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CERTIFICATE OF ANALYSIS

Product : Progesterone Micronized **Batch No. :** EU-HTT200601M
Quantity : 450kg **Specification:** EP10
Mfg. date: 2020.06.03 **Retest date:** 2025.06.02

Item	Specifications	Results
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	IR:Comparison: progesterone CRS.	Sample spectrum is similar to that of reference standard.
	TLC results A: The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with the test solution is similar in position, fluorescence in ultraviolet light at 365 nm/254nm and size to the principal spot in the chromatogram obtained with the reference solution.
Specific optical rotation	+186° ~ +194°	+191.1°
Loss on drying	≤0.5 %	0.14%
Related substances	Impurity B ≤0.2%	0.06%
	Impurity J≤0.15%	Not detected
	Impurity K≤0.15%	Not detected
	Impurity C ≤0.2%	0.15%
	ImpurityM≤0.15%	Not detected
	Impurity L≤0.15%	Not detected
	Impurity I ≤0.6%	Not detected
	Impurity D+E≤0.15%	Not detected
	Impurity G≤0.15%	0.04%
	Impurity H≤0.15%	0.02%
	Unspecified impurity≤0.10%	Not detected
	Total impurities(without impurity H)≤0.3%	0.24%
Residual Solvents	Methanol ≤3000ppm	Not detected
	Ethanol ≤5000ppm	501ppm
Assay	97.0 ~ 102.0 %	99.3%
Particle Size	99%<30μm; 90%<25μm	Conform

Conclusion: Complies with the requirements of EP10

Q.C. director: **QP:**

Date: 2020.06.12 **Date:** 2020.6.12

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