

**杭州东瑞医药科技有限公司**  
**HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.**

**CERTIFICATE OF ANALYSIS**

**Glatiramer Acetate**

<b>Batch No.:</b> DR20140808	<b>Piece:</b> 1070.4g
<b>Manufacture Date:</b> 2014.08.08	<b>Expiry Date:</b> 2016.08.07

**TESTS:**

<b>Items</b>	<b>Specification</b>	<b>Results</b>
Appearance	White to slightly yellowish solid material	Conforms
Solubility	Freely soluble in water and glacial acetic acid;insoluble in acetonitrile, methanol, and N,N-dimethylformamide	Conforms
Specific optical rotation	$\alpha = -75^{\circ} \sim -92^{\circ}$ (calculated with reference to the anhydrous, acetic acid-free substance)	$-76^{\circ}$
IR	The IR absorption spectrum of the sample exhibits the following characteristic vibration modes:1640-1660,1530-1570,1380-1420 and 1240-1300 $\text{cm}^{-1}$ .	Conforms
UV	The Light absorption spectrum of the sample in the range of 190nm to 400nm exhibits, $\lambda_1$ about 275nm, $\lambda_2$ should about 220-230nm, $\lambda_3$ between 195-210nm(the allowable error of $\lambda_1$ and $\lambda_3$ should not exceed $\pm 2\text{nm}$ ).	Conforms
Amino acid analysis	Glu:0.129~0.153 Ala:0.392~0.462 Tyr:0.086~0.100 Lys:0.300~0.374	0.147 0.452 0.089 0.312
Molecular weight of peak max(Mp)	5000~9000Da	7822Da
MW	7700~9200Da	8005Da
MN	5300~6200Da	5671Da
Molecular weight distribution	+ISD:3300~3800Da -ISD:12300~14900Da	3567Da 12859Da
PH	5.5~7.0	5.5
Water content	$\leq 10.0\%$	4.1%

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Acetic acid content	8.0%~12.0%	9.3%
Bromo-tyrosine	≤0.1%	N.D.
Residual solvent	Piperidine:≤1000ppm 1,4-Dioxane:≤380ppm Tetrahydrofuran:≤720ppm Dichloromethane:≤600ppm	287.7ppm N.D. N.D. N.D.
Bacterial endotoxins	<6.0EU/mg	Conforms
Microbial limit	Bacteria:≤200cfu/g Moulds and yeasts:≤50cfu/g	Conforms
Assay	95%~105.0% calculated with reference to the anhydrous substance.	98.7%

Conclusion: The results conform with the standard.



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