

METAPHARMACEUTICAL

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0271125

18/09/2025

AVIK PHARMACEUTICAL LIMITED

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

Phone : (0260) 2401593, E-mail: avikpharma@avikpharma.com

CERTIFICATE OF ANALYSIS

Name of Product : BETAMETHASONE VALERATE EP		CAS. No : [2152-44-5]
IUPC name : 9-Fluoro-11 β , 21-dihydroxy-16 β -methyl-3, 20-dioxopregna-1, 4-diene-17-yl pentanoate.		
Batch No. :	BV/M/013/25	A. R. No. : AVK/BV/017/25
Mfg. Date :	May.- 2025	Exp. Date : Apr.- 2030
Batch size :	30500 gm	Batch out put : 30100 gm
Date of released :	08/09/2025	
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. 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 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). D) By chemical: The colour is discharged and a clear solution remains	Conforms Conforms Conforms Conforms
SPECIFIC OPTICAL ROTATION	+ 77° to + 83° (dried substance).	+81°
RELATED SUBSTANCES (BY HPLC)	Impurity A : NMT 0.7 % Impurity B : NMT 0.15 % Impurity I : NMT 0.15 % Impurity C : NMT 0.15 % Impurity H : NMT 0.15 % Impurity D : NMT 0.15 % Impurity E : NMT 0.3 % Impurity G : NMT 0.3 % Unspecified impurity : NMT 0.10 % Total impurities : NMT 1.5 %	ND ND ND ND ND ND 0.09 % ND ND 0.09 %
LOSS ON DRYING	Maximum 0.5 %	0.2 %
ASSAY (By UV)	Not Less Than 97.0 % - 103.0 % (Dried basis)	99.8 %
A) RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene chloride : NMT 600 ppm Ethyl acetate : NMT 5000 ppm	98 ppm 692 ppm 105 ppm Below detection limit
B) PARTICLE SIZE (BY VOLUME BASIS)	99 % < 20 μ m	7.40 μ m

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

PREPARED BY:
NAME: NAGESH SUTAR
DESIGNATION: ASST. MANAGER-QC
DATE: 08/09/2025

CHECKED BY:
NAME: HEMANT KEVAT
DESIGNATION: SR. MANAGER-QC
DATE: 08/09/2025

APPROVED BY:
NAME: DIVYA MISHRA
DESIGNATION: Dy. MANAGER-QA/RA
DATE: 08/09/2025

QC/GENF-056.01.04