

3.2.A.4.8 CoA of DP lot 20150502



Certificate of Analysis Test Report

Test Report No.CoA-PRT-KN035-0021

Sample name: KN035DP Lot Number: 20150502 Test Completion Date: 2016.02.03 Report Date: 2016.06.12			
Category	Test Item	Acceptance Criteria	Results
Identity	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 7.97-9.43; and five main peaks are in the pI range of 8.66-9.20. Conform to the reference standard.
	Relative binding activity	Conform to the reference standard	Conform to the reference standard
General	Appearance	Clear and colorless to orange red liquid, with the faint opalescence.	Orange red clear liquid, with the faint opalescence
	pH	6.0~7.0	6.5
	Filling volume	No less than 1.5ml	No less than the label volume. The average volume is 1.704ml
	Subvisible particles	≥10 μm: no more than 6000; ≥25μm: no more than 600	≥10 μm: no more than 131; ≥25μm: no more than 0.
	Visible particles	Practically free from visible particles	Free from visible particles
	Osmolality	300~450 mOsmol/kg	341 mOsmol/kg
Purity	SE-HPLC	Monomer ≥95.0%	99.8%
		Aggregate <3.0%	0.1%
		Fragment : report results	0.02%
	WCX-HPLC	Sum of acidic peak 1 <20.0%	3.1%
		Sum of acidic peak 2: report results	58.0%
		Sum of K0, K1 and K2: report results	35.2%
		Sum of other basic peaks: report results	3.7%
Safety	Bacterial endotoxin	<0.5 EU/mg	< 0.05EU/mg
	Sterility test	Sterile	Sterile
Potency	Relative blocking activity	70-130 %of RS	86%
	Relative binding activity	70-130% of RS	96%
Content	Protein content	180.0~220.0 mg/ml	196.3 mg/ml
Conclusion: This DP is tested according to KN035DP specifications(SPC-PRT-KN035-005(01)), and the results meet the specifications.			

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

2016.06.13

苏州康宁杰瑞生物科技有限公司 AlphamabCo.,Ltd.1 / 1

[KN035, Alphamab Co., Ltd]