METAPHARMACEUTICAL

N DE LOTE: 041025

AVIK PHARMACEUTICAL LIMITED

A- 1/7 & A- 1/8, 1st Phase, GIDC., Vapi - 396 195.Dist-Valsad, Gujarat State, India
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20/05/2025

CERTIFICATE OF ANALYSIS

Name of Product : BETAMETHASONE VALERATE EP	CAS. No : [2152-44-5]
IUPC name : 9-Fluoro-11β, 21-dihydroxy-16β-methyl-3, 20-dioxopregna-1, 4-diene-17-yl pentanoate.	

Batch No.	:	BV/M/002/25	A. R. No.	:	AVK/BV/003/25
Mfg. Date	:	Jan.- 2025	Exp. Date	:	Dec.- 2029
Batch size	:	30920 gm	Batch out put	:	30460 gm
Date of released	:	13/01/2025			

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
APPEARANCE	White or almost white crystalline powder.	White crystalline powder.
SOLUBILITY	Practically insoluble in water, freely soluble in acetone and in Methylene chloride, soluble in ethanol (96 %).	Conforms
MELTING POINT	About 192 °C, with decomposition.	193.1°C
IDENTIFICATION	A) **By I.R:** Infrared absorption spectrum of the sample should be in concordant with the IR spectrum of Betamethasone 17-Valerate working standard.	Conforms
	B) **By TLC:** The principal spot in the chromatogram obtained with the test solution is similar in position, colour, and size to the principal spot in the chromatogram obtained with the reference solution	Conforms
	C) **By HPLC:** The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (b).	Conforms
	D) **By chemical:** The colour is discharged and a clear solution remains	Conforms
SPECIFIC OPTICAL ROTATION	+ 77° to + 83° (dried substance).	+78°
RELATED SUBSTANCES (BY HPLC)	Impurity A : NMT 0.7 %	ND
	Impurity B : NMT 0.15 %	ND
	Impurity I : NMT 0.15 %	ND
	Impurity C : NMT 0.15 %	ND
	Impurity H : NMT 0.15 %	ND
	Impurity D : NMT 0.15 %	ND
	Impurity E : NMT 0.3 %	0.12 %
	Impurity G : NMT 0.3 %	ND
	Unspecified impurity : NMT 0.10 %	ND
	Total impurities : NMT 1.5 %	0.12 %
LOSS ON DRYING	Maximum 0.5 %	0.3 %
ASSAY (By UV)	Not Less Than 97.0 % - 103.0 % (Dried basis)	99.4 %
A) RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm	Below quantification limit
	Acetone : NMT 5000 ppm	1029 ppm
	Methylene chloride : NMT 600 ppm	ND
	Ethyl acetate : NMT 5000 ppm	ND
B) PARTICLE SIZE (BY VOLUME BASIS)	99 % < 20 µm	8.23 µm

REMARKS: The Batch **CONFORMS** as per EP-11.4 Specifications.

PREPARED BY:
NAME: PRATIK PATEL
DESIGNATION: EXECUTIVE-QC
DATE: 13/01/2025

CHECKED BY:
NAME: HIRAL PATEL
DESIGNATION: Dy.MANAGER-QC
DATE: 13/01/2025

APPROVED BY:
NAME: VINU PATEL
DESIGNATION: SR. MANAGER-QA (DOC)
DATE: 13/01/2025

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