

SYMBIOTEC

CERTIFICATE OF ANALYSIS

PHARMALAB PVT. LIMITED

Formerly Known as Symbiotec Pharnalab Ltd.

PRODUCT	DESOXIMETASONE USP (MICRONISED) (CAS No.: 382-67-2)		
BATCH No.	DSMy19003	MFG DATE	December 2019
AR No.	FP191240	RETEST DATE	November 2023
DATE OF SAMPLING	18/12/2019		

S. No.	Test	Result	Specification
1.	Description	White, (micronised) 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	Concordant	IR Spectrum of the sample dispersed, shall be concordant with that of the working standard.
	B. TLC	Complies ✓	The major spot from the test solution corresponds in R _f value (about 0.25) and appearance to that obtained from the Standard solution.
4.	Melting range	210.4°C – 211.3°C	Between 206° and 218°, but the range between beginning and end of melting does not exceed 4°.
5.	Specific rotation (At 25°C)	+109.27°	Between +107° and +112°, calculated on the dried basis.
6.	Loss on drying (At 105° C)	0.38 %	NMT 1.0 % w/w
7.	Residue on ignition	0.05 %	NMT 0.2 % w/w
8.	Assay (By HPLC)	99.34 %	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
1.	Additional Test Related substances (By HPLC)		
	Impurity B (Dexamethasone)	0.04 %	NMT 0.15 %
	Impurity G (Desoximetasone Acetate)	0.02 %	NMT 0.15 %
	Unspecified impurities	0.06 %	NMT 0.10 %
	Total impurities	0.25 %	NMT 1.0 %
2.	Residual solvents (By GC)		
	Methylene chloride	< 1.0 ppm	NMT 100 ppm
	Tetrahydrofuran	< 1.0 ppm	NMT 100 ppm
	Methanol	33 ppm	NMT 1000 ppm
	Acetone	1472 ppm	NMT 2000 ppm
	Ethyl Acetate	254 ppm	NMT 2000 ppm
3.	Particle Size Malvern (By dry method)	2.62 µm 6.49 µm 14.42 µm	50.0 % < 5 µm 90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 42 specification.

Date of Release: 03/01/2020

Reprint on: 13/01/2020

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