



LAMPIRAN

Lampiran 1. Sertifikat Analisis Triamsinolon Asetonida


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



CERTIFICATE OF ANALYSIS
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Product	Triamcinolone Acetonide	Manufacturing date	2017.04.16	
Batch No.	NET 170404	Report date	2017.04.27	
Test criteria	EP5/ USP38	Expiry date	2022.04.16	
	Specifications (EP5)	Result	Specifications (USP38)	Result
Appearance	White or almost white, crystalline powder	White crystalline powder	White to cream-colored, crystalline powder, having not more than a slight odor	White crystalline powder
Identification	A: IR, B: TLC	Conforms	A: IR, B: UV	Conforms
Specific optical rotation	+100° ~ +107°	+104°	+118° ~ +130°	+126°
Related substances	Any impurity ≤ 0.25% Total impurities ≤ 0.5%	Max: 0.11% Total: 0.24%	—	—
Chromatographic purity	—	—	Any impurity ≤ 0.3% Total impurities ≤ 0.8%	Max: 0.10% Total: 0.24%
Water	≤ 2.0%	0.87%	—	—
Loss on drying	—	—	≤ 1.5%	0.63%
Heavy metals	—	—	≤ 0.0020%	Conforms
Assay*	97.0% ~ 103.0%	99.8%	97.0% ~ 102.0%	100.6%
Residual solvent	Chloroform ≤ 80ppm	ND	Chloroform ≤ 60ppm	ND
	Dimethylformamide ≤ 600ppm	132ppm	Dimethylformamide ≤ 600ppm	132ppm
	Methanol ≤ 3000ppm	27ppm	Methanol ≤ 3000ppm	27ppm
Particle size	Microsized	Conforms	Microsized	Conforms
Batch size	55.61 kg			
Quantity	5 kg			
Conclusion	The above product conforms to EP5 and USP38.			

*Storage conditions: Kept in a well-closed container and protected from light
 *Calculated on the dried basis

Checked by: *Handwritten Signature* Approved by: *Handwritten Signature* 2018.4.27


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