

Table 2. Analytical results to assess all mAb charge variant fractions

Test material ^a	Isoelectric pH (pI) (n = 4) ^b	Protein concentration (mg/mL)	Osmolality (mOsm/kg)	Endotoxin (EU/mg protein)	Ion Exchange Chromatography (IEC)			Size Exclusion Chromatography (SEC)		
					% acidic	% main	% basic	% aggregate	% monomer	% fragment
Acidic Peak	8.7–8.9 ^c	29.8	161	0.09	95.0	5	ND ^d	0.3	98.9	0.9
Main Peak	9.0 ^c	30.7	162	0.01	4.4	93.5	2.2	0.1	99.9	ND ^d
Basic Peak	9.1 ^c	30.4	162	0.16	ND ^d	5.6	94.2	10.0	90.0	ND ^d
Starting Material	8.7–9.1 ^c	29.9	171	<0.01	19.8	68.7	11.6	0.2	99.7	0.2

^aAcceptance criteria for test material: Concentration (30 ± 3 mg/mL); Osmolality (112–208 mOsm/kg); Endotoxin limits (<5 EU/kg which translates to <0.5 EU/mg of mAb based on the 10 mg/kg dose in rats). ^bn, number of samples per test material. ^cR², Coefficient of determination = 0.997. ^dND, Not Detected.