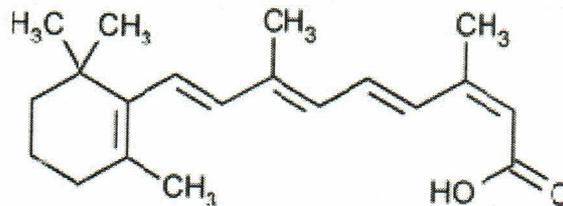




Isotretinoin USP43

Batch no ITTN-250803
Mf date Aug 10 2025
Retest Aug 09 2027

Molecular Structure



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

Oct 28 2025

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	Yellow or orange crystalline powder	Yellow-orange crystalline powder
Solubility	Soluble in chloroform, sparingly soluble in alcohol, in isopropyl alcohol, and in polyethylene glycol 400, practically insoluble in water	Conforms
Identification	IR, UV	Positive
Related substances	Tretinoin $\leq 1.0\%$	0.17%
Heavy metals	$\leq 0.002\%$	$< 0.002\%$
Loss on drying	$\leq 0.5\%$	0.15%
Residue on ignition	$\leq 0.1\%$	0.04%
Assay (odb)	98.0 ~ 102.0% of $C_{20}H_{28}O_2$	99.7%

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