

XI'AN HARMONIOUS NATURAL BIO-TECH CO.,LTD

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Certificate of Analysis

Product Name: Triamcinolone Acetonide

Batch Number: HNB210312 Batch Quantity: 80kg

Manufacture Date: Mar.12th,2021 Analysis Date: Mar.13th,2021

Specification:EP 9.0

Storage Store in cool & dry place. Store in well-closed containers. Shelf life 24 Months when properly stored in tight containers.

ITEMS OF ANALYSIS	SPECIFICATIONS	RESULT
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol	Complies
Identification(IR,TLC)	Complies with the standard	Complies
Specific optical rotation	+110° ~+117°	+115°
Water	No more than 2.0%	0.28%
Residual Solvents	Methanol≤3000ppm	188ppm
	Dimethyformamide≤880ppm	n.d
	Acetone≤5000ppm	413ppm
	Dichloromethane≤600ppm	n.d
Particle size	90%≤30um	Complies
Related substances		
Impurity B	No more than 0.2%	0.05%
Impurity C	No more than 0.15%	0.02%
Unspecified impurity	No more than 0.1%	0.06%
Total impurities	No more than 0.5%	0.26%
Assay	97%~103%	98.3%
Conclusion	Comply with the requirements of EP 9.0	

QC MANAGER: 五葉☆

INSPECTOR:杨是道