

## CERTIFICATE OF ANALYSIS

### Isotretinoin USP43

Batch Number	ITTN-260402
Manufacture Date	Apr 02 2026
Retest Date	Apr 01 2028
Molecular Weight	300.44
CAS Number	4759-48-2

Tests	Specifications	Results
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%	0.09%
Heavy metals	$\leq$ 0.002%	$<$ 0.002%
Loss on drying	$\leq$ 0.5%	0.09%
Residue on ignition	$\leq$ 0.1%	0.04%
Assay (odb)	98.0 - 102.0% of C <sub>20</sub> H <sub>28</sub> O <sub>2</sub>	99.8%

Conclusion	Material complies with USP43
Storage Conditions	Preserve in tight containers, protected from light

**Storage Disclaimer:** Storage conditions are provided by the manufacturer and are intended to maximise product shelf life during long-term storage.

**Certificate Disclaimer:** This certificate is a reformatted interpretation of analytical results supplied on the original manufacturer's Certificate of Analysis. Results and specifications are based on information provided by the manufacturer.

Active pharmaceutical ingredient supplied for pharmacy compounding.

