

3.2.A.4.5 CoA of DS lot 150107DS



ALPHAMAB

Certificate of Analysis
Test Report

Test Report No.CoA-PRT-KN035-0018

| Sample name: KN035DS Lot Number: 150107DS Test Completion Date: 2015.12.22 Report Date: 2016.06.21 | | | |
|--|------------------------------|--|--|
| Category | Items | Acceptance Criteria | Results |
| Identity | Isoelectric point (pI) | Nine peaks in total in the pI range of 7.75-9.55; and five main peaks are in the pI range of 8.50-9.25. Conform to the reference standard. | Nine peaks in total in the pI range of 7.98-9.44; and five main peaks are in the pI range of 8.65-9.20. Conform to the reference standard. |
| | Peptide mapping | Conform to the reference standard. RSD of retention time of the characteristic peaks should not be higher than 3.00% | Conform to the reference standard. RSD of retention time of the characteristic peaks should not be higher than 0.28% |
| | Western blot | React to Fc specific antibodies | React to Fc specific antibodies |
| | Relative binding activity | Conform to reference standard | Conform to reference standard |
| Appearance | Visual inspection | Clear and colorless to orange red liquid, with the faint opalescence. | Clear and colorless, with the faint opalescence |
| Purity | SE-HPLC | Monomer $\geq 95.0\%$ | 99.6% |
| | | Aggregate $< 3.0\%$ | 0.1% |
| | | Fragment: report results | 0.3% |
| | WCX-HPLC | Sum of acid peak 1 $< 20.0\%$ | 3.2% |
| | | Sum of acidic peak 2: report results | 57.3% |
| | | Sum of K0, K1 and K2: report results | 35.6% |
| | | Sum of other basic peaks: report results | 4.0% |
| | CE-SDS (reducing conditions) | Main peak purity $\geq 95.0\%$ | 98.4% |
| | | Fragment: report results | 1.6% |
| Impurities | Host cell protein (HCP) | $< 100\text{ppm}$ | 14 ppm |
| | Host cell DNA | $< 0.33\text{pg/mg}$ | $< 0.13\text{ pg/mg}$ |
| Safety | Bacterial endotoxin | $< 0.2\text{EU/mg}$ | $< 0.016\text{EU/mg}$ |
| | Bioburden | $< 10\text{cfu/ml}$ | $< 1\text{ cfu/ml}$ |
| Potency | Relative blocking activity | 70-130% of the reference standard | 94% |
| | Relative binding activity | 70-130% of the reference standard | 105% |
| Content | Protein content | 13.5 ~ 16.5mg/ml | 14.9mg/ml |
| Conclusion: This DS is tested according to KN035DS specifications (SPC-PRT-KN035-004(01)), and the results meet the specifications. | | | |

QA /Date(only for released material/product by QA)

[Signature]
2016.06.22

苏州康宁杰瑞生物科技有限公司 Alphamab Co., Ltd. 1 / 1

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