Symbiotica
Speciality Ingredients Sdn. Bhd.

01/09/2022

METAPHARMACEUTICAL

N DE LOTE:
0059922

CERTIFICATE OF ANALYSIS

Product	:	Betamethasone Valerate	*Manf. Date*	: March 2022
Batch no.	:	BV 105/0322	*Retest Date*	: February 2027

Description	White crystalline powder (White or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96%))
Identification	Test A : IR - Concordant with EP standard Test B : HPLC - Complies with EP
Melting point	194° C (About 192° C, with decomposition)
Loss on drying	0.13 % w/w (NMT 0.5 % w/w)
Specific Optical Rotation (1% solution in anhydrous Ethanol)	+80° (+77° to +83° on dried basis)
Related substances (By HPLC)	Less than 0.05 % (Impurity A : NMT 0.7%) Less than 0.05 % (Impurity C : NMT 0.15%) Less than 0.05 % (Impurity E : NMT 0.3%) Less than 0.05 % (Impurity G : NMT 0.3%) 0.12 % (Impurity H : NMT 0.15%) Less than 0.05 % (Impurity I : NMT 0.15%) Complies (Unspecified Impurity : NMT 0.10%) 0.12 % (Total Impurities : NMT 1.5%)
Assay	By UV : 99.9 % w/w (NLT 97.0 % w/w and NMT 103.0 % w/w on dried basis)
Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene Chloride : NMT 600 ppm Ethyl Acetate : NMT 5000 ppm Complies as per ICH guidelines
Particle Size (By Laser Diffraction)	90 % ≤ 5.14 µm (Limits : 90 % ≤ 20 µm)

Conclusion : Complies with EP 10.1

Analytical Chemist

26/07/22

SYMBIOTICA SPECIALITY INGREDIENTS SDN. BHD. QA Accepted

Assoc. QC Manager

26/07/22