

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

CERTIFICATE OF ANALYSIS

Tolperisone HCL

Batch No.: DR20150517	Quantity : 200kg
Manufacture Date: 2015.05.17	Expiry Date: 2017.05.16

TESTS:

Items	Specification	Results
Appearance	A white crystalline powder	White crystalline powder
Identification	1) Positive assay for methylene assays combined with carbonyl 2) Positive assay for the tertiary amines test 3) Positive assay for chloride tests	Conforms
Melting point	167-174°C	169-170°C
PH	4.5-5.5	5.3
Absorbance	555-585	561
Loss on drying	≤0.5%	0.2%
Residue on ignition	≤0.1%	0.04%
Clarity and color of solution	The solution is clear and colorless	Conforms
Sulfate	≤50ppm	<0.005%
Heavy metals	≤20ppm	<20ppm
Piperidine hcl	≤0.1%	<0.1%
Volatile organic impurities,residual solvents(GC)	Toluene:≤890ppm Ethyl acetate:≤5000ppm Ethanol:≤5000ppm	<9ppm <10ppm 50ppm
Assay(Titration)	≥98.5%	100.0%
Storage	Stored at well-closed containers.	
Remarks	We hereby certify that the above information is authentic and accurate.The batch processing ,packing and analysis records were reviewed and found to be in compliance with GMP.	

Conclusion: The results conform with JP16 standard.

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

Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China

Tel:+86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 86948329

Website: http://www.dawnraypharma.com/

