

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

CERTIFICATE OF ANALYSIS

Cefaclor (Synthetic)

Batch No.: DR20140426	Quantity: 265.72kg
Manufacture Date: 2014.04.26	Expiry Date: 2016.04.25

TESTS:

Items	Specification	Results
Characteristics	White to almost white crystalline powder	Almost white crystalline powder
Identification	IR: The infrared absorption spectrum of the sample must be concordant with that of cefaclor working standard/reference standard.	Conforms
	HPLC: The retention time of the major peak as obtained in the assay test of the sample solution corresponds to that of the standard solution as obtain as obtained in the assay.	Conforms
Solubility	Slightly soluble in water , practically insoluble in methanol, chloroform, and benzene	Conforms
PH	3.0~4.5	4.0
Water	3.0%~6.5%	4.9%
Residual solvents	Meyhanol \leq 0.3%	0.002%
	Methylene cholride \leq 0.06%	0.00007%
	Acetone \leq 0.5%	0.001%
	DMF \leq 0.088%	N,D
Related substance	Any individual impurity: \leq 0.5%	0.07%
	Total impurities: \leq 2.0%	0.38%
Assay	95.0~102.0%	99.3%
Crystallinity	Should be crystalline	Conforms

Conclusion: The results conform with USP37.

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