



18/04/2024



ANUH PHARMA LTD.

CERTIFICATE OF ANALYSIS

Product Name	Betamethasone Dipropionate EP Micronised	Batch Qty.	2.00 Kg (1 x 2.00 Kg)
Batch No	APL/BDP/01184/E-24	A.R. No.	AFP/259/2024
Mfg. Date	05/2024	Exp. Date	04/2029



Sr.No.	Tests	Observations	Limits
1	Appearance	White powder.	A white to almost white, crystalline powder.
2	Solubility	Practically insoluble in water, freely soluble in acetone & in Methylene chloride, sparingly soluble in Ethanol (96%).	Practically insoluble in water, freely soluble in acetone & in methylene chloride, sparingly soluble in ethanol (96%).
3	Identification:		
	Identification A: IR	Infrared Spectrum obtained with sample is concordant with the reference spectrum of Betamethasone Dipropionate WS.	Infrared Spectrum obtained with sample is concordant with the reference spectrum of Betamethasone Dipropionate WS.
	Identification B: TLC	The Rf value of principal spot obtained from test solution is corresponds to that obtained from the standard solution.	The Rf value of principal spot obtained from test solution should corresponds to that obtained from the standard solution.
	Identification C: Color Test	The color is discharged and a clear solution is remains.	The color is discharged and a clear solution is remains.
4	Specific optical rotation (On dried basis)	+86.18°	+ 84.0° to + 88.0°
5	Related substances		
	Impurity B (RRT about 0.4)	0.02%	Not more than 0.3%
	Impurity C (RRT about 0.5)	0.29%	Not more than 0.5%
	Impurity D (RRT about 0.7)	0.005%	Not more than 0.2%
	Impurity E (RRT about 1.22)	0.02%	Not more than 0.2%
	Impurity H (RRT about 1.7)	0.11%	Not more than 0.3%
	Impurity I (RRT about 1.16)	0.006%	Not more than 0.15%
	Impurity G (RRT about 2.1)	0.04%	Not more than 0.2%
	Unspecified impurity	0.006%	Not more than 0.10%
	Total impurities	0.41%	Not more than 1.0%
6	Loss on drying (At 105°C)	0.20%	Maximum 1.0%
7	Assay (On dried basis)	99.16%	NLT 97.0 % & NMT 102.0 %

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Sr.No.	Tests	Observations	Limits
Additional Test			
1	Residual Solvent		
	Methylene chloride (Class II)	N.D.	Not more than 600 ppm
	Methanol (Class II)	N.D.	Not more than 3000 ppm
	Pyridine (Class II)	N.D.	Not more than 200 ppm
	Acetone (Class III)	403.60 ppm	Not more than 5000 ppm
	DMF (Class III)	N.D.	Not more than 880 ppm
2	Particle Size		
	< 20 Microns	Complies	100%
*Particle Size- Complies, Micropan Lab, Dated On-06/06/2024.			
Remarks: The sample Complies / does not comply as per Specification T-FP-56 (EP11)			

Analysed by	:		Approved by	:	
Name	:	S. S. Patil	Name	:	P. S. Oak
Designation	:	Jr. Officer QC	Designation	:	Manager QC
Date	:	20/06/2024	Date	:	20/06/2024

