

Career Henan Chemical Co

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CERTIFICATE OF ANALYSIS

Product Name	Glatiramer Acetate		CAS:147245-92-9
Batch No.	20190320	Batch Size	500g
Manu Date	20190320	Expiry Date	2021.03.19
Items	Specification of Standard		Result of Analysis
Appearance	White or off white powder		White powder
Solubility	Soluble in water		Conforms
Specific optical rotation	-66° to -76.0° (c =0.5%glacial acetic acid)		-69.7°
Water	NMT 10.0%		8.3%
PH	5.0-7.0		5.6
Amino acid analysis	Tyr 0.056-0.100		0.065
	Ala 0.39-0.46		0.42
	Glu 0.13-0.17		0.15
	Lys 0.30-0.37		0.32
	No more than the traces of the amino acids are present		conforms
Relate Substance	Unspecified impurity for each impurity:NMT 1.0% Total impurity :NMT 2.0%		3.18(Single largest impurity) 1.83%
Acetic acid	15%		7.6%
Assay	95.0~105.0		99.3%
Conclusion	The product complies with specification.		



Analyst: 连俊昊

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