

ANUH PHARMA LTD.

CERTIFICATE OF ANALYSIS

Product Name	:	Clobetasol Propionate EP Micronised	Batch Size	:	80.0 Kgs
Batch No	:	APL/01160/G-19	A.R. No.	:	AFP/157/2019
Mfg. Date	:	07/2019	Exp. Date	:	06/2024

Sr. No.	Tests	Observations	Limits
1	Character- Appearance	Almost white, crystalline powder.	White or almost white; crystalline powder.
2	Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (95%).	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (95%).
3	Identification-IR	Complies	Infrared Spectrum obtained with sample is concordant with the reference spectrum of Clobetasol Propionate WS
4	Specific optical rotation on dried basis	+115.28°	Between + 112.0° & +118.0°
5	Related substances		
	Impurity-A	N.D.	Not more than 0.2%
	Impurity-B	0.12%	Not more than 0.3%
	Impurity-C	N.D.	Not more than 0.3%
	Impurity-D	N.D.	Not more than 0.5%
	Impurity-E	N.D.	Not more than 0.7%
	Impurity-L	N.D.	Not more than 0.2%
	Impurity-M	N.D.	Not more than 0.2%
	Unspecified impurity	0.06%	Not more than 0.10%
	Total impurities	0.30%	Not more than 2.0%
6	Loss on drying	0.27%	Maximum 0.5%
7	Sulphated ash	0.05%	Maximum 0.1%
8	Assay (On dried basis)	99.40%	97.0% to 102.0%

Additional Test

1	Residual solvents		
	Methylene chloride	N.D.	Not more than 600 ppm
	Acetone	N.D.	Not more than 5000 ppm
	Ethyl Acetate	N.D.	Not more than 5000 ppm
	Methanol	869.33 ppm	Not more than 3000 ppm
	Pyridine	N.D.	Not more than 200 ppm
	DMF	N.D.	Not more than 880 ppm
2	Particle Size		
	< 20 Microns	Complies	100.0%

Remarks: The sample complies/ ~~does not comply~~ as per Specification T-FP-32 (EP10).

For Anuh Pharma Ltd.

Signature
17/06/2024
Authorized Signatory.