

Megestrol Acetate USP43

Batch no 6024-240101 Mf date Jan 05 2024 Retest Jan 04 2027 Batch size 100 kg

Molecular Structure

Molecular Formula C₂₄H₃₂O₄
Molecular Weight 384.51
CAS Registry Number 595-33-5

Mar 07 2024

<u>Tests</u>	<u>Specifications</u>		<u>Results</u>
Апполиона	With a second second	, 	
Appearance	White or cream white crystalline powder		White crystalline powder
Identification	IR		Positive
Completeness of solution	Meets the requirements		Conforms
Melting point	213 ~ 220°C		216.5 ~ 218°C
Specific rotation	+8.8 ~ +12°		+9.1°
Water	≤ 0.5%		0. 04%
Residue on ignition	≤ 0.2%		0. 02%
Heavy metals	≤ 0.002%		Conforms
Residual solvents	Methanol	≤ 1000 ppm	50 ppm
	Ethanol	≤ 1000 ppm	ND
*	Methylene chloride	≤ 500 ppm	ND
	Tetrahydrofuran	≤ 300 ppm	ND
	Benzene	≤ 2 ppm	ND
Particle size	$D(90) \leq 10 \text{ um}$		Conforms
Assay (oab)	97.0 \sim 103.0% of $C_{24}H_{32}O_4$		100. 3%

Packaging and storage	Preserve in well-closed containers,	protected from light
Conclusion	Material complies with USP43	

