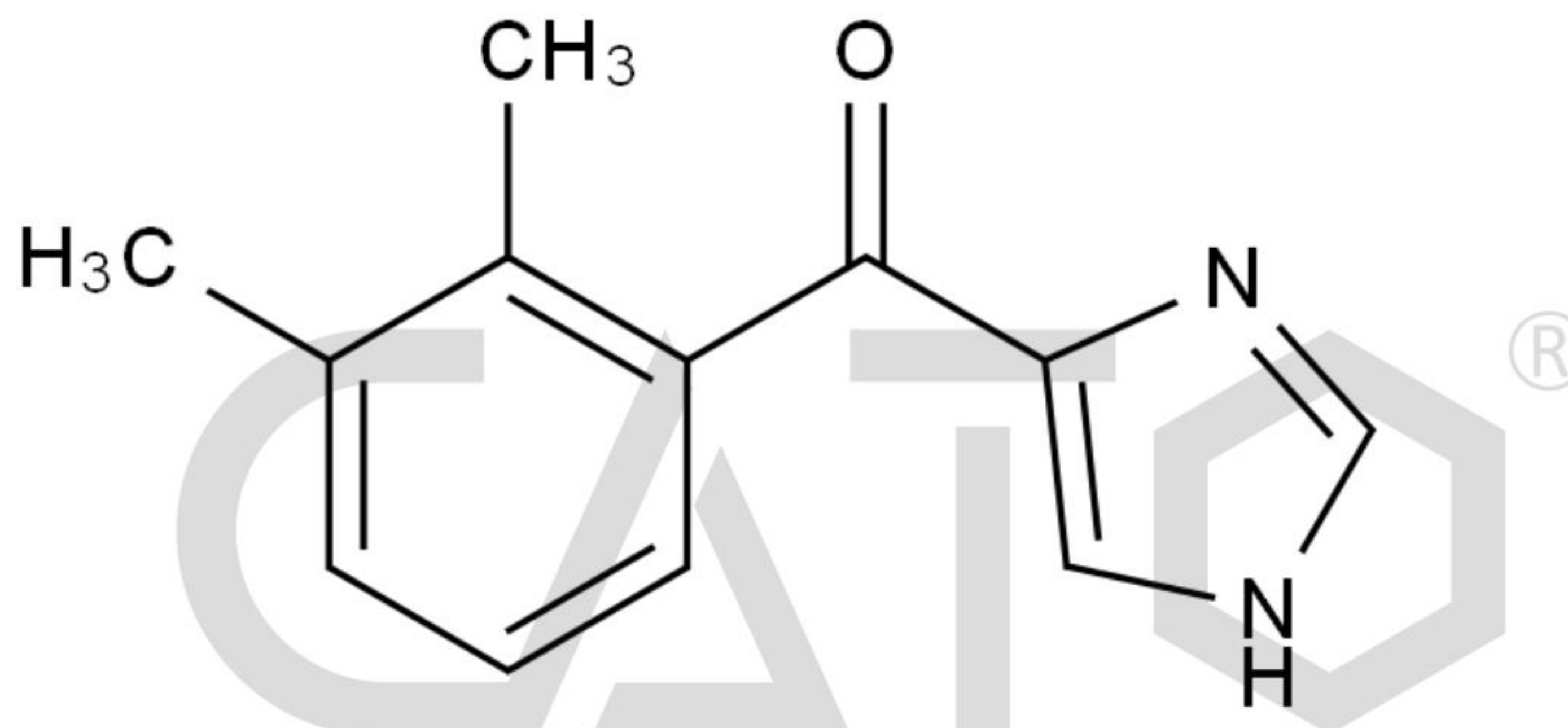


Certificate of Analysis

Reference Material & Standard

Product Name:	Dexmedetomidine hydrochloride USP Impurity A	Catalogue Number:	C4X-12306
Synonyms:	N/A	Lot Number:	0617-RE-0042
CAS Number:	91874-85-0	Expiry Date:	Jun 26, 2026
Molecular Formula:	C ₁₂ H ₁₂ N ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	200.24		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Brown-Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.856%
Loss on Drying	TGA	0.0536%
Assay		99.8%

Comment:

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

$\text{Assay (\%)} = (100\% - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$

Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Hin Lam

Reviewed by:

Nacy

Approved by General Manager:

David

Date: Jun 27, 2023

Date: Jun 27, 2023

Date: Jun 27, 2023



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