15/11/2023

F&A PHARMA

METAPHARMACEUTICAL

N DE LOTE:
0091123

COPY QA APPROVED
Date 14.11.23
Signature
F.&A. PHARMA Handels GmbH

ANUH PHARMA LTD.

CERTIFICATE OF ANALYSIS

Product Name	Betamethasone Dipropionate EP Micronised	**Batch Qty.**	**4.00 Kg** (1 x 4.00 Kg)
Batch No	APL/BDP/06050/J-23	**A.R. No.**	AFP/509/2023
Mfg. Date	05/2023	**Exp. Date**	04/2028

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	0.062	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)	+85.98°	+ 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*)	0.32%	Not more than 0.5%
	Impurity D (*RRT about 0.7*)	N.D.	Not more than 0.2%
	Impurity E (*RRT about 1.22*)	N.D.	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*)	0.16%	Not more than 0.2%
	Unspecified impurity	0.01%	Not more than 0.10%
	Total impurities	0.51%	Not more than 1.0%
6	**Loss on drying** (At 105°C)	0.17%	Maximum 1.0%

SK
We Serve Since 1932
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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Sr.No.	Tests	Observations	Limits
7	**Assay** (On dried basis)	99.97%	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)*	N.D.	Not more than 3000 ppm
	Pyridine *(Class II)*	N.D.	Not more than 200 ppm
	Acetone *(Class III)*	557.67 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/02075/2023-24,Dated On -25/10/2023.			
Particle Size- Complies, Micropan Lab, Dated On-23/10/2023			
Remarks: The sample Complies / ~~does not complies~~ as per Specification T-FP-56 (EP10)			

Analysed by	:		**Approved by**	:	
Name	:	S. S. Patil	**Name**	:	C. R. Shirke
Designation	:	Jr. Officer QC	**Designation**	:	Sr.Manager QC/RA
Date	:	30/10/2023	**Date**	:	30/10/2023

ANUH PHARMA LIMITED MUMBAI 400 018

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