

afh
21/10/2022

CERTIFICATE OF ANALYSIS

Product : Clobetasol Propionate
Batch no. : CLO 121/1021

Manf. Date : October 2021
Retest Date : September 2026

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 at 20 °C)	+116 (+112 to +118 on dried basis)
Related substances (By HPLC)	Less than 0.05 % (Impurity A: NMT 0.2 %) 0.20 % (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 %) 0.20 % (Total impurities: NMT 1.0 %)
Loss on drying	0.15 % w/w (NMT 0.5 % w/w)
Sulphated Ash	0.04 % w/w (NMT 0.1 % w/w)
Assay	By HPLC: 99.3 % 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
Particle Size (By Laser Diffraction)	80 % ≤ 11.0 µm (Limit: 80 % ≤ 30 µm)

Conclusion : Complies with EP 10.4

Analytical Chemist

afh 02/12/21

OC Manager



02/12/21