

Table 4. Comparison of all charge variant fractions to evaluate their kinetics of binding to rat FcRn, binding responses (in response unit) and their in vitro binding specific activity

Test material	Kinetic analysis and binding affinity to rat FcRn at pH 6.0 (n = 4) ^a				Response unit (RU) (n = 8)		% Specific activity (%CV) ^c
	k_{a1} ($10^4 \text{ M}^{-1} \text{ s}^{-1}$)	k_{d1} (10^{-2} s^{-1})	K_{D1} (10^{-7} M)	Chi ² (RU ²)	25 nM	250 nM	
Acidic Peak	6.84 ± 1.28	4.57 ± 0.51	6.96 ± 2.09	0.259 ± 0.063	10.0 ± 1.3	32.3 ± 3.4	83 (10)
Main Peak	8.76 ± 0.83	4.67 ± 0.28	5.38 ± 0.76	0.214 ± 0.045	11.9 ± 1.3	35.7 ± 3.7	98 (17)
Basic Peak	8.18 ± 0.97	4.34 ± 0.39	5.40 ± 1.07	0.284 ± 0.037	11.9 ± 1.3	36.5 ± 4.0	95 (10)
Starting Material ^b	7.99 ± 0.87	4.48 ± 0.22	5.67 ± 0.82	0.213 ± 0.042	11.9 ± 1.4	35.7 ± 4.0	100 (11)

^a k_{a1} , first association rate constant; k_{d1} , first dissociation rate constant; K_{D1} , first dissociation equilibrium constant; Chi², a measure of the average squared residual (the difference between the experimental data and the fitted curve). All statistical analyses were performed using multiple regressions. The data shown are mean ± standard deviation. ^bBinding of mAb starting material to rat FcRn is shown for reference only. ^cIn vitro binding potency analysis by inhibiting cell proliferation of all mAb fractions compared with reference material; CV, coefficient of variation of n = 3.