SYMBIOTEC
PHARMALAB PVT. LIMITED
Formerly Known as Symbiotec Pharmalab Ltd.

CERTIFICATE OF ANALYSIS

PRODUCT	**DESOXIMETASONE USP (MICRONISED) (CAS No.: 382-67-2)**		
BATCH No.	**DSMγ21003**	**MFG DATE**	**October 2021**
AR No.	**FP21833**	**RETEST DATE**	**September 2025**
DATE OF SAMPLING	**05/10/2021**		

S. No.	Test	Result	Specification
1.	Description	White, crystalline powder.	White to practically white, crystalline powder.
2.	Solubility	Freely soluble in alcohol, in acetone, and in chloroform, insoluble in water.	Freely soluble in alcohol, in acetone, and in chloroform, insoluble in water.
3.	Identification A. IR B. Assay (By HPLC)	 Concordant Complies	 IR Spectrum of the sample dispersed, shall be concordant with that of the working standard. The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.
4.	Assay (By HPLC)	99.34 %	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
5.	Residue on ignition	0.05 %	NMT 0.2 % w/w
6.	Organic impurities (By HPLC) Desoximetasone diacetal	 0.11 %	 NMT 0.15 %
	Desoximetasone related compound A	Not detected	NMT 0.15 %
	Desoximetasone acid	0.02 %	NMT 0.15 %
	Any individual unspecified impurity	0.03 %	NMT 0.10 %
	Total impurities	0.23 %	NMT 0.5 %
7.	Optical rotation (5 mg/mL in alcohol at 25°C)	+126.15°	Between +123° and +129°, calculated on the dried basis.
8.	Loss on drying (At 105°C to constant weight)	0.37 %	NMT 1.0 % w/w
1.	Additional test Residual solvents (By GC) Methylene chloride Tetrahydrofuran Methanol Acetone Ethyl Acetate	 < 1.0 ppm < 1.0 ppm 7 ppm 678 ppm 192 ppm	 NMT 100 ppm NMT 100 ppm NMT 1000 ppm NMT 2000 ppm NMT 2000 ppm
2.	Particle Size Malvern (By dry method)	2.31 µm 5.13 µm 8.31 µm	50.0 % < 5 µm 90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed Current USP-NF specification.
Date of Release: 08/10/2021
Reprint on: 26/10/2021

Prepared by: Sons 26/10/21
(S. Soni)
(Chemist – QC)

Checked by: Wagadre 26/10/21
(R. Wagadre)
(Manager – QC)

Approved by: 26/10/21
(M. K. Mourya)
(DGM – QC)

Manufacturing site: 385/2, Pigdamber, Off. A. B. Road, Rau, Indore : 453 331 (M. P.), India
Tel.: +91-731-4200052, Fax: +91-731-4201222
Email: symbiotec@symbiotec.in