

METAPHARMACEUTICAL

N DE LOTE:

0280925

19/09/2023

F&A PHARMA



CERTIFICATE OF ANALYSIS

Product Name		Dexamethasone Micronized	
Reference Specification No.		FPS-028-02	
Batch No.	DXMFE25002	A.R.No.	FP25QCD-0357
Batch Quantity	42.150 Kg	Mfg. Date	Aug-2025
Grade	BP/EP	Retest Date	Jul-2030
Mfg. Lic. No.	G/25/2056	Released On	04/09/2025

Sr. No.	Test	Specification	Result
1.0	Description	White or almost white crystalline powder.	White crystalline powder
2.0	Solubility	Practically insoluble in water, sparingly soluble in anhydrous ethanol, slightly soluble in Methylene chloride.	Complies
		1) By IR: The infra-red absorption spectrum of sample is concordant with to that of the standard.	Complies
3.0	Identification	2) By TLC: The principal spot in the chromatogram obtained with the test solution is similar in position, colour in and size to the principal spot in the chromatogram obtained with reference solution.	Complies
4.0	Specific Optical Rotation	+86° to +92° (On dried basis).	+91.28°
5.0	Related Substances (By HPLC)	Impurity B : NMT 0.15 % w/w Impurity J : NMT 0.15 % w/w Impurity K : NMT 0.15 % w/w Impurity F : NMT 0.15 % w/w Impurity G : NMT 0.3 % w/w Unspecified impurity : NMT 0.10 % w/w Total impurities : NMT 0.5 % w/w	Not detected Not detected Not detected Not detected Not detected 0.05% 0.05%
6.0	Loss on Drying	NMT 0.5% w/w.	0.42%
7.0	Assay (By UV)	97.0% to 103.0% of C ₂₂ H ₂₉ FO ₅ (On dried basis).	99.1%
Additional Tests:			
8.0	Residual solvent (By GC)	Methanol :NMT 3000 ppm Methylene Chloride :NMT 600 ppm Di iso propylether :NMT 5000 ppm Dimethyl Formamide :NMT 880 ppm Acetone :NMT 5000 ppm	Not Detected 466 ppm Not Detected Not Detected Not Detected
9.0	Particle Size	99% < 30 µm	Complies
Remark: The sample <u>complies</u> Does not comply with prescribed standard as per above specification.			
Prepared By:		Checked By:	Approved By:
Sign./Date: 04/09/2025		Sign./Date: 04/09/2025	Sign./Date: 04/09/2025
Name: Hitendra Chudavat		Name: Bunty Patel	Name: Pulin Soni
Designation : Executive-QC		Designation : Sr.Executive-QC	Designation : Manager-QC

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