



# 武汉福鑫化工有限公司

## Wuhan Fortuna Chemical Co.,Ltd

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### CERTIFICATE OF ANALYSIS

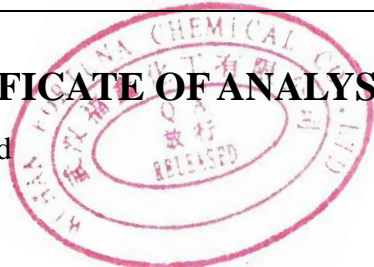
Product: Levonorgestrel micronized

Mfg. date: May, 21, 2022

Exp. date: May, 20, 2027

Lot No.: 0120220601F

Quantity: 2.0kg



Items	Specifications	Results
Appearance	White crystalline powder	Conforms
Identification	IR spectrum of the sample corresponds to that of the reference standard	Conforms
	Specific optical rotation: $-30^{\circ} \sim -35^{\circ}$	$-33^{\circ}$
Solubility	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 per cent).	Conforms
Melting range	$232^{\circ}\text{C} \sim 239^{\circ}\text{C}$ (Melts with a range of $4^{\circ}\text{C}$ )	$234^{\circ}\text{C} \sim 238^{\circ}\text{C}$
Loss on drying	$\leq 0.5\%$	0.05%
Residue on ignition	$\leq 0.3\%$	0.05%
Limit of ethynyl group	7.81~8.18%	8.05%
Chromatographic purity (TLC)	Any individual impurity $\leq 0.5\%$	$< 0.5\%$
	Total impurities $\leq 2.0\%$	$< 2.0\%$
Residual solvents	Acetone $\leq 5000\text{ppm}$	Not detected
	Dichloromethane $\leq 600\text{ppm}$	98ppm
	Ethyl acetate $\leq 5000\text{ppm}$	Not detected
	Tetrahydrofuran $\leq 720\text{ppm}$	Not detected
	Methanol $\leq 3000\text{ppm}$	Not detected
	Chloroform $\leq 60\text{ppm}$	Not detected
Assay(UV)	98.0% ~ 102.0%	99.2%
Particle size	90% not more than 10 microns	8.56 $\mu\text{m}$
Storage	Preserve in well-closed, light resistant container.	
Conclusion	The product conforms to the standard of USP43.	

QC:

Tester:

Re-tester: