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SYMBIOTICA
SPECIALITY INGREDIENTS SDN. BHD



CERTIFICATE OF ANALYSIS

Product : Betamethasone 17 Valerate
Batch no. : BV 105/0618

Manf. Date : June 2018
Retest Date : May 2023

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 standard (EP)) Test B : HPLC (Complies (EP))
Melting point	196 °C (About 192° C with decomposition)
Loss on drying	0.32 % w/w (NMT 0.5 % w/w)
Specific Optical Rotation (1% solution in Anhydrous Ethanol)	+80° (+77° to +83° on dried basis)
Related substances (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%) Less than 0.05 % (Impurity H : NMT 0.15%) Less than 0.05 % (Impurity I : NMT 0.15%) Complies (Unspecified Impurity : NMT 0.10%) Less than 0.05 % (Total Impurities : NMT 1.5%)
Assay	By UV : 99.3 % 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 % ≤ 4.96 µm (Limit : 90 % ≤ 20 µm)

Conclusion : Complies with EP 9

Analytical Chemist

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QC Manager

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Manufacturing Site: No. 518, Jalan Waja 4, Taman Industri Waja, 09000 Kulim, Kedah. Malaysia.