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METAPHARMACEUTICAL

N DE LOTE:

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10/02/2022



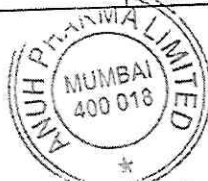
ANUH PHARMA LTD.

CERTIFICATE OF ANALYSIS

Product Name	: Clobetasol Propionate EP Micronised	Batch Qty.	: 1.00 Kg (1 x 1.00 Kg)
Batch No	: APL/CLP/06003/A-22	A.R. No.	: AFP/039/2022
Mfg. Date	: 01/2022	Exp. Date	: 12/2026
Sr.No.	Tests	Observations	Limits
1	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 (96%).	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96%).
3	Identification : By IR	Complies	Infrared Spectrum obtained with sample is concordant with the reference spectrum of Clobetasol Propionate WS.
4	Specific optical rotation (On dried basis)	+114.87°	Between +112° and +118°
5	Related substances		
	Impurity A	0.05%	Not more than 0.2%
	Impurity B	0.09%	Not more than 0.3%
	Impurity D	N.D.	Not more than 0.2%
	Impurity E	N.D.	Not more than 0.3%
	Unspecified impurities	0.08%	Not more than 0.10%
	Total impurities	0.29%	Not more than 1.0%
6	Loss on drying	0.25%	Not more than 0.5%
7	Sulphated ash	0.05%	Not more than 0.1%
8	Assay (On dried basis)	99.90%	NLT 97.0 % & NMT 102.0 %
Additional test			
1	Residual solvents		
	Methylene chloride	N.D.	Not more than 600 ppm
	Methanol	N.D.	Not more than 3000 ppm
	Pyridine	N.D.	Not more than 200 ppm
	Acetone	N.D.	Not more than 5000 ppm
	DMF	332.80 ppm	Not more than 880 ppm
	Ethyl Acetate	N.D.	Not more than 5000 ppm
2	Particle Size		
	< 20 Microns	Complies	100.0%

Remarks: The sample complies/ does not comply as per Specification T-FP-32 (EP10.1).

Analysed by	:	Approved by	:
Name	: G.B. Shibe	Name	: S.B. Jadhav
Designation	: Officer QC	Designation	: Manager QC
Date	: 31/01/2022	Date	: 31/01/2022



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Factory : M/s. Great Pacific Exports Pvt. Ltd., Plot No. D - 5/8 & 5/9, MIDC Turbhe, T.T.C Industrial Area, Navi Mumbai - 400 703, India.

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