

大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: DEXAMETHASONE CAS No.: 50-02-2

Molecular Formula: C22H29FO5Molecular Weight: 392.47Batch No.: HDC20231126Batch Quantity: 227.00kg

Manufacturing Date: Nov 26th, 2023 Retest Date: Nov 25th, 2025

Test Items Appearance		Specifications White or almost white crystalline powder	Test Results White crystalline powder
В	Meets the requirements	Conforms	
Specific Optical Rotation		$+86^{\circ} \sim +92^{\circ}$ (On the anhydrous basis)	+89°
Related Substances	Impurity G	Not more than 0.3%	< 0.05%
	Impurity B	Not more than 0.15%	< 0.05%
	Impurity F	Not more than 0.15%	< 0.05%
	Impurity J	Not more than 0.15%	< 0.05%
	Impurity K	Not more than 0.15%	0.05%
	Unspecified impurity	Not more than 0.10%	RRT(1.27) 0.07%
	Total impurities	Not more than 0.5%	0.12%
Loss on Drying		Not more than 0.5%	0.1%
Assay		$97.0\% \sim 103.0\%$ (on the anhydrous basis)	100.1%
Residual Solvents	Methanol	Not more than 3000 ppm	Not detected
	Acetone	Not more than 5000 ppm	230 ppm
	Methylene Chloride	Not more than 600 ppm	Not detected

Conclusion: The testing results of this batch are complied with the Standard of EP 11.0.

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

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