



SYMBIOTICA
SPECIALITY INGREDIENTS SDN. BHD.



CERTIFICATE OF ANALYSIS

Product : Clobetasol Propionate **Manf. Date** : October 2015
Batch no. : CLO 029/1015 **Retest Date** : September 2020

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 standard (EP)
Specific Optical Rotation (1% Solution In Acetone)	+116 ° (+112 ° to +118° on dried basis)
Related substances (HPLC)	0.07 % (Impurity A : NMT 0.2 %) 0.18 % (Impurity B : NMT 0.3 %) Less Than 0.05 % (Impurity C : NMT 0.3 %) Less Than 0.05 % (Impurity D : NMT 0.5 %) Less Than 0.05 % (Impurity E : NMT 0.7 %) Less Than 0.05 % (Impurity L : NMT 0.2 %) Less Than 0.05 % (Impurity M : NMT 0.2 %) Complies (Unspecified impurity : NMT 0.10 %) 0.25 % (Total impurities : NMT 2.0 %)
Loss on drying	0.26 % w/w (NMT 0.5 % w/w)
Sulphated Ash	0.06 % w/w (NMT 0.1 % w/w)
Assay	By HPLC : 100.6 % 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% ≤ 21.3 µm (Limit: 80 % ≤ 30 µm)

Conclusion : Complies with EP 8.6

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