

CERTIFICATE OF ANALYSIS

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Product	Triamcinolone Acetonide		Manufacturing date	2020.03.29
Batch No.	NET200401		Report date	2020.04.09
Test criteria	EP9/ USP42		Expiry date	2025.03.29
	Specifications (EP9)	Result	Specifications (USP42)	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; C: HPLC	Conforms	A: IR; B: UV	Conforms
Specific optical rotation	+110° ~ +117°	+113°	+118° ~ +130°	+122°
Related substances	Impurity B ≤ 0.2% Impurity C ≤ 0.15% Unspecified impurities ≤ 0.10% Total impurities ≤ 0.5%	0.08% 0.06% Conforms Total: 0.14%	-----	-----
Chromatographic purity	-----	-----	Any impurity ≤ 0.3% Total impurities ≤ 0.8%	Max: 0.08% Total: 0.19%
Water	≤ 2.0%	0.2%	-----	-----
Loss on drying	-----	-----	≤ 1.5%	0.1%
Assay*	97.5% ~ 102.0%	99.3%	97.0% ~ 102.0%	99.0%
Residual solvent	Chloroform ≤ 60ppm Dimethylformamide ≤ 880ppm Methanol ≤ 3000ppm	ND 106ppm 59ppm	Chloroform ≤ 60ppm Dimethylformamide ≤ 880ppm Methanol ≤ 3000ppm	ND 106ppm 59ppm
Batch size	55kg			
Quantity	10kg			
Conclusion	The above product conforms to EP9 and USP42.			

*Storage conditions: Preserve in well-closed containers, protected from light.

*Calculated on the dried basis.

Checked by: Li Juan 李娟

Approved by: Jia Yuping 贾玉平

April 17, 2020