

## CERTIFICATE OF ANALYSIS

### Aprotinin

<b>Batch No.:</b> DR20160817	<b>Quantity:</b> 1739.8g
<b>Manufacture Date:</b> 2016.08.17	<b>Retest Date:</b> 2018.08.16
<b>Total activity:</b> 10786.76M KIU	

**TESTS:**

Items	Specification	Results
Appearance	Almost white powder, hygroscopic	Conforms
Solubility	Soluble in water and 0.9% NaCl solution practically insoluble in organic solvents(5mg/ml)	Conforms
Clarity of solution	≅ Ref.III(15Ph.Eur.U./ml)	Conforms
Absorbance	A ≅ 0.80(absorption- <:277nm±2nm; 3.0 Ph.Eur.U./ml)	0.708
Identification A	positive	Conforms
Identification B	positive	Conforms
Aprotinin oligomers	≤1.0%	0.0%
Pyroglutamyl-aprotinin and related compounds	Pyroglutamyl-aprotinin ≤1.0% Any other impurity ≤0.5% Sum of impurity other than pyroglutamyl-aprotinin ≤1%	Pyroglutamyl-aprotinin:0.0% Any other impurity:0.177% Sum of impurity:0.260%
Des-Ala-Aprotinin And des-Ala-des-Gly-aprotinin	Des-Ala-Aprotinin ≤7.5% Des-Ala-des-Gly-aprotinin ≤8.0%	Des-Ala-Aprotinin:6.17% Des-Ala-des-Gly-aprotinin:5.59%
Loss on drying	≅ 6.0%(0.100g, drying in vacuo)	4.90%
Activity	≅ 3.0 Ph.Eur.U./ml	3.44EPU/mg(6200KIU/mg)
pH	5.5~ 7.0	6.2
Endotoxin	≅ 0.14 EE/Ph.Eur.U.	Conforms
pyrogens	Absent at 15 Ph.Eur.U./kg/rabbit	Conforms
Microbial limit	TAMC: ≅ 10 <sup>2</sup> CFU/g API TYMC: ≅ 10 <sup>2</sup> CFU/g API	Conforms
	Escherobacteriaceae, pseudomonas aeruginose and staphylococcus aureus should be absent.	Conforms
Abnormal toxicity	Non toxic at 2 Ph.Eur.U./ml	Conforms
histamine	0.1µg histamine base/3 Ph.Eur.U.	Conforms

**Conclusion: The results conform with the EP 8 standard.**



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