

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

18 A03-B05

Director Técnico

CERTIFICATE OF ANALYSIS

SYMBIOTEC

PHARMALAB PVT. LIMITED

Formerly Known as Symbiotec Pharmalab Ltd.

Product Name	METHYLPREDNISOLONE EP (MICRONISED) (CAS No. 83-43-2)		
Batch No.	ZMPRy17006-M	Mfg. Date	November 2017
A. R. No.	P2FPS17451	Retest Date	October 2020
Date of Sampling	25/11/2017		

S. No.	Test	Results	Specification
1.0	Characters Appearance	Almost white, (Micronised) crystalline powder.	White or almost white, crystalline powder.
	Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 per cent), slightly soluble in acetone and in methylene chloride.	Practically insoluble in water, sparingly soluble in ethanol (96 per cent), slightly soluble in acetone and in methylene chloride.
2.0	Identification A. IR	Concordant	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Methylprednisolone working standard.
	B. Retention time (By HPLC)	Complies	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c).
3.0	Specific optical rotation (C = 1 %, ethanol, at 20°C)	+98.98°	Between +97.0° and +103.0°. (dried substance)
4.0	Related substances (By HPLC)		
	Impurity D	BLQ	NMT 0.5 %
	Impurity A	0.07 %	NMT 0.3 %
	Sum of impurities G and I	Not Detected	NMT 0.3 %
	Impurity B	0.08 %	NMT 0.2 %
	Impurity H	Not Detected	NMT 0.2 %
	Impurity C	Not Detected	NMT 0.15 %
	Impurity E	BLQ	NMT 0.15 %
	Impurity F	BLQ	NMT 0.15 %
	Unspecified impurities	BLQ	NMT 0.10 %
	Total impurities	0.19 %	NMT 2.0 %
5.0	Loss on drying (At 105°C)	0.22 % w/w	NMT 1.0 % w/w
6.0	Assay (By HPLC)	98.99 % w/w	Between 97.0 % and 102.0 % w/w. (dried substance)
1.0	Additional Test Residual solvents (By GC) Methylene dichloride Methanol Acetone	109 ppm 185 ppm < 50 ppm	NMT 600 ppm NMT 3000 ppm NMT 5000 ppm
2.0	Particle Size (by Microscopic method)	< 4.98 µm < 6.64 µm	90.0 % < 10 µm 99.0 % < 25 µm

Opinion: The above material complies with the prescribed EP 9.0 specifications.

BLQ = Below limit of Quantitation,

Date of Release: 29/11/2017

Prepared by
Mahendra Mandloi
(Executive - QC)

Checked by
Rajesh Jha
(Sr. Executive - QC)

Approved by
Ashok Sharma
(Head - QC)

Manufacturing Site: Plot No. 5, 6, 7 & 8 SEZ Phase - II, Pharma Zone
Pithampur Dist. Dhar - 454774 (M.P.) India
Telephone: +917292-667602, Fax : +91-7292-667677
Email: symbiotec@symbiotec.in

Addendum No. MPR/00/Fagron/R0