



SYMBIOTICA

SPECIALITY INGREDIENTS SDN. BHD.

CERTIFICATE OF ANALYSIS

Lot: 0040811

Product : Betamethasone Valerate Manf. Date : July 2011
Batch no. : BV-BLT 166/0711 Exp. Date : June 2016

Description	White crystalline powder (White to almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96%))
Identification	Test C : IR (Concordant with standard (EP)) Test D : TLC (Complies (EP))
Melting point	194 °C (184° C to 196° C)
Loss on drying	0.16 % w/w (NMT 0.5 % w/w)
Specific Optical Rotation (1% solution in Dioxan)	+80.00° (+75° to +82° on dried basis)
Related substances (HPLC)	0.56 % (Any individual Impurity : NMT 1.5%) 0.22% (Single Other Impurity : NMT 1.0%) 0.84 % (Total Impurities : NMT 3.0%)
Assay	By UV: 100.8 % w/w (NLT 97.0 % w/w and NMT 103.0 % w/w on dried basis)
Residual solvents	Methanol : NMT 3000 ppm Methylene Chloride : NMT 600 ppm Ethyl Acetate : NMT 5000 ppm Acetone : NMT 5000 ppm Complies as per ICH guidelines
Particle Size (By Microscopic Analysis)	Micronized

Conclusion : Complies with EP 6

Analytical Chemist

QC Manager

