



SYMBIOTICA

SPECIALITY INGREDIENTS SDN. BHD.

Lote: 30208J3

CERTIFICATE OF ANALYSIS

Issued to	: Siemgluss Iberica S.A.	Country	: Spain
Purchase ref.	: 245/13	SeO ref.	: 373/13 Rev 1
Product	: Betamethasone Dipropionate	Manf. Date	: July 2013
Batch no.	: BDP-BLT 096/0713	Retest Date	: June 2018
Quantity	: 1 kg	Date of issue	: 18/07/13

Description	White crystalline powder (White to 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)	+84.60 ° (+84° to +88° on dried basis)
Related substances (By HPLC)	Less than 0.05 % (Impurity A : NMT 0.5 %) 0.10 % (Impurity B : NMT 0.3 %) 0.39 % (Impurity C : NMT 0.5 %) 0.08 % (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 %) 0.57 % (Total impurities : NMT 1.0 %)
Loss on drying	0.33 w/w (NMT 1.0 % w/w)
Assay	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	Micronized

Conclusion : Complies with EP 7.4

Analytical Chemist

QC Manager

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