



F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D-46286 Dorsten • Germany
Phone: +49 (0) 2369-9261947 • Fax: +49 (0) 2369-9261950

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09/02/2023



METAPHARMACEUTICAL

N DE LOTE:

0120223



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/06002/A-23	A.R. No.	: AFP/026/2023
Mfg. Date	: 11/2022	Exp. Date	: 10/2027
Sr.No.	Tests	Observations	Limits
1	Character-Appearance	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-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)	+115.47°	Between +112.0° & +118.0°
5	Related substances		
	Impurity-A	0.01%	Not more than 0.2%
	Impurity-B	0.03%	Not more than 0.3%
	Impurity-D	N.D.	Not more than 0.2%
	Impurity-E	N.D.	Not more than 0.3%
	Unspecified impurity	0.03%	Not more than 0.10%
	Total impurities	0.09%	Not more than 1.0%
6	Assay (On dried basis)	99.43%	97.0% to 102.0%
7	Loss on drying	0.34%	Maximum 0.5%
8	Sulphated ash	0.08%	Maximum 0.1%
Additional Test			
1	Residual Solvent		
	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	N.D.	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%
*IR- Micropan Lab, Report No. MPL/2191/2022-23, Dated On, 20/01/2023.			
*Particle Size- Micropan Lab, Dated On, 19/01/2023.			
Remarks: The sample complies/ does not comply as per Specification T-FP-32 (EP10.1).			
Analysed by	: S	Approved by	: [Signature]
Name	: P. P. Shinde	Name	: C. R. Shirke
Designation	: Jr.Officer QC	Designation	: Sr. Manager QC/RA
Date	: 20/01/2023	Date	: 20/01/2023



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Office : 3-A Shivsagar Estate, North Wing, Dr. Annie Besant Road, Worli, Mumbai - 400 018. India.
Tel. : +91-22-6622 7575 • Fax : +91-22-6622 7600 / 7500 • Email : anuh@sk1932.com
CIN : L24230MH1960PLC011586

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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