

CERTIFICATE OF ANALYSIS

af 09/09/2022

Product : Betamethasone Dipropionate
Batch no. : BDP 102/0422

Manf. Date : April 2022
Retest Date : March 2027

Description	White crystalline powder (White or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, sparingly soluble in ethanol (96%))
Identification	Test A: IR (Concordant with standard (EP))
Specific Optical Rotation (1% solution in Anhydrous Ethanol)	+86 ° (+84° to +88° on dried basis)
Related substances (By HPLC)	0.05 % (Impurity B : NMT 0.3 %) 0.36 % (Impurity C : NMT 0.5 %) Less than 0.05 % (Impurity D : NMT 0.2 %) Less than 0.05 % (Impurity E : NMT 0.2 %) Less than 0.05 % (Impurity G : NMT 0.2 %) Less than 0.05 % (Impurity H : NMT 0.3 %) 0.05 % (Impurity I : NMT 0.15 %) Complies (Unspecified Impurities : NMT 0.10 %) 0.56 % (Total impurities : NMT 1.0 %)
Loss on drying	0.15 % w/w (NMT 1.0 % w/w)
Assay	By HPLC : 99.2 % w/w (NLT 97.0 % w/w and NMT 102.0 % w/w on dried basis)
Residual solvents	Methanol : NMT 3000 ppm Methylene Chloride : NMT 600 ppm Acetone : NMT 5000 ppm Ethyl Acetate : NMT 5000 ppm Isopropyl Alcohol : NMT 5000 ppm Pyridine : NMT 200 ppm Complies as per ICH guidelines
Particle Size (By Malvern Diffraction)	90 % ≤ 7.57 μm (Limit : 90 % ≤ 20 μm)

Conclusion : Complies with EP 10.3

Analytical Chemist

ABV 18/08/22

QC Manager

