

A-Table 4: Summary of bioequivalence and bioavailability studies: salmeterol pharmacokinetic results

Study	Treatments	Geometric mean (min-max)			Median (min-max)		
		C _{max} [pg/mL]	AUC _{0-last} [h pg/mL]	AUC _{0-inf} [h pg/mL]	t _{1/2} (h)	t _{max} (h)	
-01	PulmoJet SAL/FP low	T1	538 (337-775)	335 (196-521)	499 (277-815)	3.13 (1.780-5.690)	0.10 (0.10-0.12)
		T2	546 (195-906)	345 (119-560)	524 (179-874)	3.12 (2.260-6.930)	0.10 (0.10-0.15)
	Seretide Diskus mite	R1	334 (200-540)	271 (168-454)	414 (248-768)	2.97 1.590-5.440	0.10 (0.10-0.15)
		R2	320 (155-518)	272 (164-410)	410 (262-784)	2.68 (1.930-8.470)	0.10 (0.10-0.12)
-09	PulmoJet SAL/FP high	T	444 (137-849)	719 (291-1494)	842 (345-1717)	6.38 (4.53-10.4)	0.08 (0.07-0.13)
		TC	413 (192-887)	486 (221-853)	581 (260-1881)	6.63 (4.47-10.8)	0.08 (0.07-0.13)
	Seretide Diskus forte	R	495 (198-1041)	828 (387-2238)	958 (461-2849)	6.15 (4.73-9.16)	0.08 (0.07-0.28)
		RC	428 (168-990)	534 (314-994)	626 (355-1261)	6.65 (5.05-9.28)	0.08 (0.07-0.13)

AUC_{0-last} = Area under the concentration time curve from zero to the last time point, AUC_{0-∞} = Area under the plasma concentration-time data pairs extrapolated to infinity, C = charcoal, R = reference, C_{max} = maximum observed serum concentration, max = maximum, min = minimum, R1/R2 = reference treatment in period 1 or 2, SD = standard deviation, T = test treatment, t_{1/2} = terminal disposition half-life, T1/T2 = test treatment in period 1 or 2, t_{max} = Time to maximum observed serum concentration.

Data source: Module 5.3.1.2, CSR [redacted] 01, TT16 and TT17; Module 5.3.1.2, CSR [redacted] 09, Table 14.2.2.2.