Symbiotica
Speciality Ingredients Sdn. Bhd.

METAPHARMACEUTICAL

N DE LOTE:
0140125

16/01/2025

CERTIFICATE OF ANALYSIS

Product : Mometasone Furoate
Batch no. : MOM002/0424

Manf. Date : April 2024
Retest Date : March 2029

Description	White powder (White or almost white powder)
Solubility	Complies (Practically insoluble in water, soluble in acetone and in methylene chloride, slightly soluble in ethanol (96%))
Identification	Test A : IR (Concordant with standard (EP)) Test D : The principal peak in the chromatogram obtained with test solution (b) is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c) Test E : Loss on drying (see Tests)
Loss on drying	0.17 % w/w (NMT 0.5 % w/w)
Specific Optical Rotation (0.5 % solution in Ethanol (96%))	+ 52° (+50° to +55° on dried basis)
Related substances	0.08 % (Impurity J : NMT 0.15 %) Complies (Unspecified impurities : NMT 0.10 %) 0.08 % (Total impurities : NMT 0.3 %)
Assay	By HPLC : 100.6 % w/w (NLT 98.0 % w/w and NMT 102.0 % w/w on dried basis)
Residual solvents	Methanol : NMT 3000 ppm Methylene Chloride : NMT 600 ppm Acetone : NMT 5000 ppm Complies as per ICH guidelines
Particle Size (By Lazer Diffraction)	90 % ≤ 4.69 µm (Limits : 90 % ≤ 20 µm)

COS no.	:	R1-CEP 2009-313-Rev 01	***Security Seal no.***	:	N/A
Revision no.	:	N/A	***Date***	:	21/01/2016
Conclusion	:	Complies with Current EP			

Regulatory Note: This Certificate of Analysis corresponds to the product supplied as per CoS No. R1-CEP 2009-313-Rev 01. The regulatory label affixed behind confirms the validity of this certificate and supply as per the same.

Analytical Chemist

07/06/24

QC Manager

SYMBIOTICA SPECIALITY INGREDIENTS SDN. BHD. ★ QA Accepted

07/06/24