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

CERTIFICATE OF ANALYSIS

PRODUCT	**METHYLPREDNISOLONE ACETATE USP (MICRONISED) (CAS No.: 53-36-1)**		
BATCH No.	**MPAγ20002**	**MFG DATE**	**February 2020**
AR No.	**FP20138**	**RETEST DATE**	**January 2024**
DATE OF SAMPLING	**04/02/2020**		

S. No.	Test	Result	Specification
1.	Description	White, crystalline powder. M. P. 228.2°C, with some decomposition.	White or practically white, crystalline powder Melts at about 225°, with some decomposition.
2.	Solubility	Practically insoluble in water; soluble in dioxane; sparingly soluble in acetone, in alcohol, in chloroform, and in methanol; slightly soluble in ether.	Practically insoluble in water; soluble in dioxane, sparingly soluble in acetone, in alcohol, in chloroform, and in methanol; slightly soluble in ether.
3.	Identification A. IR B. UV	Concordant Complies	IR Spectrum of the sample dispersed in KBr shall be similar with that of the Working standard. Absorptivities, calculated on the dried basis, do not differ by more than 3.0 %.
4.	Optical rotation (10 mg per ml in dioxane at 25°C)	+101.13°	Between +97° and +105°, calculated on the dried basis.
5.	Loss on drying (At 105° for 3 hrs.)	0.21 %	NMT 0.5 % w/w
6.	Residue on ignition	0.07 %	NMT 0.2 % w/w
7.	Organic impurities (By HPLC) Individual impurity Total impurities	 0.04 % 0.09 %	 NMT 1.0 % NMT 2.0 %
8.	Assay (By HPLC)	100.90 %	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
1.	Additional test Related substances (By HPLC) (As per PhEur 9.4) Impurity J	 Not detected	 Maximum 0.3 %
	Impurity G	BRL	Maximum 0.2 %
	Impurity A	Not detected	Maximum 0.2 %
	Impurity E	Not detected	Maximum 0.15 %
	Impurity K	Not detected	Maximum 0.15 %
	Unspecified impurities	BRL	Maximum 0.10 %
	Total impurities	0.09 %	Maximum 1.0 %
2.	Residual Solvents (By GC) Pyridine Methylene dichloride Methanol Acetone	 < 2.0 ppm < 2.0 ppm 8 ppm 509 ppm	 NMT 100 ppm NMT 400 ppm NMT 1500 ppm NMT 2000 ppm
3.	Particle Size Malvern (By dry method)	 5.50 µm 9.64 µm	 90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 42 specification.
Date of Release: 07/02/2020
Reprint on: 10/02/2020

Prepared by: 10/02/20
(S. Agnihotri)

Checked by: 10/02/20
(R. Wagadre)

Approved by: 10/02/20
(M. K. Mourya)

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CERTIFICATE OF ANALYSIS

PRODUCT	**METHYLPREDNISOLONE ACETATE USP (MICRONISED) (CAS No.: 53-36-1)**		
BATCH No.	**MPAγ20003**	**MFG DATE**	**January 2021**
AR No.	**FP21020**	**RETEST DATE**	**December 2024**
DATE OF SAMPLING	**07/01/2021**		

S. No.	Test	Result	Specification
1.	Description	White, crystalline powder. M. P. 226.9°C, with some decomposition.	White or practically white, crystalline powder. Melts at about 225°, with some decomposition.
2.	Solubility	Practically insoluble in water; soluble in dioxane; sparingly soluble in acetone, in alcohol, in chloroform, and in methanol; slightly soluble in ether.	Practically insoluble in water; soluble in dioxane; sparingly soluble in acetone, in alcohol, in chloroform, and in methanol; slightly soluble in ether.
3.	Identification A. IR B. UV	 Concordant Complies	 IR Spectrum of the sample dispersed in KBr shall be similar with that of the Working standard. Absorptivities, calculated on the dried basis, do not differ by more than 3.0 %.
4.	Optical rotation (10 mg per ml in dioxane at 25°C)	+101.06°	Between +97° and +105°, calculated on the dried basis.
5.	Loss on drying (At 105° for 3 hrs.)	0.28 %	NMT 0.5 % w/w
6.	Residue on ignition	0.05 %	NMT 0.2 % w/w
7.	Organic impurities (By HPLC) Individual impurity Total impurities	 0.03 % 0.05 %	 NMT 1.0 % NMT 2.0 %
8.	Assay (By HPLC)	99.54 %	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
1.	Additional test Related substances (By HPLC) (As per PhEur 9.4) Impurity J	 Not detected	 Maximum 0.3 %
	Impurity G	BRL	Maximum 0.2 %
	Impurity A	Not detected	Maximum 0.2 %
	Impurity E	Not detected	Maximum 0.15 %
	Impurity K	BRL	Maximum 0.15 %
	Unspecified impurities	0.05 %	Maximum 0.10 %
	Total impurities	0.06 %	Maximum 1.0 %
2.	Residual Solvents (By GC) Pyridine Methylene dichloride Methanol Acetone	 < 2.0 ppm < 2.0 ppm 26 ppm 1120 ppm	 NMT 100 ppm NMT 400 ppm NMT 1500 ppm NMT 2000 ppm
3.	Particle Size Malvern (By dry method)	 6.65 µm 11.54 µm	 90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 42 specification.
Date of Release: 20/01/2021

Prepared by: 20/01/21
(K. Patel)

Checked by: 20/01/21
(R. Wagadre)

Approved by: 20/01/21
(M. K. Mourya)

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CERTIFICATE OF ANALYSIS

PRODUCT	**METHYLPREDNISOLONE ACETATE USP (MICRONISED) (CAS No.: 53-36-1)**		
BATCH No.	**MPAγ20004**	**MFG DATE**	**January 2021**
AR No.	**FP21021**	**RETEST DATE**	**December 2024**
DATE OF SAMPLING	**07/01/2021**		

S. No.	Test	Result	Specification
1.	Description	White, crystalline powder. M. P. 226.8°C, with some decomposition.	White or practically white, crystalline powder. Melts at about 225°, with some decomposition.
2.	Solubility	Practically insoluble in water; soluble in dioxane; sparingly soluble in acetone, in alcohol, in chloroform, and in methanol; slightly soluble in ether.	Practically insoluble in water; soluble in dioxane; sparingly soluble in acetone, in alcohol, in chloroform, and in methanol; slightly soluble in ether.
3.	Identification A. IR B. UV	 Concordant Complies	 IR Spectrum of the sample dispersed in KBr shall be similar with that of the Working standard. Absorptivities, calculated on the dried basis, do not differ by more than 3.0 %.
4.	Optical rotation (10 mg per ml in dioxane at 25°C)	+100.78°	Between +97° and +105°, calculated on the dried basis.
5.	Loss on drying (At 105° for 3 hrs.)	0.21 %	NMT 0.5 % w/w
6.	Residue on ignition	0.06 %	NMT 0.2 % w/w
7.	Organic impurities (By HPLC) Individual impurity Total impurities	 0.05 % 0.08 %	 NMT 1.0 % NMT 2.0 %
8.	Assay (By HPLC)	99.60 %	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
1.	Additional test Related substances (By HPLC) (As per PhEur 9.4) Impurity J	BRL	Maximum 0.3 %
	Impurity G	BRL	Maximum 0.2 %
	Impurity A	Not detected	Maximum 0.2 %
	Impurity E	BRL	Maximum 0.15 %
	Impurity K	BRL	Maximum 0.15 %
	Unspecified impurities	0.05 %	Maximum 0.10 %
	Total impurities	0.12 %	Maximum 1.0 %
2.	Residual Solvents (By GC) Pyridine Methylene dichloride Methanol Acetone	 < 2.0 ppm < 2.0 ppm 11 ppm 688 ppm	 NMT 100 ppm NMT 400 ppm NMT 1500 ppm NMT 2000 ppm
3.	Particle Size Malvern (By dry method)	6.63 µm 11.38 µm	90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 42 specification.
Date of Release: 20/01/2021

Prepared by: 20/01/21
(K. Patel)

Checked by: 20/01/21
(R. Wagadre)

Approved by: 20/01/21
(M. K. Mourya)

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