



METAPHARMACEUTICAL

N DE LOTE:

0130223

09/02/2023



F&A PHARMA

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ANUH PHARMA LTD.

CERTIFICATE OF ANALYSIS

Product Name	Betamethasone Dipropionate EP Micronised	Batch Qty.	1.00 Kgs (1 x 1.00 Kgs)
Batch No	APL/BDP/01253/K-22	A.R. No.	AFP/444/2022
Mfg. Date	11/2022	Exp. Date	10/2027

Sr.No.	Tests	Observations	Limits
1	Appearance	White Crystalline 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: First Identification B & Second Identification A,C,D,E		
	First Identification B: 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.
	Second Identification A: UV	0.05	The absorbance at 419 nm is not more than 0.10
	Second Identification C: 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.
	Second Identification D: Colour Test 1	The color is discharged and a clear solution is remain.	The color should discharged and a clear solution should remains.
	Second Identification E: Colour Test 2	The test solution is yellow and the blank is red.	The test solution should yellow and the blank should red.
4	Specific optical rotation (On dried basis)	+86.63°	+ 84.0° to + 88.0°
5	Related substances		
	Impurity B (RRT about 0.4)	0.01%	Not more than 0.3%
	Impurity C (RRT about 0.5)	0.34%	Not more than 0.5%
	Impurity D (RRT about 0.7)	0.01%	Not more than 0.2%
	Impurity E (RRT about 1.22)	0.02%	Not more than 0.2%
	Impurity H (RRT about 1.7)	N.D.	Not more than 0.3%
	Impurity I (RRT about 1.16)	N.D.	Not more than 0.15%
	Impurity G (RRT about 2.1)	0.02%	Not more than 0.2%
	Unspecified impurity	N.D.	Not more than 0.10%

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Mfg. Date	11/2022	Exp. Date	10/2027

Sr.No.	Tests	Observations	Limits
	Total impurities	0.40%	Not more than 1.0%
6	Loss on drying (At 105°C)	0.29%	Maximum 1.0%
7	Assay (On dried basis)	99.93%	NLT 97.0 % & NMT 102.0 %

Additional Test

1	Residual Solvent		
	Methylene chloride (Class II)	N.D.	Not more than 600 ppm
	Methanol (Class II)	345.58 ppm	Not more than 3000 ppm
	Pyridine (Class II)	N.D.	Not more than 200 ppm
	Acetone (Class III)	192.51 ppm	Not more than 5000 ppm
	DMF (Class III)	N.D.	Not more than 880 ppm
	Ethyl Acetate (Class III)	N.D.	Not more than 5000 ppm
2	Particle Size		
	<20 Microns	Complies	100%

*IR- Complies, Micropan Lab, Report No. MPL/1760/2022-23, Dated On -28/11/2022

Particle Size- Complies, Micropan Lab, Dated On-26/11/2022

Remarks: The sample Complies / does not complies as per Specification T-FP-56 (EP10)

Analysed by	: A	Approved by	: [Signature]
Name	: A.S.Gorade	Name	: C.R.Shirke
Designation	: Jr. Officer QC	Designation	: Sr. QC/RA Manager
Date	: 09/01/2023	Date	: 09/01/2023

