



SYMBIOTICA
SPECIALITY INGREDIENTS SDN BHD

Lot: 0161020



CERTIFICATE OF ANALYSIS

Product : Clobetasol Propionate
Batch no. : CLO 112/0620

Manf. Date : June 2020
Retest Date : May 2025

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)	+118 (+112 to +118 on dried basis)
Related substances (By HPLC)	0.08 % (Impurity A : NMT 0.2 %) 0.17 % (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 %) 0.25 % (Total impurities : NMT 1.0 %)
Loss on drying	0.16 % 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
Particle Size (By Laser Diffraction)	80 % $\leq$ 9.85 μ m (Limit : 80 % $\leq$ 30 μ m)

Conclusion : Complies with EP 10.1

Analytical Chemist

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Assoc. QC Manager



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A Member of BMM

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