

Certificate of Analysis

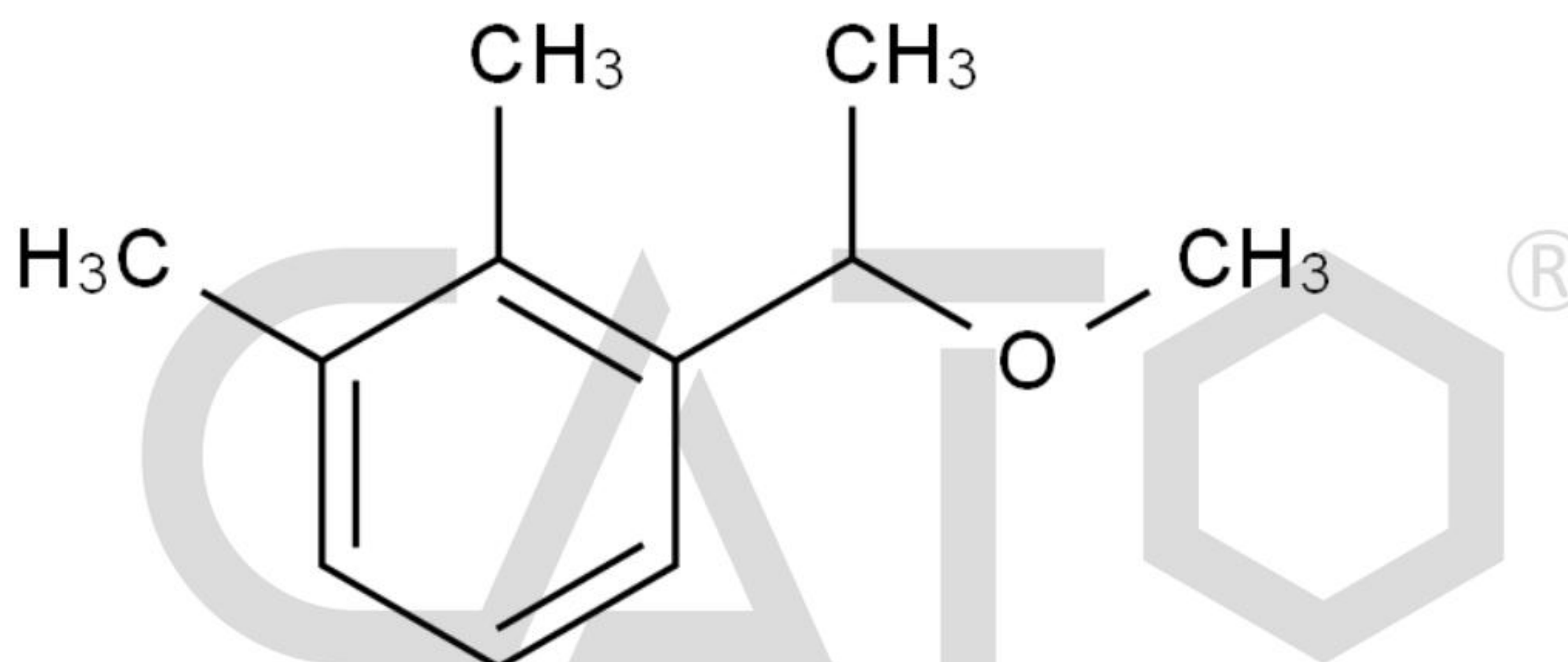
Reference Material & Standard

Product Name:	Dexmedetomidine Impurity 21	Catalogue Number:	C4X-123021
Synonyms:	N/A	Lot Number:	0728-RH-0044
CAS Number:	2514763-84-7	Expiry Date:	Jan 12, 2030
Molecular Formula:	C ₁₁ H ₁₆ O	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	164.24	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Liquid
Identification	GCMS&HNMR	Confirmed
Purity	HPLC	98.5795%
Water Content	Karl Fischer	0.000%
Residual Solvents	NMR	Not detected in NMR
Assay		98.6%

Comment:

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

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

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Jul 29, 2026

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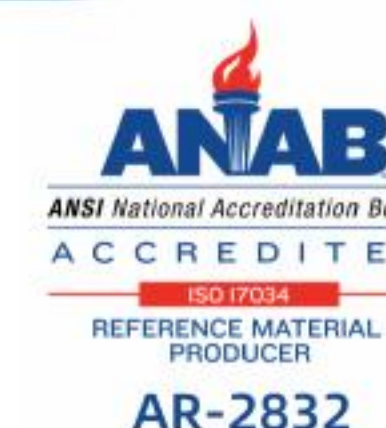
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Page 1 of 5



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