

12/12/2023

CERTIFICATE OF ANALYSIS

Product : Clobetasol Propionate
Batch no. : CLO 006/0823

Manf. Date : August 2023
Retest Date : July 2028

Description	White, crystalline powder (White or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 %))
Identification	IR : Concordant with EP standard
Specific Optical Rotation (1% Solution In Acetone)	+116° (+112 ° to +118° on dried basis)
Related substances (HPLC)	0.05 % (Impurity A : NMT 0.2 %) 0.08 % (Impurity B : NMT 0.3 %) Less than 0.05 % (Impurity D : NMT 0.2 %) Less than 0.05 % (Impurity E : NMT 0.3 %) Complies (Unspecified impurity : NMT 0.10 %) 0.13 % (Total impurities : NMT 1.0 %)
Loss on drying	0.13 % w/w (NMT 0.5 % w/w)
Sulphated Ash	0.04 % w/w (NMT 0.1 % w/w)
Assay	By HPLC: 99.9 % 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 Dimethyl Formamide : NMT 880 ppm Pyridine : NMT 200 ppm Complies as per ICH guidelines

Conclusion : Complies with EP 10.5

Analytical Chemist

Assoc. QC Manager

29/11/23



29/11/23