



ENVEE DRUGS
PVT. LTD.

CERTIFICATE OF ANALYSIS

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QUALITY CONTROL DEPARTMENT

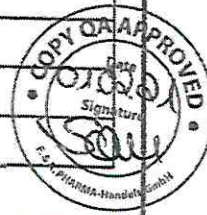
Material Name :	Betamethasone Di Propionate	Batch No.	EV/BD-346/20
Grade :	BP/EP	Mfg Date :	08.01.21
Molecular Formula :	C ₂₈ H ₃₇ FO ₇	Exp. Date :	07.01.25
Molecular Weight :	504.6	Release Date :	11.01.21
A.R.No :	F/347/20-21		

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 %).
	Complies	A. IR Test
	Complies	B. TLC
	Complies	C. Chemical
4 - Specific optical rotation (ODB):	+86°	+84.0° to +88.0°
	0.10%	Impurity B : NMT 0.3%
	0.40%	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%
	0.22%	Impurity H : NMT 0.3%
	ND	Un specified impurities : NMT 0.10%
	0.87%	Total Impurities : NMT 1.0%
6 - Loss on Drying :	0.61%	NMT 1.0%
7 - Assay (ODB) :	98.7%	97.0 % to 102.0 %

Additional Tests

1- Particle Size :	Complies	100% less than 20 microns
	Complies	Pyridine : NMT 200 ppm
2- Residual solvents :	Complies	MDC : NMT 600 ppm
	Complies	Methanol : NMT 3000 ppm

* The above sample is complies as per BP/EP



Prepared By : Q.C Officer	Checked By : Q.C Manager
Sign : <i>Devenishree</i>	Sign : <i>Malathi Purna</i>
Name : <i>Devenishree V. Chakkore</i>	Name : <i>Malathi Purna</i>
Date : <i>12/01/2021</i>	Date : <i>12/01/2021</i>