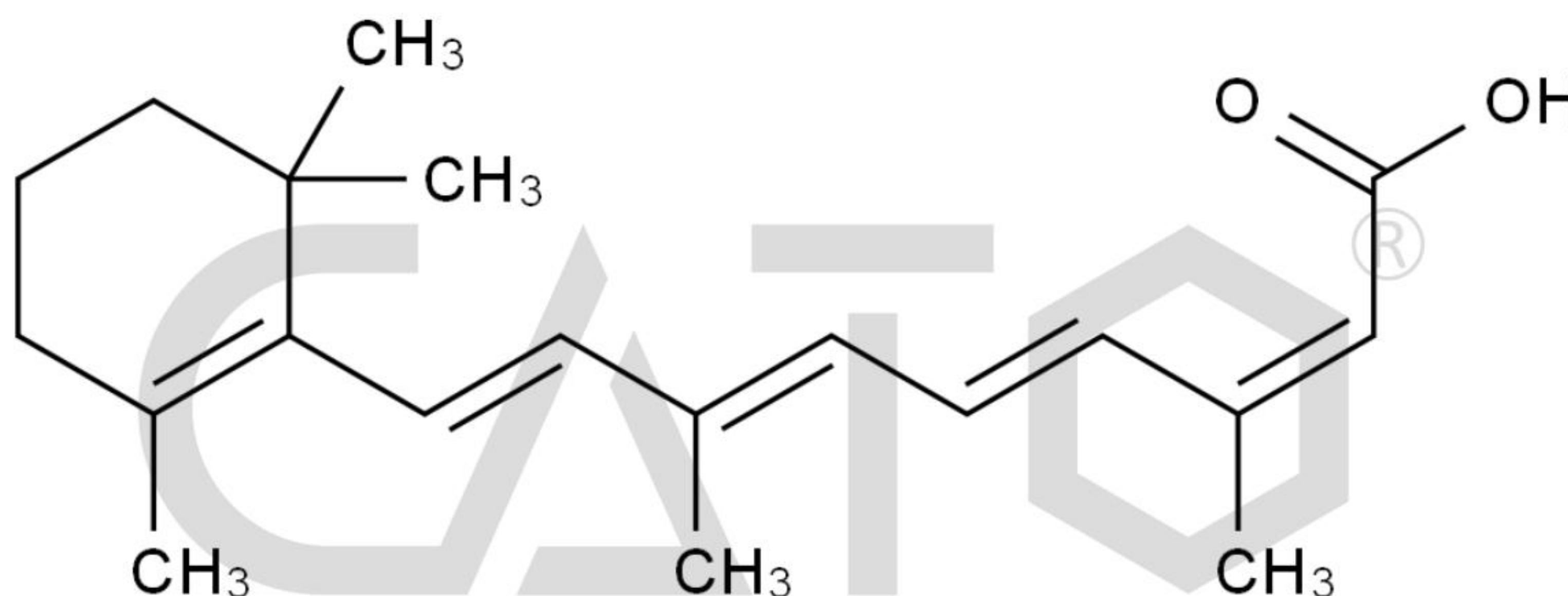


Certificate of Analysis

Reference Material & Standard

Product Name:	Isotretinoin	Catalogue Number:	CCAD300815
Synonyms:	N/A	Lot Number:	0303-RH-0067
CAS Number:	4759-48-2	Expiry Date:	Mar 08, 2028
Molecular Formula:	C ₂₀ H ₂₈ O ₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	300.44	Shipping Condition:	Shipping with Ice Packs
Solubility:	Dichloromethane	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Orange Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.918%
Water Content	Karl Fischer	0.1706%
Assay		98.7%
Uncertainty		±0.3%

Comment:

1. The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content}) * \text{Purity HPLC (\%)} / 100\%$$

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

Nice

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Mar 09, 2026

Date: Mar 10, 2026

Date: Mar 10, 2026



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