

Certificate of Analysis

No.: C01-2024266

Product name:	Progesterone, Micronized	Batch No.:	C01-240922
Quantity:	15kg	Packaging:	5kg/carton
Manuf. Date:	Oct. 10, 2024	Sampling date:	Oct. 16, 2024
Retest date:	Oct. 09, 2027	Report date:	Oct. 28, 2024
Standard:	EP11.0		
Items	Specifications	Results	
1. Appearance:	White or almost white, crystalline powder or colorless crystals	White crystalline Powder, Micronized	
2. Identification: A. Infrared absorption spectrophotometry: B. Thin-layer chromatography	A: IR spectrum of sample should correspond to that of working standard. B: Conforms to Results (254nm)	Complies	
3. Loss on drying:	0.5% Max.	0.24%	
4. Specific rotation:	+ 186° to + 194°	+ 186°	
5. Related substances:	Impurity B: 0.2% Max.	0.06%	
	Impurity C: 0.3% Max.	0.18%	
	Impurity D+E: 0.15% Max.	Not detected	
	Impurity G: 0.15% Max.	0.06%	
	Impurity H: 0.15% Max.	<0.05%	
	Impurity I: 0.6% Max.	Not detected	
	Impurity J: 0.15% Max.	Not detected	
	Impurity K: 0.15% Max.	Not detected	
	Impurity L: 0.15% Max.	Not detected	
	Impurity M: 0.15% Max.	Not detected	
	Any unspecified impurity: 0.10% Max.	Not detected	
	Sum of impurities other than H: 1.0% Max.	0.30%	
6. Assay:	97.0% to 102.0%	99.9%	
7. Residual solvents:	Ethanol: 5000ppm Max. Methanol: 3000ppm Max. Toluene: 890ppm Max. Cyclohexanone: 50ppm Max.	239ppm Not detected Not detected Not detected	
Conclusion: The above product conforms to EP11.0.			

Prepared by:



Reviewed by:



Approved by:



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10/12/2024

