

3.2.A.4.6 CoA of DS lot 151202DS



ALPHAMAB

Certificate of Analysis
Test Report

Test Report No.CoA-PRT-KN035-0019

Sample name: KN035DS Lot Number: 151202DS Test Completion Date: 2016.02.02 Report Date: 2016.06.24			
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 7.95-9.47; and five main peaks are in the pI range of 8.66-9.24. 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 0.04%
	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	Colorless to orange red clear liquid, with the faint opalescence	Orange red clear liquid, with the faint opalescence
Purity	SE-HPLC	Monomer $\geq 95.0\%$	99.1%
		Aggregate $< 3.0\%$	0.9%
		Fragment: report results	0.0%
	WCX-HPLC	Sum of acid peak 1 $< 20.0\%$	3.0%
		Sum of acidic peak 2: report results	58.4%
		Sum of K0, K1 and K2: report results	35.6%
		Sum of other basic peaks: report results	3.1%
	CE-SDS (reducing conditions)	Main peak purity $\geq 95.0\%$	98.1%
		Fragment: report results	1.9%
Impurities	Host cell protein (HCP)	$< 100\text{ppm}$	20 ppm
	Host cell DNA	$< 0.33\text{pg/mg}$	$< 0.13\text{ pg/mg}$
Safety	Bacterial endotoxin	$< 0.2\text{EU/mg}$	$< 0.03\text{EU/mg}$
	Bioburden	$< 10\text{cfu/ml}$	$< 1\text{ cfu/ml}$
Potency	Relative blocking activity	70-130% of the reference standard	103%
	Relative binding activity	70-130% of the reference standard	115%
Content	Protein content	13.5 ~ 16.5mg/ml	15.2mg/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)

2016.06.24

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