

METAPHARMACEUTICAL

N DE LOTE:

0040921

02/09/2021



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**ENVIE DRUGS
PVT. LTD.**

CERTIFICATE OF ANALYSIS

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QUALITY CONTROL DEPARTMENT

Material Name :	Detamethasone Di Propionate	Batch No.	EV/BD-081/21
Grade :	BP/EP	Mfg Date :	13.06.21
Molecular Formula :	C ₂₈ H ₃₇ FO ₇	Exp. Date :	12.06.25
Molecular Weight :	504.6	Release Date :	17.06.21
A.R.No :	F/087/21-22		

TEST	OBSERVATIONS	SPECIFICATIONS
1 - Description :	Almost white crystalline powder	White or almost white, crystalline powder.
2 - Solubility :	Complies	Practically insoluble in water, freely soluble in acetone & in methylene chloride, sparingly soluble in ethanol (96 %).
3 - Identification :	Complies	A. IR Test
	Complies	B. TLC
	Complies	C. Chemical
4 - Specific optical rotation (ODB):	+85°	+84.0° to +88.0°
5 - Related Substances :	0.11%	Impurity B : NMT 0.3%
	0.37%	Impurity C : NMT 0.5%
	ND	Impurity D : NMT 0.2%
	0.15%	Impurity E : NMT 0.2%
	ND	Impurity G : NMT 0.2%
	ND	Impurity I : NMT 0.15%
	0.23%	Impurity H : NMT 0.3%
	0.05%	Un specified impurities : NMT 0.10%
6 - Loss on Drying :	0.57%	Total Impurities : NMT 1.0%
7 - Assay (ODB) :	98.6%	NMT 1.0%
		97.0 % to 102.0 %
Additional Tests		
1 - Particle Size :	Complies	100% less than 20 microns
2 - Residual solvents :	Complies	Pyridine : NMT 200 ppm
	Complies	MDC : NMT 600 ppm
	Complies	Methanol : NMT 3000 ppm

• The above sample is complies as per BP/EP

QC Officer <i>Kutresh Bhai</i> Date: 17/06/21	Checked By: Q.C Manager <i>Mahesh Dole</i> Date: 17/06/21
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