

CERTIFICATE OF ANALYSIS

Product : Clobetasone 17 Butyrate **Manf. Date** : June 2021
Batch no. : CSB 403/0621 **Retest Date** : May 2024

Description	White powder (White or almost white powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, slightly soluble in ethanol (96%))
Melting Point	180 °C (About 178 °C with decomposition)
Identification	IR : Concordant with standard (EP)
Specific Optical Rotation (1 % solution in Ethanol)	+134° (+131° to +138° on dried basis)
Related substances (By HPLC)	Less than 0.05 % (Any unspecified impurities : NMT 0.10%) Less than 0.05 % (Total impurities : NMT 0.5 %)
Loss on drying	0.16 % w/w (NMT 0.5 % w/w)
Assay	By UV : 100.0 % 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 Dimethylformamide : NMT 880 ppm Pyridine : NMT 200 ppm Complies as per ICH guidelines
Particle Size	Micronized

Conclusion : Complies with EP 10

Analytical Chemist

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QC Manager

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