

F&A PHARMA



METAPHARMACEUTICAL

N DE LOTE:

0161125

Signature 07/11/2025



ANUH PHARMA LTD.

CERTIFICATE OF ANALYSIS

Product Name	Clobetasol Propionate EP Micronised	Batch Qty.	5.00 Kg (1x 5.0 kg)
Batch No	APL/CLP/01141/F-25	A.R. No.	AFP/405/2025
Mfg. Date	06/2025	Exp. Date	05/2030

Sr. No.	Tests	Observations	Limits
1	Appearance	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 should be concordant with the reference spectrum of Clobetasol Propionate WS.
4	Specific optical rotation (On dried basis)	+115.80°	Between +112° and +118°
5	Related substances		
	Impurity A	0.03%	Not more than 0.2%
	Impurity B	0.04%	Not more than 0.3%
	Impurity D	0.03%	Not more than 0.2%
	Impurity E	N.D.	Not more than 0.3%
	Unspecified impurities	0.03%	Not more than 0.10%
	Total impurities	0.19%	Not more than 1.0%
6	Loss on drying (At 105°C for 3 hrs.)	0.24%	Not more than 0.50%.
7	Sulphated ash	0.06%	Not more than 0.1%.
8	Assay by HPLC (on dried basis)	99.50%	NLT 97.0 % & NMT 102.0 %
Additional Tests			
	Residual Solvent		
	DMF	N.D.	Not more than 880 ppm
	Methylene chloride	N.D.	Not more than 600 ppm
1	Methanol	476.48 ppm	Not more than 3000 ppm
	Pyridine	N.D.	Not more than 200 ppm
	Acetone	N.D.	Not more than 5000 ppm
	Ethyl Acetate	N.D.	Not more than 5000 ppm
2	Particle Size		
	<20 Microns	Complies	100.0%
*Particle Size- Complies, Micropan Lab, Dated On, 27/10/2025.			
Remarks: The sample Complies / does not comply as per Specification GP/STP/CLP/02 (EP 11.0)			
Analysed by		Checked by	Approved by
Name		Name	Name
Designation		Designation	Designation
Date		Date	Date



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GP/F/GQC/089/04-00