

LOTE: ES091003



天津天药药业股份有限公司
TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

LOTE: 0110110

500gr - 8.4

CERTIFICATE OF ANALYSIS



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Product	Fluocinolone Acetonide	Manufacturing date	2009.10.26
Batch No.	ES 091003	Report date	2009.10.30
Test criteria	EP5.0	Expiry date	2014.10.26
Specifications			Result
Appearance	White or almost white, crystalline powder		White crystalline powder
Identification	A: IR B: LC		Positive
Specific optical rotation	+100° ~ +104°		+102°
Related substances	Total impurities ≤ 2.5% 0.5% < Only one impurity ≤ 1.0% Other single impurity ≤ 0.5%		Total: 0.84% Max: 0.41% Conforms
Loss on drying	≤ 1.0%		0.12%
Assay*	97.0% ~ 103.0%		99.4%
Particle size	Micronized		Conforms
Residual solvent	Acetone ≤ 5000 ppm Ethyl acetate ≤ 5000 ppm Methanol ≤ 3000 ppm		6 ppm 839 ppm ND
Quantity	2 kg		
Conclusion	The above product conforms to EP5.0.		

*Storage conditions: Protected from light

*Calculated on the dried basis

Checked by:

24/3

2010.1.13

Approved by:

2010.1.13