

CERTIFICATE OF ANALYSIS

Product : Betamethasone Valerate
Batch no. : BV 105/0423

Manf. Date : April 2023
Retest Date : March 2028

Description	A white crystalline powder (White or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96%))
Identification	Test A : IR (Concordant with standard (EP)) Test B : HPLC (Complies (EP))
Melting point	192 °C (About 192° C with decomposition)
Loss on drying	0.17 % w/w (NMT 0.5 % w/w)
Specific Optical Rotation (1% solution in Anhydrous Ethanol)	+81° (+77 ° to +83° on dried basis)
Related substances (HPLC)	Less than 0.05 % (Impurity A : NMT 0.7%) Less than 0.05 % (Impurity C : NMT 0.15%) Less than 0.05 % (Impurity E : NMT 0.3%) Less than 0.05 % (Impurity G : NMT 0.3%) Less than 0.05 % (Impurity H : NMT 0.15%) Less than 0.05 % (Impurity I : NMT 0.15%) Complies (Unspecified Impurity : NMT 0.10%) Less than 0.05 % (Total Impurities : NMT 1.5%)
Assay	By UV : 100.4 % w/w (NLT 97.0 % w/w and NMT 103.0 % w/w on dried basis)
Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene Chloride : NMT 600 ppm Ethyl Acetate : NMT 5000 ppm Complies as per ICH guidelines
Particle Size (By Laser Diffraction)	90 % ≤ 5.64 µm (Limits : 90 % ≤ 20 µm)

Conclusion

Complies with EP 11

Analytical Chemist

20/09/23

Assoc. OC Manager



20/09/23