

3.2.A.4.4 CoA of DS lot 141230DS



Certificate of Analysis
Test Report

Test Report No.CoA-PRT-KN035-0017

Sample name: KN035DS Lot Number: 141230DS Test Completion Date: 2015.12.22 Report Date: 2016.06.12			
Category	Items	Specification	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 7.98-9.45; and five main peaks are in the pI range of 8.66-9.21. 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 0.06%
	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 $\geq 95.0\%$	99.9%
		Aggregate $< 3.0\%$	0.1%
		Fragment: report results	0.0%
	WCX-HPLC	Sum of acid peak 1 $< 20.0\%$	3.5%
		Sum of acidic peak 2: report results	57.1%
		Sum of K0, K1 and K2: report results	35.5%
	CE-SDS (reducing conditions)	Sum of other basic peaks: report results	3.9%
		Main peak purity $\geq 95.0\%$; Fragment: report results	98.1% 1.9%
Impurities	Host cell protein (HCP)	$< 100\text{ppm}$	13 ppm
	Host cell DNA	$< 0.33\text{pg/mg}$	0.28 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	91%
	Relative binding activity	70-130% of the reference standard	106%
Content	Protein content	13.5~ 16.5mg/ml	15.1mg/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] 2016.06.13

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