

Kalchem International

Chemicals & Compounding Supplies

Certificate Of Analysis

Name of Product : Progesterone, USP Micronized
Lot Number : 5124-150311
Manufacture Date : March 23, 2015
Re-Test Date : March 22, 2018

Test	Specification	Result
Characters	White or creamy white crystalline powder	White Crystalline powder, Micronized
Identification		
A : Infrared Absorption <197K>	The IR spectrum of sample exhibits maxima only at the same wavelength as that a similar preparation of USP Progesterone RS	Complies
B : Ultraviolet Absorption <197U>	The UV absorption spectra of the test solution and the standard solution exhibit maxima at the same wavelengths.	Complies
Melting Range <741>	Between 126°C and 131°C	129 ~ 131°C
Solubility	Practically insoluble in water, freely soluble in ethanol, sparingly soluble in acetone, and in fatty oils	Complies
Specific Rotation <781S> (on dried basis)	Between +175° and +183°	+180°
Loss on Drying <731>	0.5% Max.	0.20%
Related Substances	Any Impurity: 0.5% Max	019%
	Total Impurities: 0.8% Max	0.29%
Residual Solvents <467>	Methanol: 500ppm Max.	None Detected
	Ethanol: 2000ppm Max.	204ppm
	Toluene: 300ppm Max.	None Detected
	Cyclohexanone: 50ppm Max.	None Detected
Assay (on dried basis)	97.0% ~ 103.0%	99.3%
Particle Size		100% passes 20µm

Conclusion : **The Specification conforms with USP37 Standards**

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