

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

CERTIFICATE OF ANALYSIS

Carbamazepine

Batch No.: DR20140720	Quantity : 1000KG
Manufacture Date: 2014.07.20	Expiry Date: 2018.07.19

TESTS:

Items		Specification	Results
Characteristics		White or almost white, crystalline powder	White crystalline powder
Solubility		Conform	Conform
Identification	m. p.	189~193°C	190.2---190.7°C
	IR	Conform	Conform
Acidity		Conform	Conform
Alkalinity		Conform	Conform
Related substances (HPLC)	Any other impurity	≤0.2%	Conform
	Total impurity	≤0.5%	0.32%
Chlorides		≤140ppm	Conform
Heavy metals		≤10ppm	Conform
Loss on drying		≤0.5%	0.28%
Sulfated ash		≤0.1%	0.05%
Assay(on the dried basis) /(HPLC)		98.0~102.0%	99.78%

Conclusion: The results conform with USP36.

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