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

CERTIFICATE OF ANALYSIS

Naltrexone hydrochloride

Batch No.: DR20140116	**Piece:**10kg
Manufacture Date: 2014.01.16	**Expiry Date:** 2019.01.15

TESTS:

Items	Specification	Results
Appearance	White or almost white powder，very hygroscopic	Conforms
Solubility	Freely souble in water，slightly soluble in ethanol 96%， practically insoluble in methylene chloride	Conforms
Identification	1）IR:meet the requirements 2）It gives reaction（a）of chloride	Conforms
Residue on ignition	≤0.1%	0.05%
Specific optical rotation	-187°～-195°	-192°
Water	≤10%	6.6%
Relate substance（HPLC)	ImpurityA：≤0.1% ImpurityB：≤0.1% ImpurityC：≤0.2% ImpurityD：≤0.2% ImpurityE：≤0.2% ImpurityF：≤0.2% ImpurityG：≤0.2% ImpurityH：≤0.1% ImpurityI：≤0.1% ImpurityJ：≤0.1% Each other impurity：≤0.1% Total impurities：≤1.0%	<0.05% <0.05% <0.05% <0.05% <0.05% <0.05% <0.05% <0.05% <0.05% <0.05% Conforms Conforms
Assay (HPLC)	98.0~102.0% (On drid basis）	99.1%
Residual solvents	Toluene content：≤890ppm	<20ppm
Conclusion: The results conform to EP7.0		

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

质检专用章 QUALITY STAMP

Add:1018 Guangyin Building No.42 E. Fengqi Road,Hangzhou,310012 China
Tel:+86-571- 85335020 **Fax: +86-571- 86948329**
E-mail: agnes@dawnraypharma.com **Website: http://www.dawnraypharma.com/**