

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

CERTIFICATE OF ANALYSIS

Hydrocortisone acetate

Batch No.: DR20130121	Piece: 220kg
Manufacture Date: 2013.01.21	Expiry Date: 2017.01.20

TESTS:

Items	Specification	Results
Appearance	White or almost white crystalline powder	Conforms
Identification	A;B	Conforms
Specific optical rotation	+158~+167°	+166°
Related substance	Prednisolone acetate: ≤0.6% Hydrocortisone: ≤0.4% 21-Dexioizing hydrocortisone: ≤0.3% Cortisone acetate: ≤0.3% Hydrocortisone acetate 11-degreasing: ≤0.3% Hydrocortisone acetate 11-acetylate: ≤0.15% Unspecified impurity: ≤0.1% Total: ≤1.0%	0.05% 0.06% < 0.05% < 0.05% < 0.05% 0.12% < 0.05% 0.23%
Loss on drying	≤0.5%	0.1%
Assay	97.0%~102.0%	99.4%

Conclusion: The results conform with EP7.5

Analyst: _____

Checker: _____

QA.Manager: _____



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