Lote: 002067

SYMBIOTICA
SPECIALITY INGREDIENTS SDN BHD

CERTIFICATE OF ANALYSIS

Product	:	Betamethasone Dipropionate	***Manf. Date***	:	April 2017
Batch no.	:	BDP 101/0417	***Retest Date***	:	March 2022

Description	White crystalline powder (White or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, sparingly soluble in ethanol (96%))
Identification	Test B : IR (Concordant with standard (EP))
Specific Optical Rotation (1% solution in Anhydrous Ethanol)	+87 º (+84º to +88º on dried basis)
Related substances (By HPLC)	Less than 0.05 % (Impurity A : NMT 0.5 %) Less than 0.05 % (Impurity B : NMT 0.3 %) 0.06 % (Impurity C : NMT 0.5 %) 0.05 % (Impurity D : NMT 0.2 %) Less than 0.05 % (Impurity E : NMT 0.2 %) Less than 0.05 % (Impurity G : NMT 0.2 %) Less than 0.05 % (Impurity H : NMT 0.3 %) Complies (Unspecified Impurities : NMT 0.10 %) 0.12 % (Total impurities : NMT 1.0 %)
Loss on drying	0.25 % w/w (NMT 1.0 % w/w)
Assay	By HPLC : 99.0 % w/w (NLT 97.0 % 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 Ethyl Acetate :NMT 5000 ppm Isopropyl Alcohol : NMT 5000 ppm Pyridine : NMT 200 ppm Complies as per ICH guidelines
Particle Size (By Malvern Diffraction)	90 % ≤ 6.99 µm (Limit : 90 % ≤ 20 µm

Conclusion : Complies with EP 9

Analytical Chemist

QC Manager

QA ACCEPTED