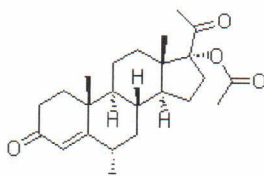




Batch no 6002-240802
Mf date Aug 21 2024
Retest Aug 20 2027
Batch size 250 kg

Molecular Structure



Molecular Formula $C_{24}H_{34}O_4$
Molecular Weight 386.53
CAS Registry Number 71-58-9

Oct 23 2024

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White to off-white crystalline powder	White crystalline powder
Solubility	Insoluble in water, freely soluble in chloroform; soluble in acetone and in dioxane; sparingly soluble in alcohol and in methanol; slightly soluble in ether	Conforms
Identification	IR, UV	Positive
Melting point	$\pm 205^{\circ}C$	$205^{\circ}C$
Specific optical rotation	$+45 \sim +51^{\circ}$	$+47^{\circ}$
Chromatographic purity	Related compound A $\leq 0.5\%$	0.2%
	Individual impurity $\leq 1.0\%$	0.35%
	Total impurities $\leq 1.5\%$	0.42%
Loss on drying (105°C, 3h)	$\leq 1.0\%$	0.11%
Residual solvents	Dichloromethane ≤ 600 ppm	ND
	Methanol ≤ 3000 ppm	172 ppm
	N,N-Dimethylformamide ≤ 880 ppm	ND
	Tetrahydrofuran ≤ 720 ppm	ND
	Ethanol ≤ 5000 ppm	17 ppm
	Pyridine ≤ 200 ppm	ND
Particle size	D(90) ≤ 10 um	Conforms
Assay (odb)	97.0 ~ 103.0% of $C_{24}H_{34}O_4$	99.8%
Packaging and storage	Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15 ~ 30°C	
Conclusion	Material complies with USP43	