

Lot: C050913

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Certificate of Analysis

Product name:	Progesterone	Batch No.:	C01-130301(M)
Quantity:	500kg	Packaging:	25kg/drum
Manuf. date:	Feb. 04, 2013	Test date:	Mar. 05, 2013
Re-test date:	Feb. 03, 2016	Report date:	Mar. 09, 2013
Standard:	EP		
Items	Specifications	Results	
1. Appearance:	White or almost white crystalline powder or colorless crystals	White crystalline powder, Micronized	
2. Solubility:	Practically insoluble in water, freely soluble in ethanol, sparingly soluble in acetone, and in fatty oils	Complies	
3. Assay:	97.0% to 103.0%	99.4%	
4. Identification: A. Infrared absorption B. Thin-layer chromatography	The transmission minima in the IR spectrum obtained with the substance correspond in position and relative size to those in the spectrum obtained with Progesterone CRS. Conforms to Results A and Results B	Complies	
5. Specific rotation:	+ 186° to + 194°	+ 189°	
6. Related substances:	Impurity B: 0.5% Max. Impurity C: 0.5% Max. Impurity G: 0.5% Max. Any unspecified impurity: 0.10% Max. Total impurities: 0.8% Max.	0.09% 0.31% 0.09% Not detected 0.49%	
7. Loss on drying:	0.5% Max.	0.26%	
8. Residual solvents:	Methanol: 500ppm Max. Ethanol: 2000ppm Max. Toluene: 300ppm Max. Cyclohexanone: 50ppm Max.	Not detected 403ppm Not detected Not detected	
9. Particle size:	100% pass 20 μ m; 90% pass 10 μ m.	Complies	
Conclusion : The above product conforms to EP.			

QA Manager: 魏文峰
2013.3.9

Reported by: 吴凤娟
2013.3.9