

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

CERTIFICATE OF ANALYSIS

Buserelin Acetate (CAS:68630-75-1)

Batch No.: DR20140401	Quantity: 100g
Molecular Formula: C ₆₀ H ₈₆ N ₁₆ O ₁₃	Molecular Weight: 1239
Manufacture Date: 2014.04.01	Expiry Date: 2016.03

TESTS:

Items	Specification	Results
Appearance	White or slightly yellowish powder	White powder
Appearance of Solution	Clear, colorless to slightly colored solution in water(10mg/ml)	Conforms
Identification by HPLC	The retention is same with the reference substance	Conforms
Specific Optical Rotation	-49.0~-58.0°[α] _D ²⁰ (c=1, water)	-53.5°
Absorbance(By anhydrous,acetic acid-free)	49~56(278nm)	51
Amino Acid Composition	Arg: 0.9~1.1 Leu: 0.9~1.1 Tyr: 0.9~1.1 Glu: 0.9~1.1 Pro: 0.8~1.2 His: 0.9~1.1 Ser:1.4~2.0 Trp: Detected	0.95 0.93 1.02 1.01 1.12 1.03 1.85 Detected
Related Substance(By HPLC)	Total Impurities(%)≤5.0% Largest Single Impurity(%)≤1.0%	1.5% 0.5%
Acetate Content(By HPLC)	3~7%	5.8%
Water Content(Karl Fischer)	≤4.0%	2.0%
Bacterial Endotoxins	≤55.5 IU/mg	Conforms
Assay(By anhydrous, Acetic acid-free)	95% ~102%	98.5%
Storage	Preserve in tight,light resistant containers.Store in freezer(-20±5℃) [Short storage in 2-8℃]	

Conclusion: The results conform with Enterprise standard.

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