

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

CERTIFICATE OF ANALYSIS

Ketotifen Fumarate

Batch No.: DR20110613	Quantity: 50kg
Manufacture Date: 2011.06.13	Expiry Date: 2014.06.13

TESTS:

Items	Specification	Results
Appearance	White to brownish-yellow powder,fine,crystalline powder	Conforms
Solubility	Sparingly soluble in water,slightly soluble in Methanol,very slightly soluble in acetonitrile	
Identification	IR,TLC conform	Conforms
Clarity and colour of solution	Clear and not more than Y4BY4B4	<BY4
Loss on drying	≤0.50%	0.21%
Sulphated ash	≤0.1%	0.02%
Related substance (HPLC)		
Impurity A	≤0.2%	0.05%
Impurity G	≤0.2%	N.D.
Single unknown impurity	≤0.1%	N.D.
Total impurities	≤0.5%	0.05%
Residual solvents	Acetone ≤5000ppm Methanol ≤5000ppm	1750ppm <1ppm
Assay(on dried basis)	98.5%~101.0%	99.6%
Conclusion: The results conform with BP2009.		



Analyst: _____

Checker: _____

QA.Manager: _____

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

Tel: +86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 85335020

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