Claim No HP-2021-000010

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

B E T W E E N:

(1) TEVA PHARMACEUTICAL INDUSTRIES LIMITED
(a company incorporated under the laws of Israel)

(2) TEVA UK LIMITED

Claimants /
Part 20 Defendants

and

NOVARTIS AG
(a company incorporated under the laws of Switzerland)

Defendant

and

NOVARTIS PHARMACEUTICALS UK LIMITED
(a company incorporated under the laws of the UK)

Part 20 Claimant

ANNEX 1
TO THE STATEMENT OF REASONS FOR AMENDMENT OF
EUROPEAN PATENTS (UK) NO. 2 964 202 AND NO. 3 124 018

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202 UNCONDITIONAL AMENDMENT

1. A swallowable film coated tablet ~~for oral administration~~ comprising deferasirox or a pharmaceutically acceptable salt thereof present in an amount from 45% to 60% by weight based on the total weight of the tablet, wherein the tablet is without sodium lauryl sulfate and lactose and comprises
   i. microcrystalline cellulose;
   ii. crospovidone;
   iii. povidone;
   iv. poloxamer 188;
   v. colloidal silicon dioxide;
   vi. magnesium stearate.

2. The swallowable film coated tablet ~~for oral administration~~ according to claim 1 wherein:
   i. microcrystalline cellulose is present in a total amount of 10% to 40 % by weight based on total weight of the tablet;
   ii. crospovidone is present in a total amount of 1% to 10 % by weight based on total weight of the tablet;
   iii. povidone is present in a total amount of 1% to 5 % by weight based on total weight of the tablet;
   iv. poloxamer 188 is present in a total amount of up to 2% by weight based on total weight of the tablet;
   v. colloidal silicon dioxide is present in a total amount of 0.1% to 1% by weight based on total weight of the tablet;
   vi. magnesium stearate is present in a total amount of 0.1% to 2% by weight based on total weight of the tablet;
   vii. the coating comprises a functional or non-functional polymer.

3. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

5. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

CONDITIONAL AMENDMENTS

202 Conditional Amendment 1

1. A swallowable film coated tablet for use in a method of treating iron overload ~~for oral administration~~ wherein the tablet comprises ~~comprising~~ deferasirox or a pharmaceutically acceptable salt thereof present in an amount from 45% to 60% by weight based on the total weight of the tablet, wherein the tablet is without sodium lauryl sulfate and lactose and comprises
   i. microcrystalline cellulose;
   ii. crospovidone;
   iii. povidone;
   iv. poloxamer 188;
   v. colloidal silicon dioxide;
   vi. magnesium stearate~~.~~

   wherein the method comprises swallowing said tablet.

2. The swallowable film coated tablet ~~for oral administration~~ for use according to claim 1 wherein:
   i. microcrystalline cellulose is present in a total amount of 10% to 40 % by weight based on total weight of the tablet;
   ii. crospovidone is present in a total amount of 1% to 10 % by weight based on total weight of the tablet;
   iii. povidone is present in a total amount of 1% to 5 % by weight based on total weight of the tablet;
   iv. poloxamer 188 is present in a total amount of up to 2% by weight based on total weight of the tablet;
   v. colloidal silicon dioxide is present in a total amount of 0.1% to 1% by weight based on total weight of the tablet;
   vi. magnesium stearate is present in a total amount of 0.1% to 2% by weight based on total weight of the tablet;
   vii. the coating comprises a functional or non-functional polymer.

3. The swallowable film coated tablet ~~for oral administration~~ for use according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ for use according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

5. The swallowable film coated tablet ~~for oral administration~~ for use according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

202 Conditional Amendment 2

1. A swallowable film coated tablet ~~for oral administration~~ comprising deferasirox or a pharmaceutically acceptable salt thereof present in an amount from 45% to 60% by weight based on the total weight of the tablet, wherein the tablet is without sodium lauryl sulfate and lactose and comprises
   i. microcrystalline cellulose;
   ii. crospovidone;
   iii. povidone;
   iv. poloxamer 188;
   v. colloidal silicon dioxide;
   vi. magnesium stearate.

   wherein the film coating is non-functional.

2. The swallowable film coated tablet ~~for oral administration~~ according to claim 1 wherein:
   i. microcrystalline cellulose is present in a total amount of 10% to 40 % by weight based on total weight of the tablet;
   ii. crospovidone is present in a total amount of 1% to 10 % by weight based on total weight of the tablet;
   iii. povidone is present in a total amount of 1% to 5 % by weight based on total weight of the tablet;
   iv. poloxamer 188 is present in a total amount of up to 2% by weight based on total weight of the tablet;
   v. colloidal silicon dioxide is present in a total amount of 0.1% to 1% by weight based on total weight of the tablet;
   vi. magnesium stearate is present in a total amount of 0.1% to 2% by weight based on total weight of the tablet;
   vii. the coating comprises a ~~functional or~~ non-functional polymer.

3. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

5. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

202 Conditional Amendment 3

1. A swallowable film coated tablet for use in a method of treating iron overload ~~for oral administration~~ wherein the tablet comprises ~~comprising~~ deferasirox or a pharmaceutically acceptable salt thereof present in an amount from 45% to 60% by weight based on the total weight of the tablet, wherein the tablet is without sodium lauryl sulfate and lactose and comprises
   i. microcrystalline cellulose;
   ii. crospovidone;
   iii. povidone;
   iv. poloxamer 188;
   v. colloidal silicon dioxide;
   vi. magnesium stearate~~.~~

   wherein the film coating is non-functional and wherein the method comprises swallowing said tablet.

2. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1 wherein:
   i. microcrystalline cellulose is present in a total amount of 10% to 40 % by weight based on total weight of the tablet;
   ii. crospovidone is present in a total amount of 1% to 10 % by weight based on total weight of the tablet;
   iii. povidone is present in a total amount of 1% to 5 % by weight based on total weight of the tablet;
   iv. poloxamer 188 is present in a total amount of up to 2% by weight based on total weight of the tablet;
   v. colloidal silicon dioxide is present in a total amount of 0.1% to 1% by weight based on total weight of the tablet;
   vi. magnesium stearate is present in a total amount of 0.1% to 2% by weight based on total weight of the tablet;
   vii. the coating comprises a ~~functional or~~ non-functional polymer.

3. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

5. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

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Claimants / Part 20 Defendants

and

NOVARTIS AG
(a company incorporated under the laws of Switzerland)

Defendant

and

NOVARTIS PHARMACEUTICALS UK LIMITED
(a company incorporated under the laws of the UK)

Part 20 Claimant

ANNEX 2
TO THE STATEMENT OF REASONS FOR AMENDMENT OF EUROPEAN PATENTS (UK) NO. 2 964 202 AND NO. 3 124 018

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018 UNCONDITIONAL AMENDMENT

1. A swallowable film coated tablet ~~for oral administration~~ which contains deferasirox or a pharmaceutically acceptable salt thereof present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose.

2. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~
~~7.29 mg polyvinylpyrrolidone;~~
~~22.68 mg crospovidone;~~
~~0.32 mg poloxamer 188;~~
~~1.62 mg colloidal silica;~~

~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

~~8. A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

~~9. A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

CONDITIONAL AMENDMENTS

018 Conditional Amendment 1

1. A swallowable film coated tablet for use in a method of treating iron overload ~~for oral administration~~ wherein the tablet comprises deferasirox or a pharmaceutically acceptable salt thereof present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose, and wherein the method comprises swallowing said tablet.

2. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;
107.23 mg microcrystalline cellulose;
7.29 mg polyvinylpyrrolidone;
22.68 mg crospovidone;
0.32 mg poloxamer 188;
1.62 mg colloidal silica;
4.86 mg magnesium stearate; and
9.72 mg coating.

8. A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;
215.45 mg microcrystalline cellulose;
14.58 mg polyvinylpyrrolidone;
45.36 mg crospovidone;
0.65 mg poloxamer 188;
3.24 mg colloidal silica;
9.72 mg magnesium stearate; and
19.44 mg coating

9. A film coated tablet for oral administration according to claim 1 comprising:

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

018 Conditional Amendment 2

1. A swallowable film coated tablet ~~for oral administration~~ which contains deferasirox or a pharmaceutically acceptable salt thereof present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a non-functional coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose.

2. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~
~~7.29 mg polyvinylpyrrolidone;~~
~~22.68 mg crospovidone;~~
~~0.32 mg poloxamer 188;~~

~~1.62 mg colloidal silica;~~
~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

8. ~~A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

9. ~~A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

018 Conditional Amendment 3

1. A swallowable film coated tablet ~~for oral administration~~ which contains deferasirox ~~or a pharmaceutically acceptable salt thereof~~ present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~, wherein deferasirox is present in free acid form,

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer 188;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose.

2. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~
~~7.29 mg polyvinylpyrrolidone;~~
~~22.68 mg crospovidone;~~

~~0.32 mg poloxamer 188;~~
~~1.62 mg colloidal silica;~~
~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

~~8. A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

~~9. A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

018 Conditional Amendment 4

1. A swallowable film coated tablet for use in a method of treating iron overload ~~for oral administration~~ wherein the tablet comprises deferasirox or a pharmaceutically acceptable salt thereof present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a non-functional coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose, and wherein the method comprises swallowing said tablet.

2. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~

~~7.29 mg polyvinylpyrrolidone;~~
~~22.68 mg crospovidone;~~
~~0.32 mg poloxamer 188;~~
~~1.62 mg colloidal silica;~~
~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

8. ~~A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

9. ~~A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

018 Conditional Amendment 5

1. A swallowable film coated tablet for use in a method of treating iron overload ~~for oral administration~~ wherein the tablet comprises deferasirox ~~or a pharmaceutically acceptable salt thereof~~ present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~ wherein deferasirox is present in free acid form,

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer 188;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose, and wherein the method comprises swallowing said tablet.

2. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~
~~7.29 mg polyvinylpyrrolidone;~~

~~22.68 mg crospovidone;~~
~~0.32 mg poloxamer 188;~~
~~1.62 mg colloidal silica;~~
~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

8. ~~A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

9. ~~A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

Conditional Amendment 6

1. A swallowable film coated tablet ~~for oral administration~~ which contains deferasirox ~~or a pharmaceutically acceptable salt thereof~~ present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~, wherein deferasirox is present in free acid form,

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer 188;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a non-functional coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose.

2. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~
~~7.29 mg polyvinylpyrrolidone;~~
~~22.68 mg crospovidone;~~

~~0.32 mg poloxamer 188;~~
~~1.62 mg colloidal silica;~~
~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

~~8. A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

~~9. A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86

Conditional Amendment 7

1. A swallowable film coated tablet for use in a method of treating iron overload ~~for oral administration~~ wherein the tablet comprises deferasirox ~~or a pharmaceutically acceptable salt thereof~~ present in an amount of from 45% to 60% by weight based on the total weight of the tablet, and wherein the tablet contains 90 mg, 180 mg or 360 mg of deferasirox, ~~or a pharmaceutically acceptable salt thereof~~ wherein deferasirox is present in free acid form,

   wherein the tablet further comprises,

   i. at least one filler in a total amount of 10% to 40 % by weight based on total weight of the tablet, wherein the filler is microcrystalline cellulose;

   ii. at least one disintegrant in a total amount of 1% to 10% by weight based on the total weight of the tablet, wherein the disintegrant is cross-linked polyvinylpyrrolidone (crospovidone);

   iii. at least one binder in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the binder is polyvinylpyrrolidone (PVP);

   iv. ~~optionally,~~ at least one surfactant in a total amount of ~~0.0%~~ up to 2% by weight based on the total weight of the tablet, wherein the surfactant is poloxamer 188;

   v. at least one glidant in a total amount of 0.1% to 1% by weight based on the total weight of the tablet, wherein the glidant is colloidal silicon dioxide;

   vi. at least one lubricant in a total amount of less than 0.1% to 2% by weight based on the total weight of the tablet, wherein the lubricant is magnesium stearate; and

   vii. a non-functional coating~~.~~

   and wherein the tablet does not contain sodium lauryl sulfate and does not contain lactose, and wherein the method comprises swallowing said tablet.

2. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 90 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

3. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 180 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

4. The swallowable film coated tablet for use ~~for oral administration~~ according to claim 1, wherein the tablet contains 360 mg of deferasirox ~~or a pharmaceutically acceptable salt thereof~~.

~~5. The film coated tablet for oral administration according to any of the preceding claims, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test.~~

~~6. A film coated tablet for oral administration according to claim 1 consisting of 90 mg deferasirox;~~
~~53.61 mg microcrystalline cellulose;~~
~~3.65 mg polyvinylpyrrolidone;~~
~~11.34 mg crospovidone;~~
~~0.16 mg poloxamer 188;~~
~~0.81 mg colloidal silica;~~
~~2.43 mg magnesium stearate; and~~
~~4.86 mg coating.~~

~~7. A film coated tablet for oral administration according to claim 1 consisting of 180 mg deferasirox;~~
~~107.23 mg microcrystalline cellulose;~~
~~7.29 mg polyvinylpyrrolidone;~~

~~22.68 mg crospovidone;~~
~~0.32 mg poloxamer 188;~~
~~1.62 mg colloidal silica;~~
~~4.86 mg magnesium stearate; and~~
~~9.72 mg coating.~~

~~8. A film coated tablet for oral administration according to claim 1 consisting of 360 mg deferasirox;~~
~~215.45 mg microcrystalline cellulose;~~
~~14.58 mg polyvinylpyrrolidone;~~
~~45.36 mg crospovidone;~~
~~0.65 mg poloxamer 188;~~
~~3.24 mg colloidal silica;~~
~~9.72 mg magnesium stearate; and~~
~~19.44 mg coating~~

~~9. A film coated tablet for oral administration according to claim 1 comprising:~~

Component	% (w/w) (range)	mg/648mg tab	mg/324mg tab	mg/162mg tab
Deferasirox	55.56	360.00	180.00	90.00
Microcrystalline cellulose PH101	15.09	97.81	48.91	24.45
Microcrystalline cellulose PH102	18.00	116.64	58.32	29.16
Poly Vinyl Pyrrolidone K-30	2.25	14.58	7.29	3.65
Crospovidone	7.00	45.36	22.68	11.34
Pluronic F68	0.10	0.65	0.32	0.16
Aerosil	0.50	3.24	1.62	0.81
Magnesium Stearate	1.50	9.72	4.86	2.43
Total	100.00	648.00	324.00	162.00
Coating				
Opadry	3.00	19.44	9.72	4.86
Final tablet weight	103.00	667.44	333.72	166.86