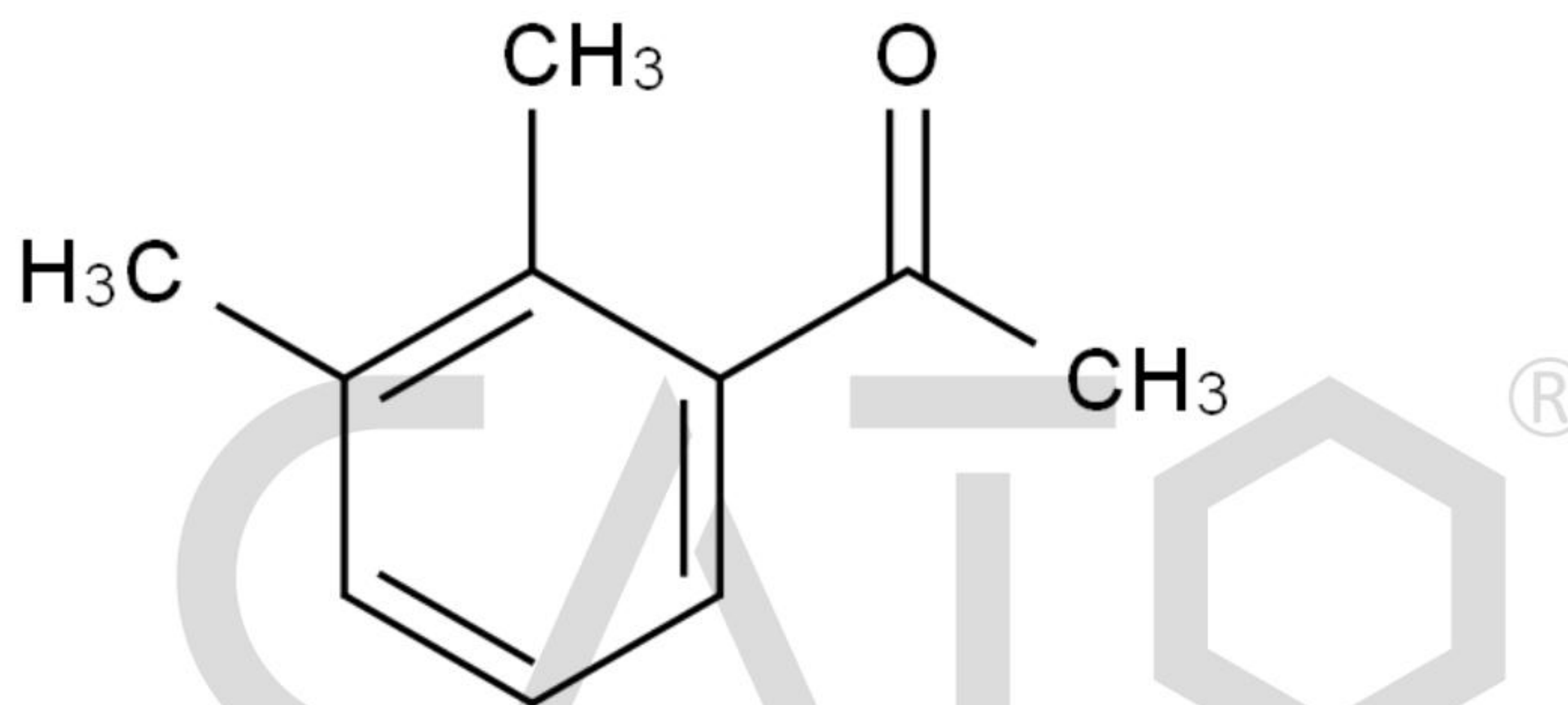


Certificate of Analysis

Reference Material & Standard

Product Name:	Dexmedetomidine Impurity 31	Catalogue Number:	C4X-123031
Synonyms:	N/A	Lot Number:	0908-RG-0160
CAS Number:	2142-71-4	Expiry Date:	Sep 07, 2029
Molecular Formula:	C ₁₀ H ₁₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	148.20		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Colourless Liquid
Identification	GCMS&HNMR	Confirmed
Purity	HPLC	99.440%
Water Content	Karl Fischer	0.6022%
Assay		98.8%

Comment:

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

Assay (%) = (100% - Water Content) * Purity HPLC (%) / 100%

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

Signature:

Prepared by:

Nice

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Sep 08, 2025

Date: Sep 09, 2025

Date: Sep 09, 2025



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