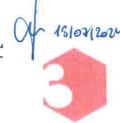






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ANUH PHARMA LTD.

			_C	ERTIFICATE C	F A	VALYS	SIS		
Product Name			: Clobetasol Propionate EP Micronised			Batch Qty.			2.00 Kg (1 x 2.00 Kg)
Batch No		:	: APL/CLP/06027/F-24			A.R. No.		:	AFP/297/2024
Mfg. Date : 05/2024			05/2024	Exp. Dat			:	04/2029	
Sr.No. Tests			ests	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)			+116.32°			Between + 112.0°& +118.0°		
5	Related substances								
	Impurity-A			0.01%			Not more than 0.2%		
	Impurity-B			0.06%			Not more than 0.3%		
	Impurity-D			0.01%			Not more than 0.2%		
	Impurity-E			N.D.			Not more than 0.3%		
	Unspecified impurity			0.02%			Not more than 0.10%		
	Total impurities			0.16%			Not more than 1.0%		
6	Assay (On dried basis)			99.52%			97.0% to 102.0%		
7	Loss on drying			0.15%			Maximum 0.5%		
8	Sulphated ash			0.04%			Maximum 0.1%		
Additi	onal Test			A V					
1	Residual Solvent			\(\frac{1}{2}\)					
	Methylene Chloride			N.D.			Not more than 600 ppm		
	Acetone			N.D.			Not more than 5000 ppm		
	Ethyl Acetate			41.83 ppm			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 S	ize	V						
4	< 20 Microns			Complies		100.0%			
				ab, Dated On, 28/06/2					
Rema	rks: The sai	mpl	le complies/ does	not comply as per Spe	ecificat	ion T-FP	-32 (E	EP1	1).
Analysed by			De		Approved by		:		Œ.
Name		:	A. P. Chorage			Name			P. S. Oak
Designation		:	Jr. Officer QC			Designation			Manager QC
Date		:	2 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		Date		:		30106/2019

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CIN: L24230MH1960PLC011586

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

Format No.GP/F/GQC/089/01-01