



SYMBIOTICA

SPECIALITY INGREDIENTS SDN. BHD.

Lote: 0021112

CERTIFICATE OF ANALYSIS

Product : Cyproterone Acetate Manf. Date : October 2012
Batch no. : CPA 001/1012 Retest Date : September 2015

Description	White crystalline powder (A white or almost white crystalline powder)
Solubility	Complies (Practically insoluble in water, very soluble in methylene chloride, freely soluble in acetone, soluble in methanol, sparingly soluble in anhydrous ethanol)
Identification	Test A : IR (Concordant with standard (EP))
Melting Point	210 °C (About 210 °C)
Specific Optical Rotation (1% Solution in Acetone)	+155.50° (+152° to +157° on dried basis)
Related substances (HPLC)	0.14 % (Impurity F : NMT 0.4%) Complies (Unspecified impurities : NMT 0.10%) 0.29 % (Total impurities : NMT 0.5%)
Loss on drying	0.08 % w/w (NMT 0.5 % w/w)
Sulphated ash	0.03 % w/w (NMT 0.1 % w/w)
Assay	By UV : 100.1 % w/w (NLT 97.0 % w/w and NMT 103.0 % w/w on dried basis)
Particle Size (By Microscopic Analysis)	Micronized

Conclusion : Complies as per EP 7

Analytical Chemist

QC Manager

