

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

CERTIFICATE OF ANALYSIS

Rebamipide

Batch No.: DR20140605	Quantity: 120kg
Manufacture Date: 2014.06.05	Expiry Date: 2016.06.04

TESTS:

Items	Specification	Results
Appearance	White crystalline powder	White crystalline powder
Rotation	1 : 20DMF shows no rotation	Shows no rotation
Identification	Should conform	Conforms
Melting point	About 291 °C	290.5 °C
M-chloro isomer	≤0.15%	N,D
O-chloro isomer	≤0.15%	N,D
Debenzoyl rebamipide	≤0.15%	N,D
Other than rebamipide	≤0.1%	0.03%
Total related substance	≤0.4%	0.10%
Chloride	≤0.028%	Conforms
Heavy metals	≤10ppm	Conforms
Loss on drying	≤3.0%	0.6%
Residue on ignition	≤0.1%	<0.1%
Residues	Methanol ≤0.3%	N,D
	Ethanol ≤0.5%	N,D
	Chloroform ≤0.006%	N,D
Assay (on dried basis)	99.0%~101.0%	99.7%

Conclusion: The results conform with the JP16 standard

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