

**A-Table 5: Summary of bioequivalence and bioavailability studies: fluticasone propionate pharmacokinetic results**

Study	Treatments	Geometric mean (min-max)			Median (min-max)	
		C <sub>max</sub> [pg/mL]	AUC <sub>0-tlast</sub> [h pg/mL]	AUC <sub>0-inf</sub> [h pg/mL]	t <sub>1/2</sub> (h)	t <sub>max</sub> (h)
-01	PulmoJet low T1	185 (87-363)	790 (387-1076)	947 (454-1524)	10.7 (5.030-29.34)	0.27 (0.10-1.00)
		186 (68-339)	812 (391-1158)	964 (435-1494)	9.69 (5.350-23.07)	0.34 (0.10-1.00)
	Seretide Diskus mite R1	111 (63-188)	569 (398-851)	639 (430-989)	7.63 (4.840-20.76)	0.33 (0.10-1.00)
		109 (47-185)	557 (335-848)	632 (364-1006)	9.06 (4.110-17.12)	0.50 (0.10-2.00)
-09	PulmoJet SAL/FP high T	362 (207-718)	3340 (1962-5438)	3701 (2147-5974)	14.6 (10.5-26.2)	0.53 (0.20-2.07)
		351 (128-654)	3318 (2080-5161)	3618 (2173-5720)	13.5 (8.15-22.2)	1.03 (0.20-4.05)
	Seretide Diskus forte R	336 (148-678)	3653 (1276-6943)	3884 (1334-7268)	10.9 (7.32-17.8)	1.03 (0.20-6.03)
		339 (147-714)	3581 (1535-7193)	3727 (1589-7468)	9.38 (7.22-17.4)	2.03 (0.37-4.05)

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

Data source: Module 5.3.1.2, CSR [REDACTED]-01, TT18, and TT19; Module 5.3.1.2, CSR [REDACTED]09, Tables 14.2.1.2.