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

CERTIFICATE OF ANALYSIS

Esmolol hydrochloride

Batch No.: DR20140217	**Piece:** 10kg
Manufacture Date: 2014.02.17	**Expiry Date:** 2017.02.16

TESTS:

Items	Specification	Results
Appearance	White to off-white crystalline powder No visible evidence of contamination by foreign matter	Conforms
Identification A	Infrared absorption spectrum corresponds to that of the reference standard	Conforms
Identification B	The retention time of the sample preparation in the assay preparation corresponds to that of the standard preparation	Conforms
Melting point	87.5℃~91.0℃	89.8℃
PH	3.0~5.0	4.3
Residue on ignition	≤0.1%	0.08%
Heavy metals	≤0.0020%	<0.002%
Sulfate	≤0.030%	<0.030%
Wate content	≤1.0%	0.12%

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Related substance	Any other individual unspecified impurity ≤0.1% Esmolol isopropylamide analog ≤0.25% Esmolol free acid ≤0.4% Esmolol dimer ≤0.5% N-ethyl esmolol ≤0.15% Total impurities ≤1.0%	0.06% 0.05% 0.04% 0.12% 0.01% 0.3%
Assay	98.0~10.2% calculated on the anhydrous basis	99.8%
Residual solvents	Ethyl acetate ≤ 2500ppm Ethyl ether ≤ 200ppm	322ppm <14ppm
Bacteria endotoxin	≤0.2EU/mg	<0.2EU/mg
Bioburden	Total microbial：≤ 100cfu/mg Total yeast&molds：≤50cfu/mg	<10cfu/mg <10cfu/gm
Conclusion: The results conform with USP35.		

Analyst: Joe Yu **Checker:** Agnes Zhong **QA.Manager:** Sun Wenhu

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