



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Betamethasone Dipropionate

CAS No.: 5593-20-4

Molecular Formula: C₂₈H₃₇FO₇

Molecular Weight: 504.6

Batch No.: HDC20200822

Batch Quantity: 92.50kg

Manufacturing Date: Aug 22th, 2020

Retest Date: Aug 21st, 2022

Test Items		Specifications	Test Results
Appearance		White or almost white crystalline powder	White crystalline powder
Identification	A: IR (2.2.24)	Meets the requirements	Conforms
Specific Optical Rotation (2.2.7)		+84° ~ +88°	+86°
Particle Size		98% pass through 30μm sieve	Conforms
Related Substances (2.2.29)	Impurity C	Not more than 0.5%	0.18%
	Impurity B	Not more than 0.3%	0.05%
	Impurity H	Not more than 0.3%	<0.05%
	Impurity D	Not more than 0.2%	<0.05%
	Impurity E	Not more than 0.2%	<0.05%
	Impurity G	Not more than 0.2%	<0.05%
	Impurity I	Not more than 0.15%	<0.05%
	Unspecified impurities	Not more than 0.1%	<0.05%
	Total impurities	Not more than 1.0%	0.23%
Loss on Drying (2.2.32)		Not more than 1.0%	0.1%
Assay (2.2.25)		97.0% ~ 102.0% (on the anhydrous basis)	99.1%
Residual Solvents	N-Heptane	Not more than 5000 ppm	77 ppm
	Acetone	Not more than 5000 ppm	27 ppm

Conclusion: The testing results of this batch are complied with the Standard of EP 10.3.

Storage Conditions: Preserved in unopened original containers in a cool dry place before using; kept away from direct sunlight, heat and moisture.