



AVIK PHARMACEUTICAL LIMITED

A- 1/7 & A- 1/8, 1st Phase, GIDC., Vapi - 396 195, Dist-Valsad, Gujarat State, India
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29/03/2025

CERTIFICATE OF ANALYSIS

Name of Product: BETAMETHASONE DIPROPIONATE EP+IHT		CAS No. : [5593-20-4]
IUPAC Name : 9-Fluoro-11 β -hydroxy-16 β -methyl-3, 20-dioxopregna-1, 4-diene-17, 21-diyl dipropionate.		
Batch No.	: BDP/M/011/25	A. R. No. : AVK/BDP/021/25
Mfg. Date	: Mar.- 2025	Exp. Date : Feb.- 2030
Batch size	: 29100 gm	Batch out put : 28560 gm
Date of released	: 29/03/2025	
TEST	SPECIFICATION	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; sparingly soluble in ethanol (96%).	Conforms
IDENTIFICATION	A). By IR.: Infrared absorption spectrum of the sample should be in concordant with the IR spectrum of Betamethasone Dipropionate working standard. B). By TLC: The principal spot in the chromatogram obtained with the test solution in similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution C). By Chemical test: The colour is discharged and a clear solution remains	Conforms
SPECIFIC OPTICAL ROTATION	+ 84° to + 88° (on dried substance).	+ 86°
RELATED SUBSTANCES (BY HPLC)	Impurity A : NMT 0.15 % Impurity B : NMT 0.3 % Impurity C : NMT 0.5 % Impurity D : NMT 0.2 % Impurity I : NMT 0.15 % Impurity E : NMT 0.2 % Impurity F : NMT 0.15 % Impurity G : NMT 0.2 % Impurity H : NMT 0.3 % Unspecified impurity : NMT 0.10 % Total impurities : NMT 1.0 %	ND ND 0.47 % 0.07 % ND ND ND ND ND ND
LOSS ON DRYING	Maximum 1.0 % w/w.	0.4 %
ASSAY (By HPLC)	97.0 % to 102.0 % (On dried substance.)	99.8 %
ADDITIONAL TESTS		
A) Residual solvents	Methanol : NMT 3000 ppm Methylene chloride : NMT 600 ppm Tetrahydrofuran : NMT 720 ppm Dimethylformamide : NMT 880 ppm	94 ppm Below quantification limit Below detection limit ND
B) Triethylamine Content	NMT 5000 ppm	ND
C) Particle Size (By Volume Basis)	99 % < 20 μ m	7.44 μ m

REMARKS: The Batch CONFORMS as per EP-11.0+IHT Specifications.

PREPARED BY:
NAME: PRATIK PATEL
DESIGNATION: EXECUTIVE-QC
DATE: 29/03/2025

CHECKED BY:
NAME: HEMANT KEVAT
DESIGNATION: MANAGER-QC
DATE: 29/03/2025

APPROVED BY:
NAME: VINU PATEL
DESIGNATION: SR. MANAGER-QA (DOC)
DATE: 29/03/2025

QC/GENF-056.01.04

