

2.3.S.5 Reference Standards or Materials

Reference standard (RS) is derived from DS lot 141230DS. The qualification test of reference standard is presented in [Table 2.9](#).

Table 2.9 Qualification test of reference standard

| Category | Test item | Specification | Results |
|-------------------|---|---|---|
| Identity | Isoelectric point (pI) | Nine peaks in total in the pI range of 7.75-9.55; five main peaks are in the pI range of 8.50-9.25. | Nine peaks in total in the pI range of 7.98-9.45; five main peaks are in the pI range of 8.66-9.21. |
| | Peptide mapping | Amino acid sequence matches the theoretical sequences 100%. | Conforms to the specification |
| | Western blot | React to anti-human Fc | React to anti-human Fc |
| Appearance | Visual inspection | Clear and colorless to orange red liquid, with the faint opalescence. | Clear and colorless liquid, with the faint opalescence. |
| Purity | SE-HPLC (%) | Monomer ≥ 95.0 | 99.7 |
| | | Aggregate < 3.0 | 0.3 |
| | | Fragment: report results | 0.0 |
| | WCX-HPLC (%) | Sum of Acid peak 1 < 20.0 , Report results for sum of acidic peak 2, sum of K0, K1 and K2, and sum of other basic peaks | Sum of acidic peak 1: 3.5 Sum of acidic peak 2: 57.1 Sum of K0, K1 and K2: 35.5 Sum of other basic peak: 3.9 |
| | CE-SDS (%) | Under reducing conditions, main peak $\geq 95.0\%$; fragment: report results | 98.1 1.9 |
| Impurities | Host cell protein (HCP) | < 100 ppm | 13 |
| | Host cell DNA | < 0.33 pg/mg | 0.28 |
| Safety | Bacterial endotoxin | < 0.2 EU/mg | < 0.016 |
| | Bioburden | < 10 cfu/ml | < 1 |
| Potency | Relative binding activity ¹ | Report the result of EC50 (ng/mL) | 41 |
| | Relative blocking activity ² | Report the result of IC50 (ng/mL) | 474 |
| Content | Protein content | 13.5 ~ 16.5mg/ml | 15.2 |