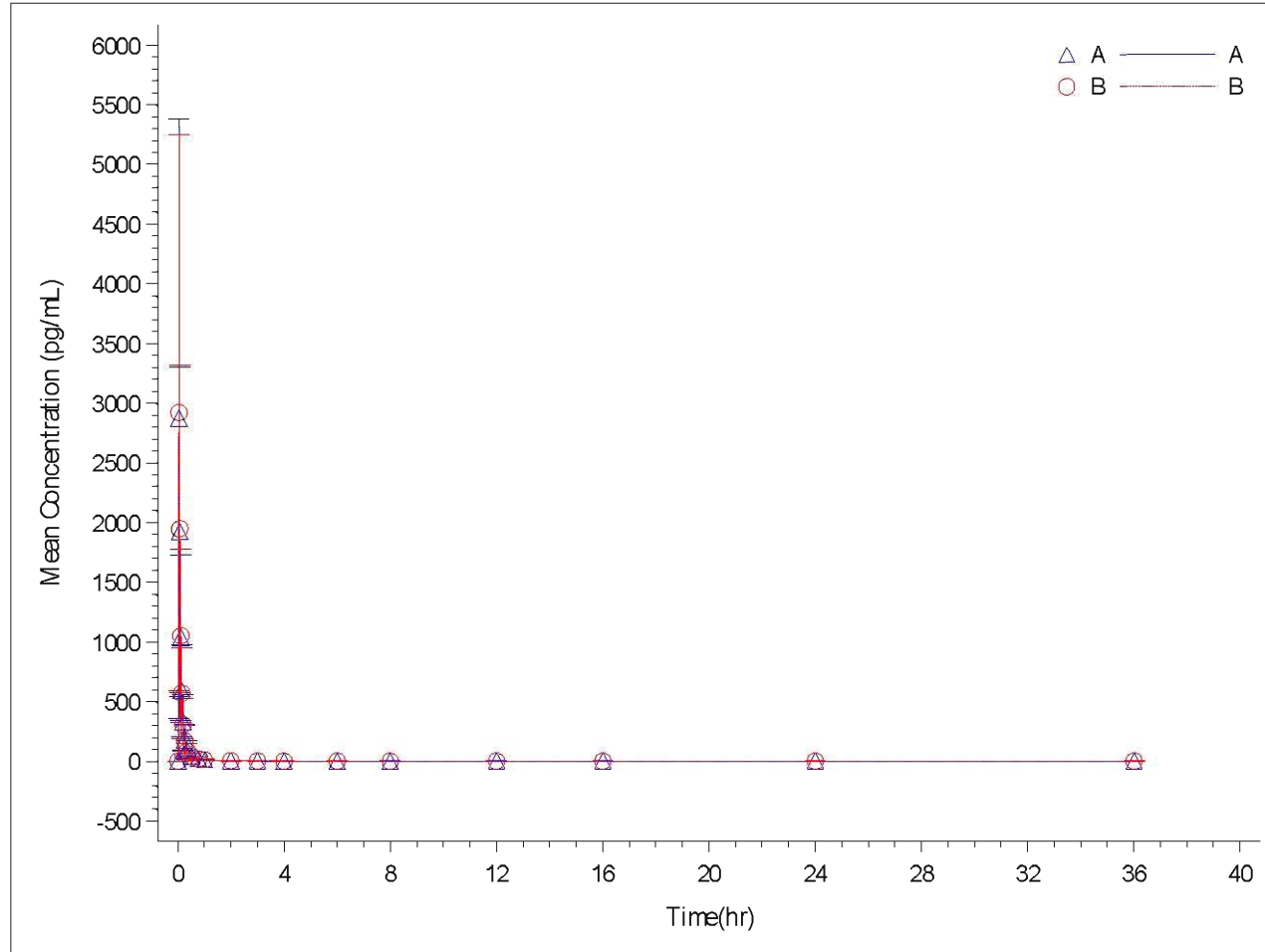


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:02 PM by Figure 14.2.2.3.2.sas

Figure 14.2.2.3.3 Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), PK Analysis Set

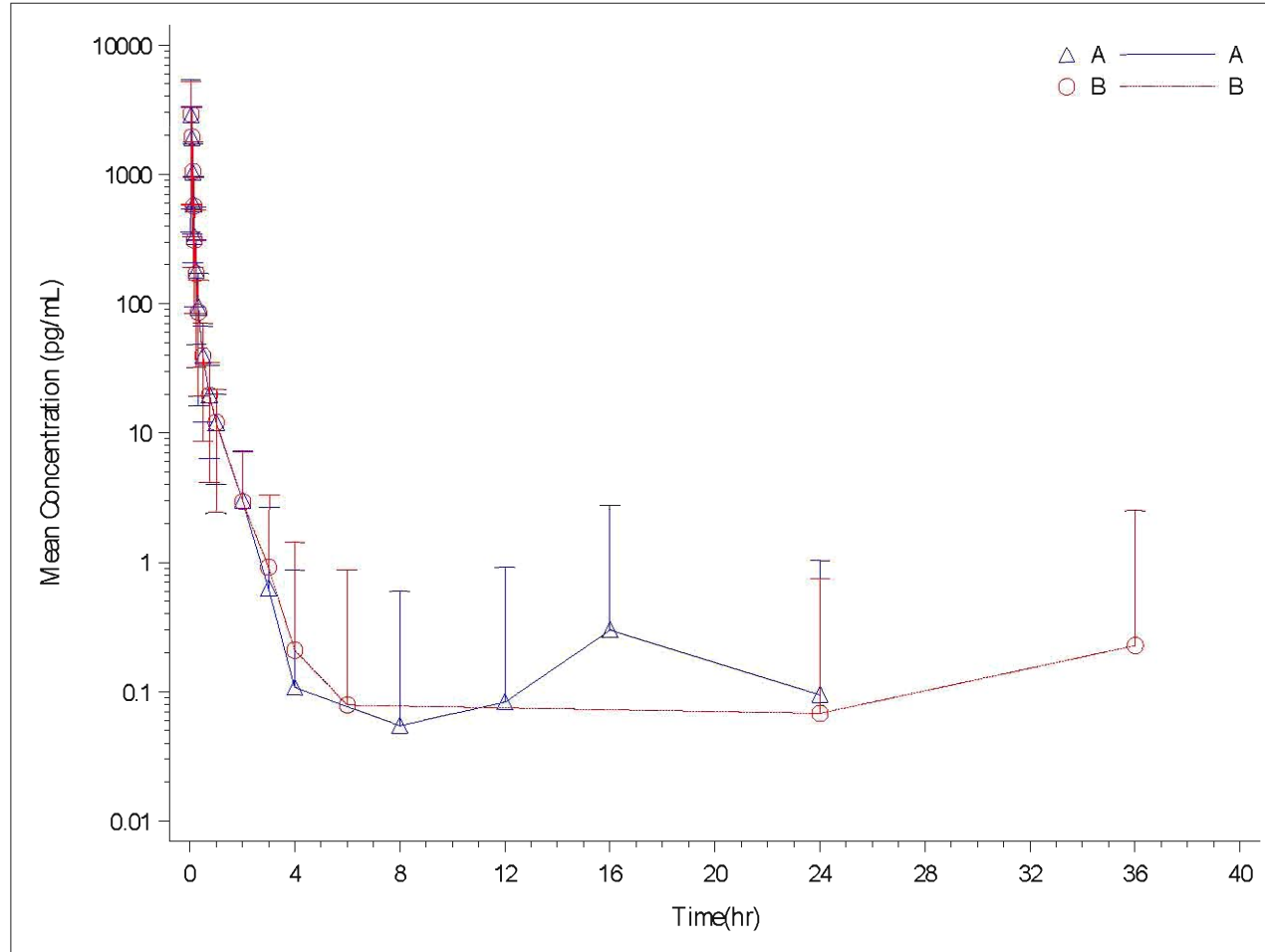


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:52 AM by Figure 14.2.2.3.3.sas

Figure 14.2.2.3.4 Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), PK Analysis Set

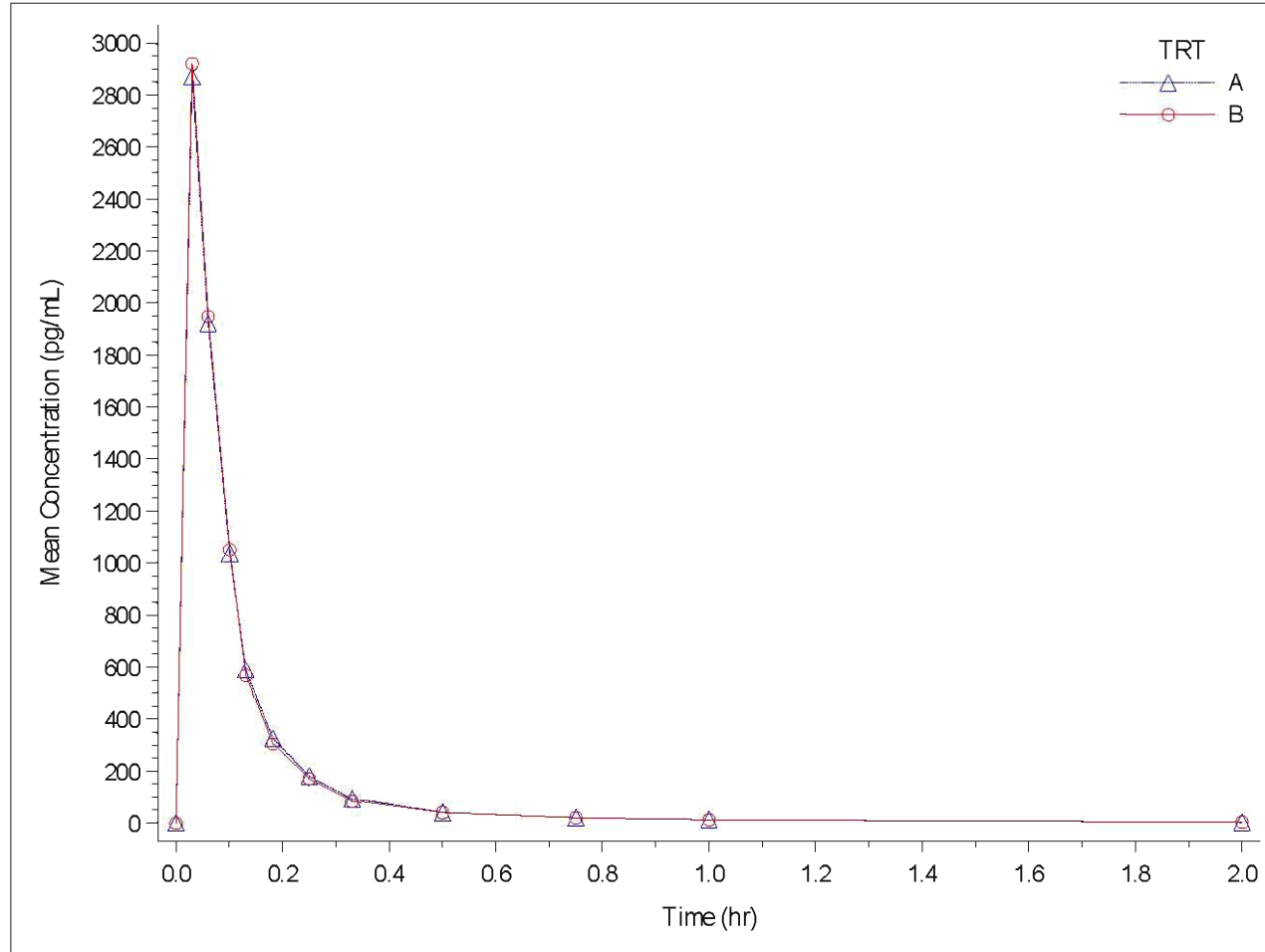


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:54 AM by Figure 14.2.2.3.4.sas

Figure 14.2.2.3.5 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (without charcoal), PK Analysis Set

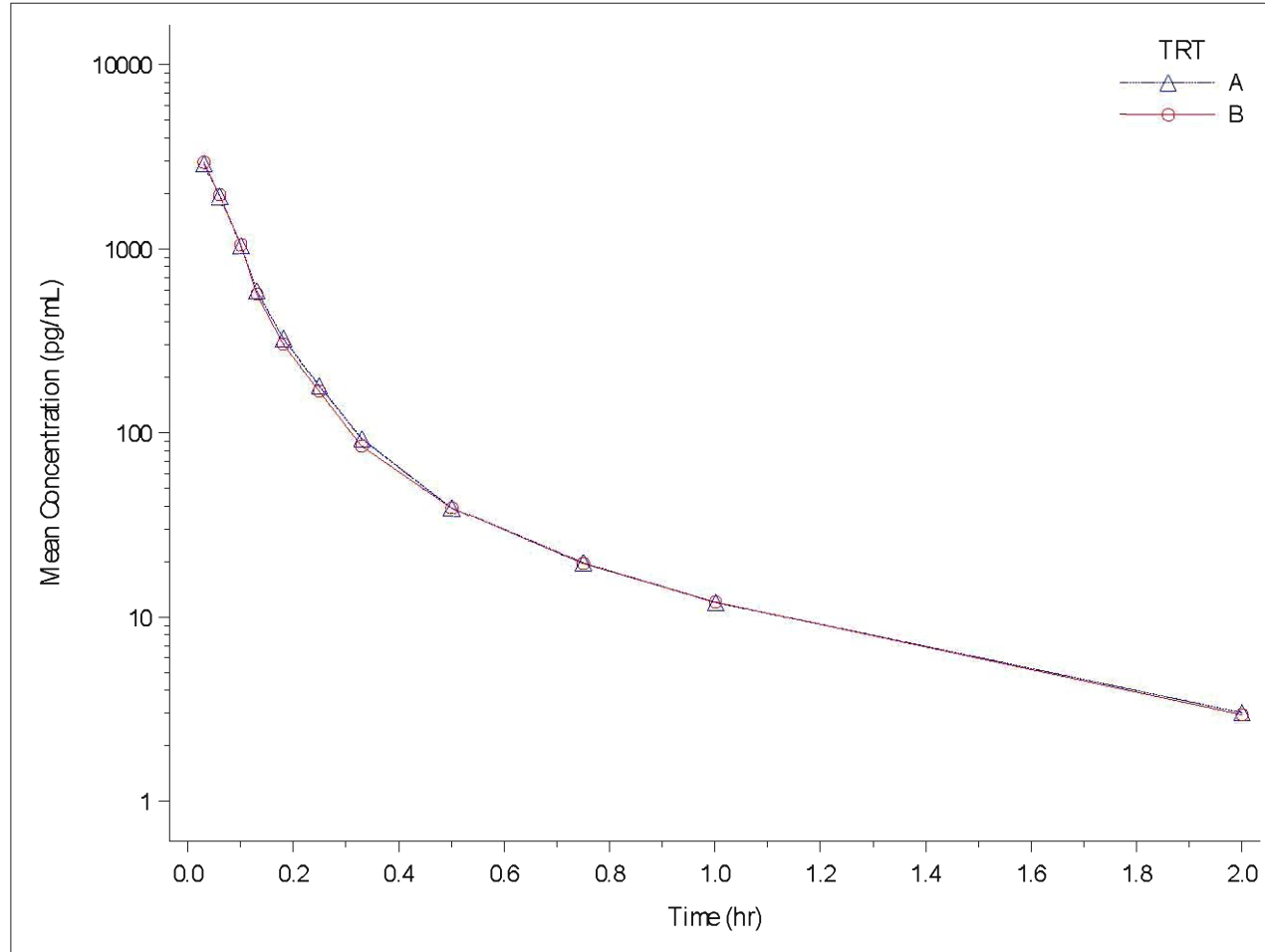


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:09 PM by Figure 14.2.2.3.5.sas

Figure 14.2.2.3.6 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (without charcoal), PK Analysis Set

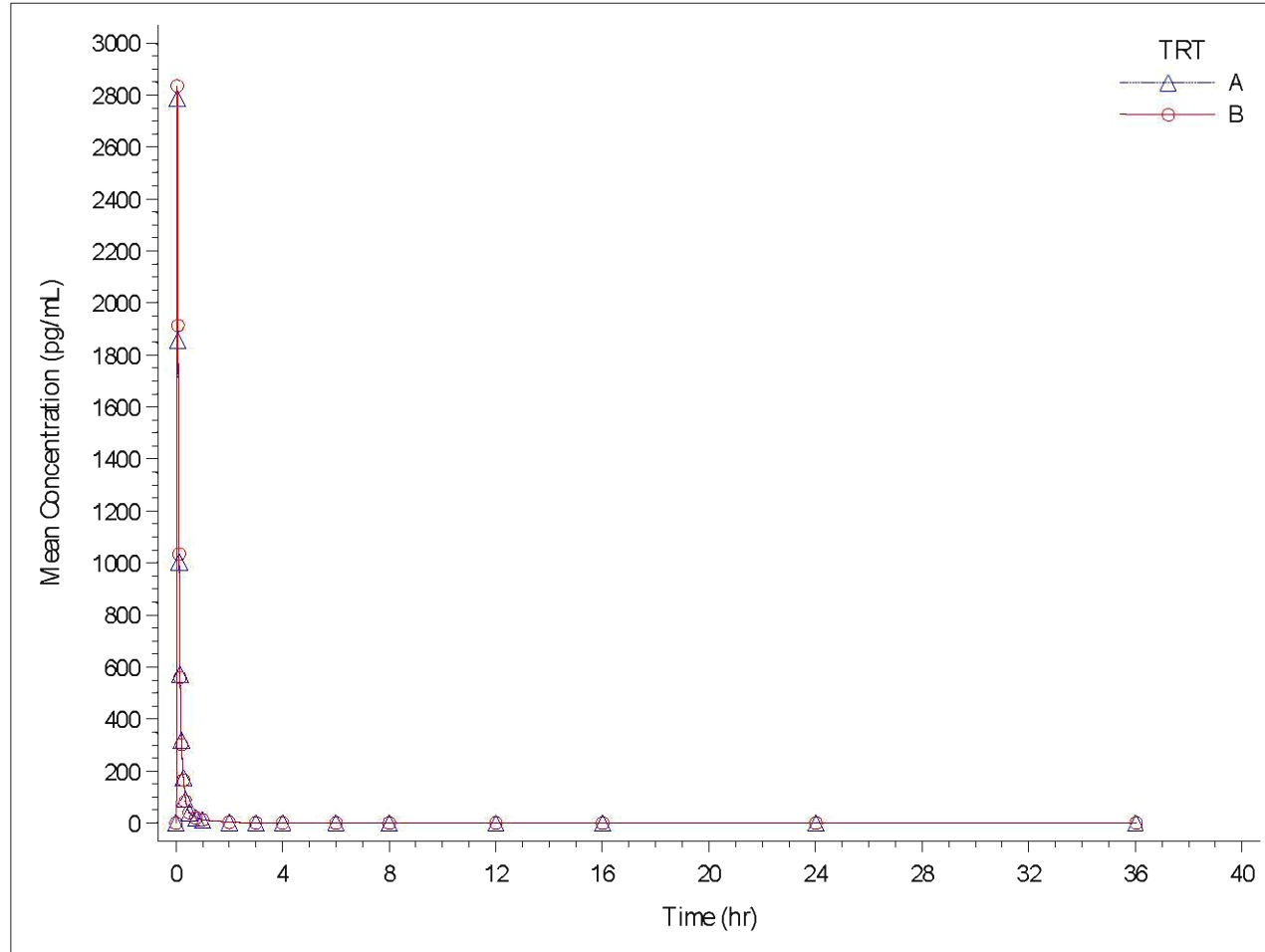


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:11 PM by Figure 14.2.2.3.6.sas

Figure 14.2.2.3.7 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), FAS

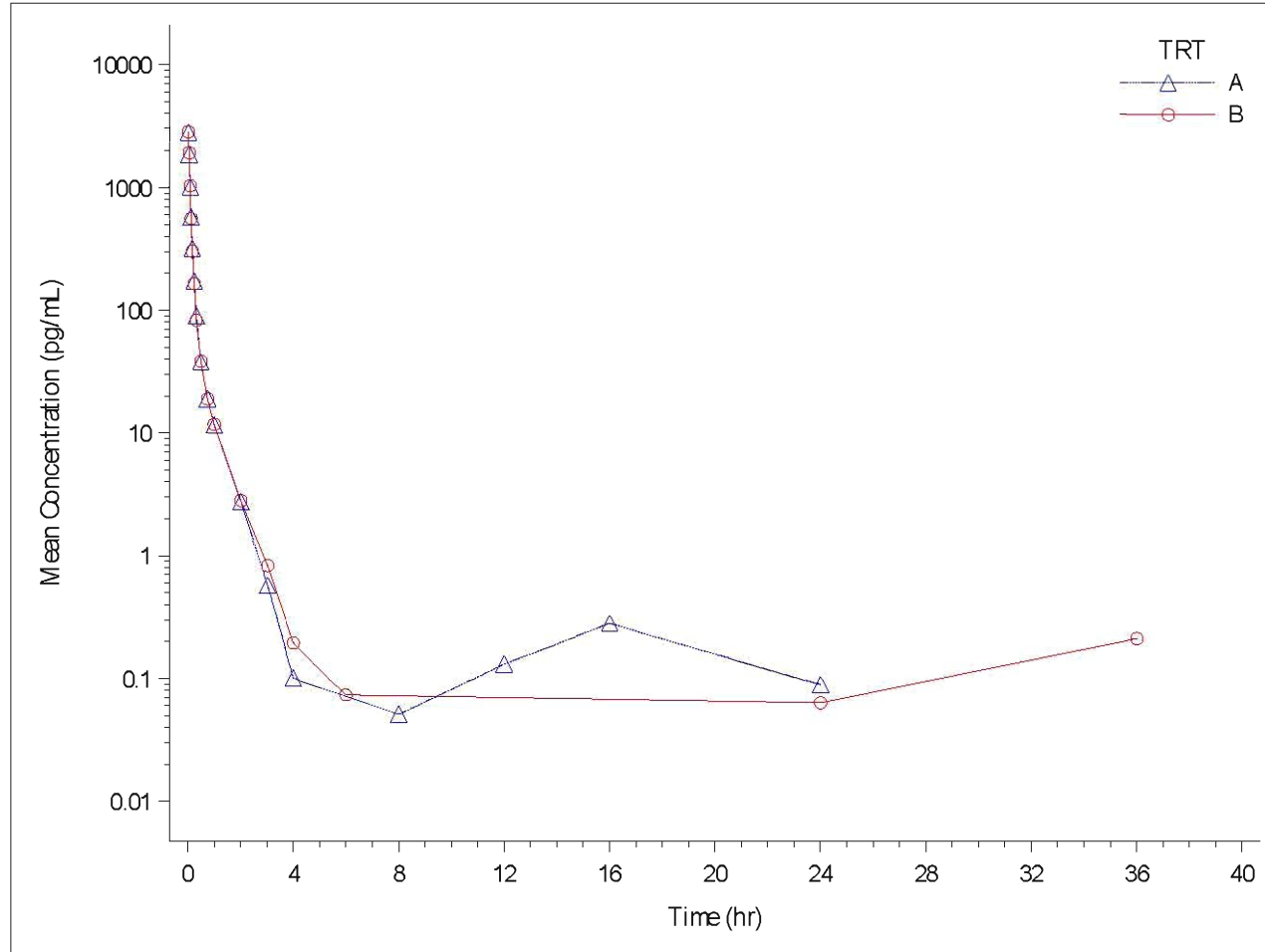


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:12 PM by Figure 14.2.2.3.7.sas

Figure 14.2.2.3.8 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), FAS

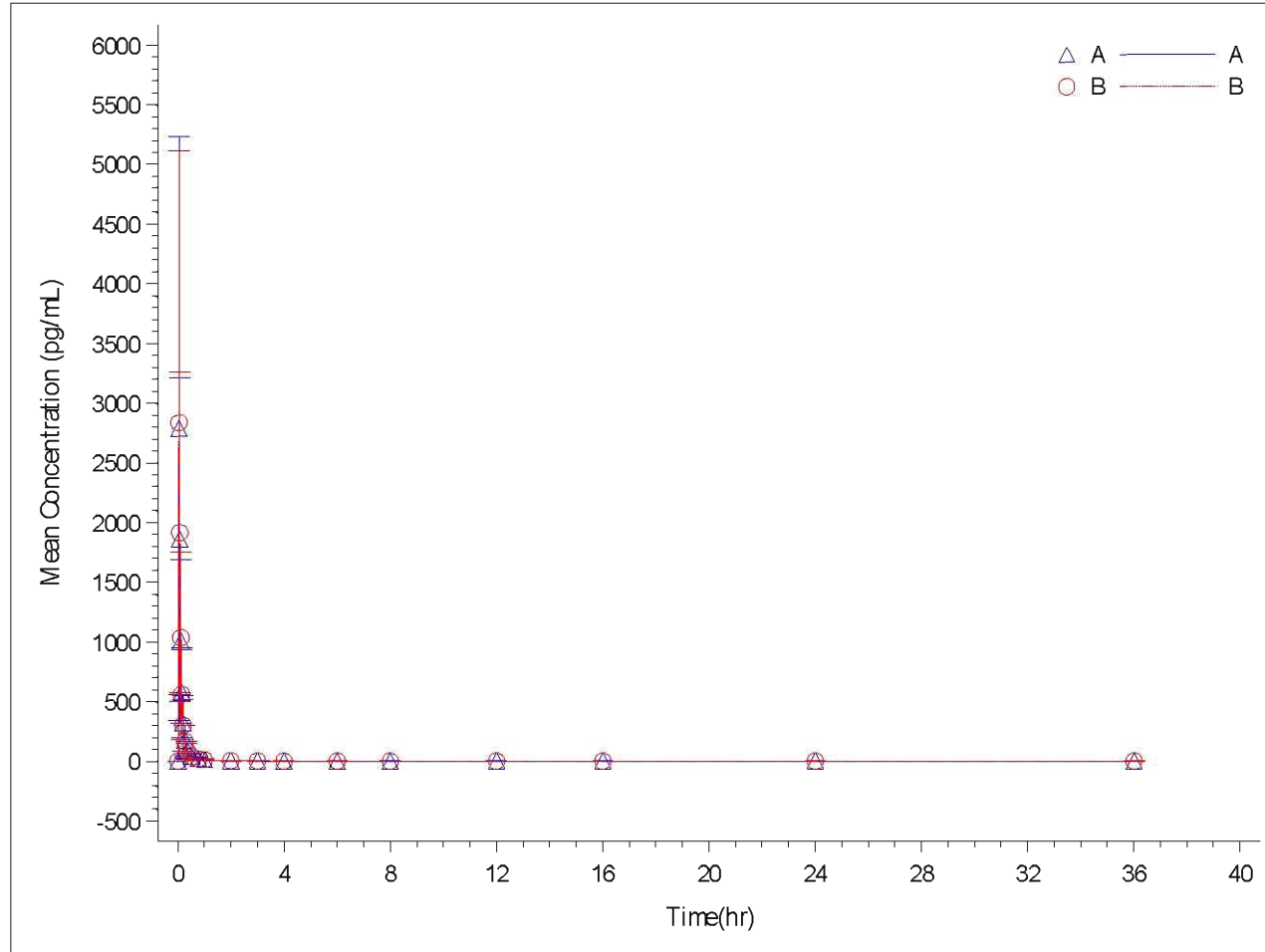


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:13 PM by Figure 14.2.2.3.8.sas

Figure 14.2.2.3.9 Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Linear Scale) (without charcoal), FAS

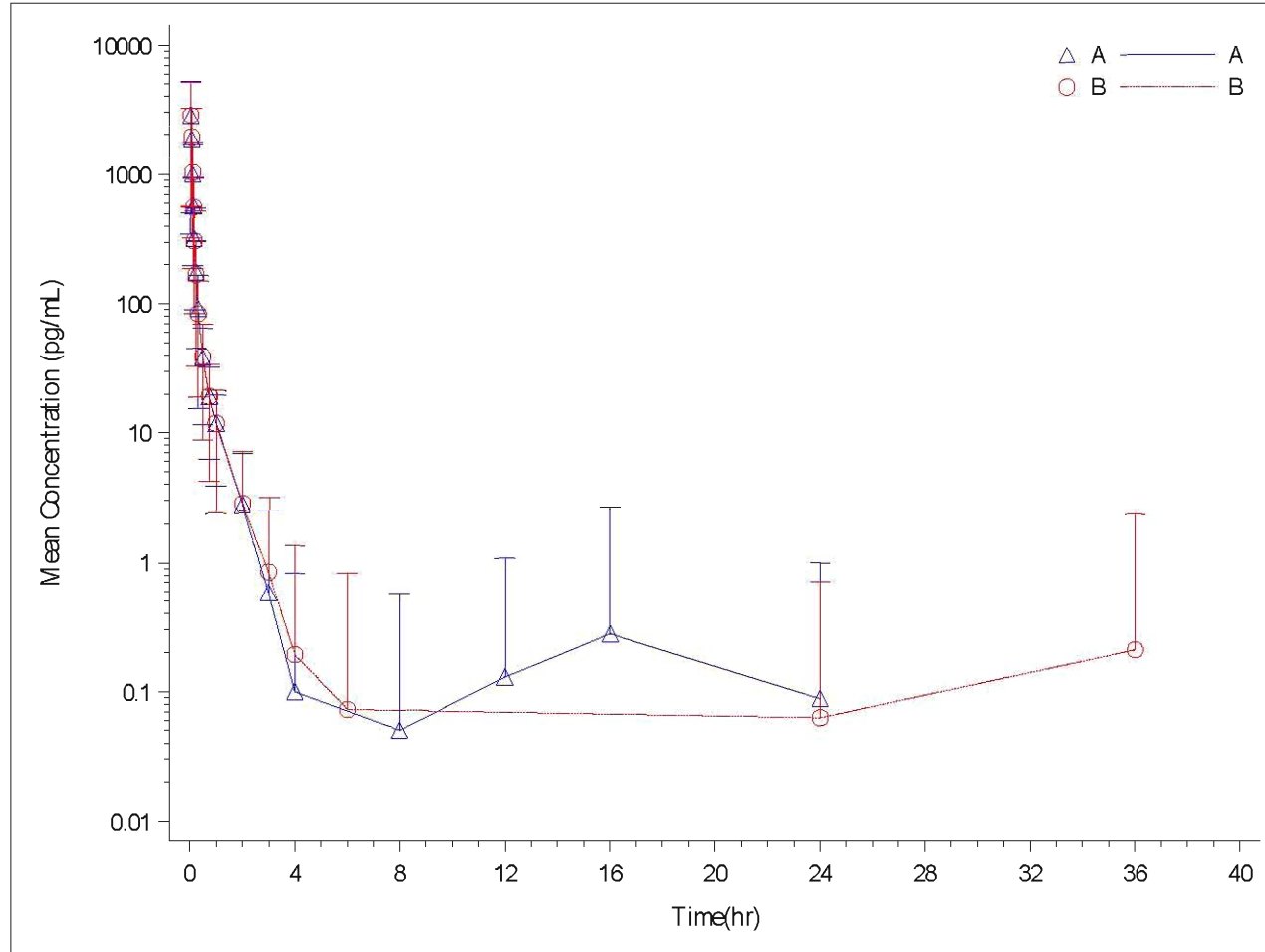


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:56 AM by Figure 14.2.2.3.9.sas

Figure 14.2.2.3.10 Arithmetic Mean (\pm SD) BDP Plasma Concentration-Time Profiles by Treatment (Semi-log Scale) (without charcoal), FAS

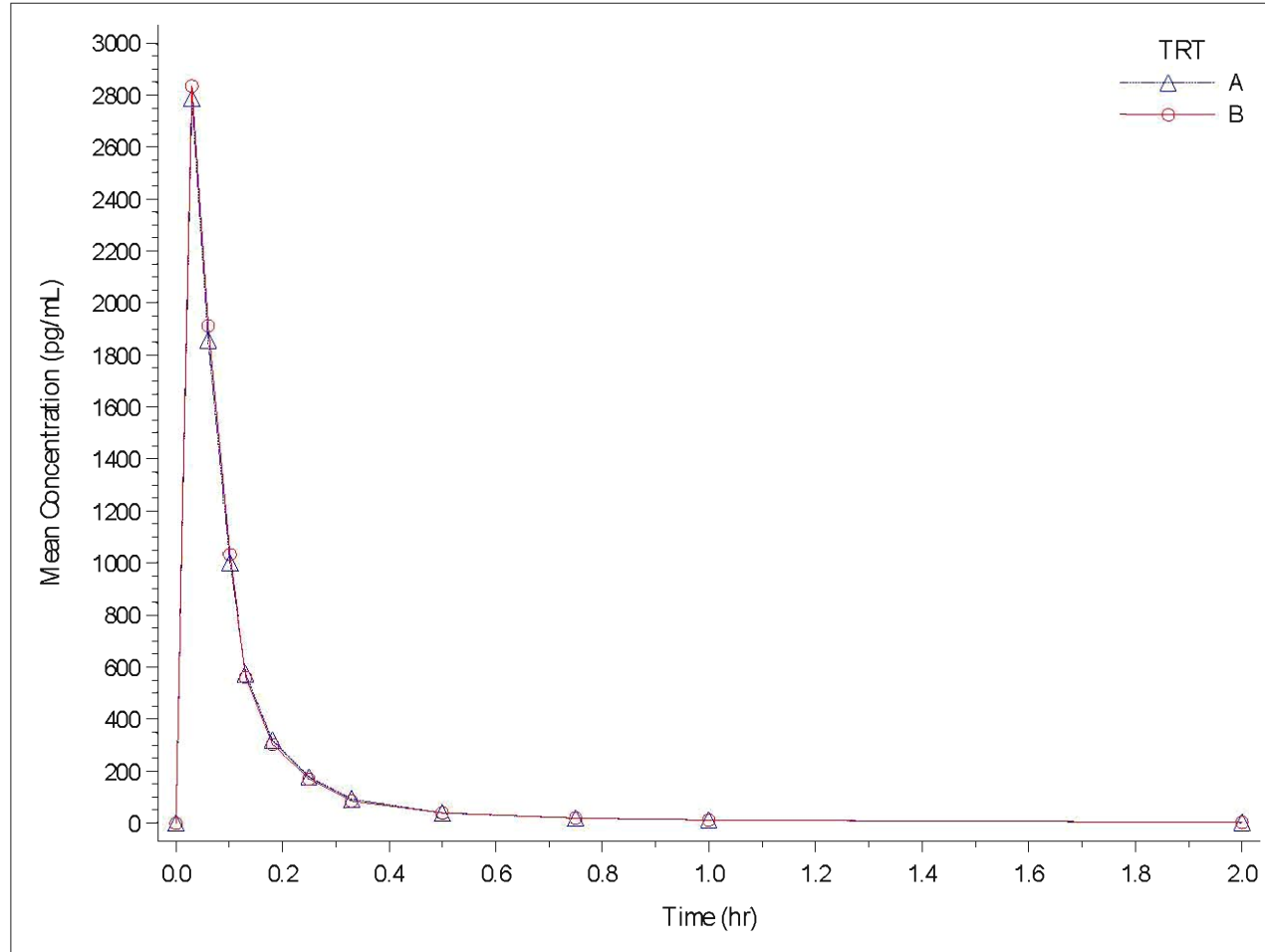


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 15FEB2020 at 11:57 AM by Figure 14.2.2.3.10.sas

Figure 14.2.2.3.11 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Linear Scale) (without charcoal), FAS

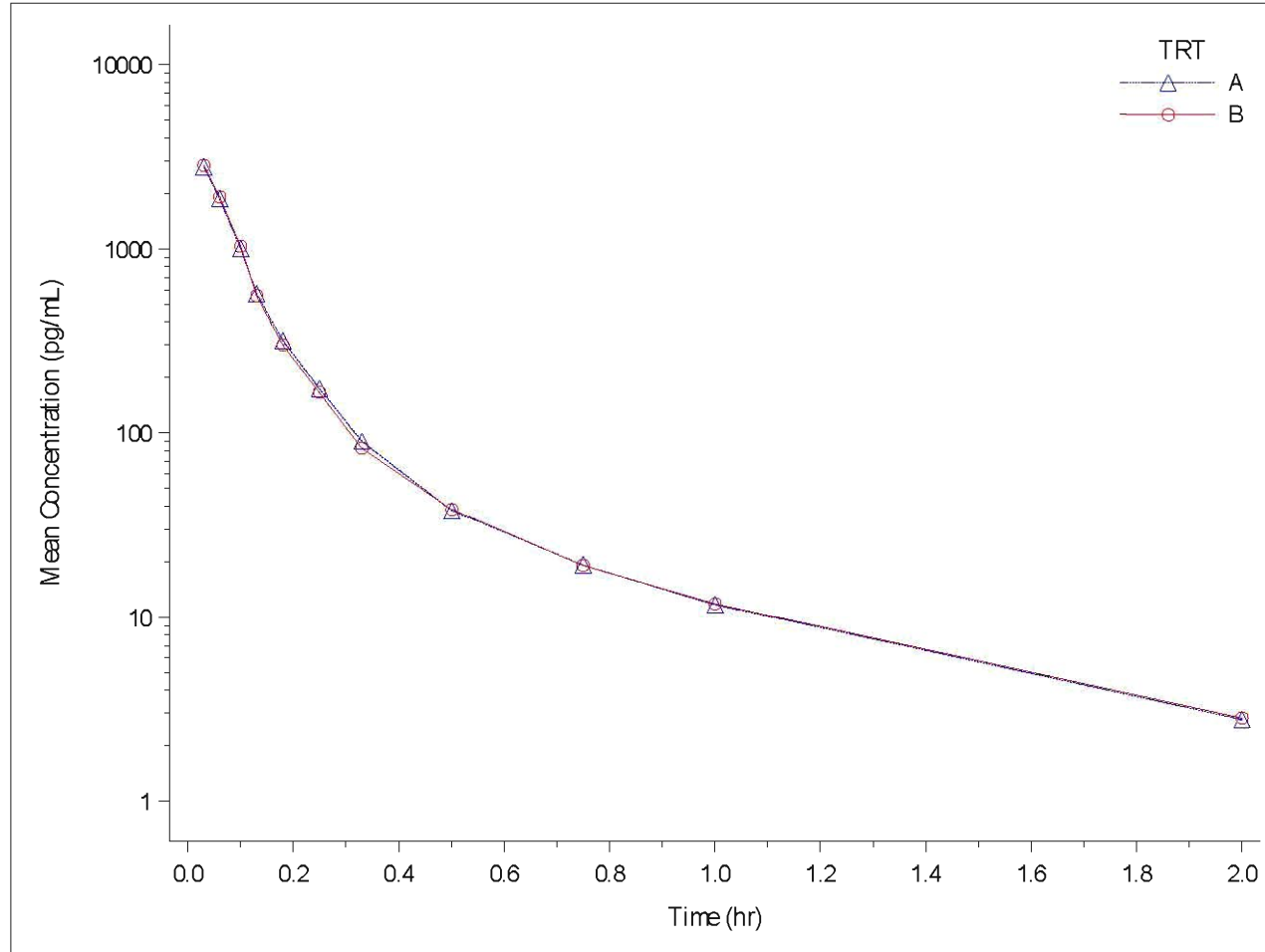


Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:25 PM by Figure 14.2.2.3.11.sas

Figure 14.2.2.3.12 Arithmetic Mean BDP Plasma Concentration-Time Profiles by Treatment, 0-2 hours (Semi-log Scale) (without charcoal), FAS



Treatment A: Lupin BDP/FF 200/6 mcg-2 inhalations

Treatment B: FOSTAIR 200/6 mcg-2 inhalations

Figure Generation: 31JAN2020 at 2:28 PM by Figure 14.2.2.3.12.sas

15. REFERENCE LIST

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16. APPENDICES

16.1 Study Information

16.1.1 Protocol and Protocol Amendments

16.1.1.1 Protocol and Amendments

16.1.1.1.1 Original Protocol, dated 13-Feb-2019

16.1.1.1.2 Protocol Amendment 01, dated 22-Mar-2019

16.1.1.2 Notes to File

16.1.2 Sample Case Report Form

16.1.3 List of Independent Ethics Committees (IECs) or Institutional Review Boards (IRBs) and Representative Written Subject/Patient Information and Sample Consent Form

16.1.4 List and Description of Investigators and Other Important Participants in the Study (Reference [Section 6](#))

16.1.5 Signatures of Principal or Coordinating Investigator(s) or Sponsor's Responsible Medical Officer

16.1.6 Listing of Subjects/Patients Receiving Test Drug(s)/Investigational Product(s) From Specific Batches (Available upon request)

16.1.7 Randomisation Scheme and Codes (Subject/Patient Identification and Treatment Assigned)

16.1.8 Audit Certificates

16.1.9 Documentation of Statistical Methods

16.1.9.1 Statistical Analysis Plan, dated 12-Jul-2019

16.1.9.2 Statistical Appendix

16.1.9.3 Data Review Meeting Minutes, dated 01-Oct-2019

16.1.10 Interlaboratory Standardization Methods

16.1.11 Publications Based on the Study (section is not applicable)

16.1.12 Important Publications Referenced in the Report

16.2 Subject Data Listings

16.2.1 Discontinued Subjects

16.2.2 Protocol Deviations

16.2.3 Subjects Excluded From the Pharmacokinetic Analysis

16.2.4 Demographic Data

16.2.5 Compliance and Drug Concentration Data

16.2.6 Individual Pharmacokinetic Response Data

16.2.7 Adverse Events

- [16.2.8](#) Individual Laboratory Measurements
- [16.2.9](#) Prior and Concomitant Medication
- [16.2.10](#) Vital Signs, Electrocardiograms, Physical Examination
- [16.3](#) Case Report Forms
- [16.3.1](#) Case Report Forms: Deaths, Other Serious Adverse Events, and Withdrawals Due to Adverse Events
- [16.3.2](#) Other Case Report Forms Submitted
- 16.4 Individual Subject/Patient Data Listings (US Archival Listings) (Available upon request)