



SYMBIOTICA

SPECIALITY INGREDIENTS SDN. BHD.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15B24-B04

Director Técnico

CERTIFICATE OF ANALYSIS

Product : Betamethasone Valerate **Manf. Date** : February 2015
Batch no. : BV 003/0215 **Retest Date** : January 2020

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	194 °C (About 192° C with decomposition)
Loss on drying	0.20 % 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%) 0.07 % (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%) 0.16 % (Total Impurities : NMT 1.5%)
Assay	By UV : 99.7 % 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)	99 % ≤ 8.17 µm ; 90 % ≤ 4.90 µm (Limits: 99 % ≤ 20 µm ; 90 % ≤ 5 µm)

Conclusion : Complies with EP 8

Analytical Chemist

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QC Manager

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