



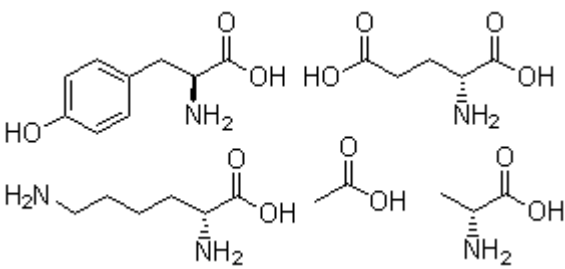
HANGZHOU DINGYAN CHEM CO.,LTD

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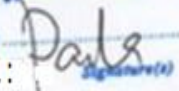
CERTIFICATE OF ANALYSIS

NO: DYC0818108142

Product name	glatiramer acetate
CAS Number	147245-92-9
Molecule Structure	
Molecule Formula	C ₂₅ H ₄₅ N ₅ O ₁₃
Batch number	20180711
Manufacture date	2018-07-11
Testing date	2018-07-11

Items	Standard	Result
Appearance	white or off-white powder	white powder
Solubility	Very soluble in water	complies
Specific optical rotation	-66.0° 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 other amino acids are present.	Conforms
Related substances	Unspecified impurity for each impurity:NMT 1.0% Total impurity:NMT 2.0%	0.18%(single largest impurity) 1.83%
Assay	95.0% to 105.0%	99.3%
Acetic acid	15.0%	7.6%

Hangzhou Dingyan Chem Co., Ltd.

QUALITY CONTROL: 

CHECK: 姚仙娟

INSPECTOR: 刘清风