METAPHARMACEUTICAL

N DE LOTE: 0270625

18/06/2025

AVIK PHARMACEUTICAL LIMITED

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

Name of Product: BETAMETHASONE DIPROPIONATE EP+IHT **CAS No. : [5593-20-4]**

IUPAC Name : 9-Fluoro-11β-hydroxy-16β-methyl-3, 20-dioxopregna-1, 4-diene-17, 21-diyl dipropanoate.

Batch No.	:	BDP/M/006/25	**A. R. No.**	:	AVK/BDP/012/25
Mfg. Date	:	Mar.- 2025	**Exp. Date**	:	Feb.- 2030
Batch size	:	29000 gm	**Batch out put**	:	28570 gm
Date of released	:	19/03/2025			

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.	Conforms
	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	Conforms
	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 %	ND
	Impurity B : NMT 0.3 %	ND
	Impurity C : NMT 0.5 %	0.43 %
	Impurity D : NMT 0.2 %	0.07 %
	Impurity I : NMT 0.15 %	ND
	Impurity E : NMT 0.2 %	ND
	Impurity F : NMT 0.15 %	ND
	Impurity G : NMT 0.2 %	ND
	Impurity H : NMT 0.3 %	ND
	Unspecified impurity : NMT 0.10 %	ND
	Total impurities : NMT 1.0 %	0.50 %
LOSS ON DRYING	Maximum 1.0 % w/w.	0.3 %
ASSAY (By HPLC)	97.0 % to 102.0 % (On dried substance.)	99.1 %
ADDITIONAL TESTS		
A) Residual solvents	Methanol : NMT 3000 ppm	76 ppm
	Methylene chloride : NMT 600 ppm	63 ppm
	Tetrahydrofuran : NMT 720 ppm	Below detection limit
	Dimethylformamide : NMT 880 ppm	ND
B) Triethylamine Content	NMT 5000 ppm	ND
C) Particle Size (By Volume Basis)	99 % < 20 µm	9.34 µm

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

PREPARED BY:
NAME: PRATIK PATEL
DESIGNATION: EXECUTIVE-QC
DATE: 19/03/2025

CHECKED BY:
NAME: HEMANT KEVAT
DESIGNATION: MANAGER-QC
DATE: 19/03/2025

APPROVED BY:
NAME: VINU PATEL
DESIGNATION: SR. MANAGER-QA (DOC)
DATE: 19/03/2025

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