

## Isotretinoin USP43

Batch no Mf date

ITTN-250101 Jan 08 2025

Retest Jan 07 2027

Molecular Structure

Molecular Formula  $C_{20}H_{28}O_2$ Molecular Weight 300.44 CAS Registry Number 4759-48-2

Feb 18 2025

<u>Tests</u>	<u>Specifications</u>	Results
Appearance	Yellow or orange crystalline powder	Yellow-orange crystalline powder
Solubility	Soluble in chloroform, sparingly soluble in alcohol, in isopropyl alcohol in polyethylene glycol 400, practically insoluble in water	Conforms
Identification Related substances Heavy metals Loss on drying Residue on ignition Assay (odb)	IR, UV  Tretinoin ≤ 1.0%  ≤ 0.002%  ≤ 0.5%  ≤ 0.1%  98.0 ~ 102.0% of C <sub>20</sub> H <sub>28</sub> O <sub>2</sub>	Positive 0.08% < 0.002% 0.07% 0.04% 99.8%

Conclusion	Material complies with USP43	
Packaging & storage	Preserve in tight containers, protected from light	
Caution	Isotretinoin is teratogenic. Avoid inhalation and skin co	ntact

