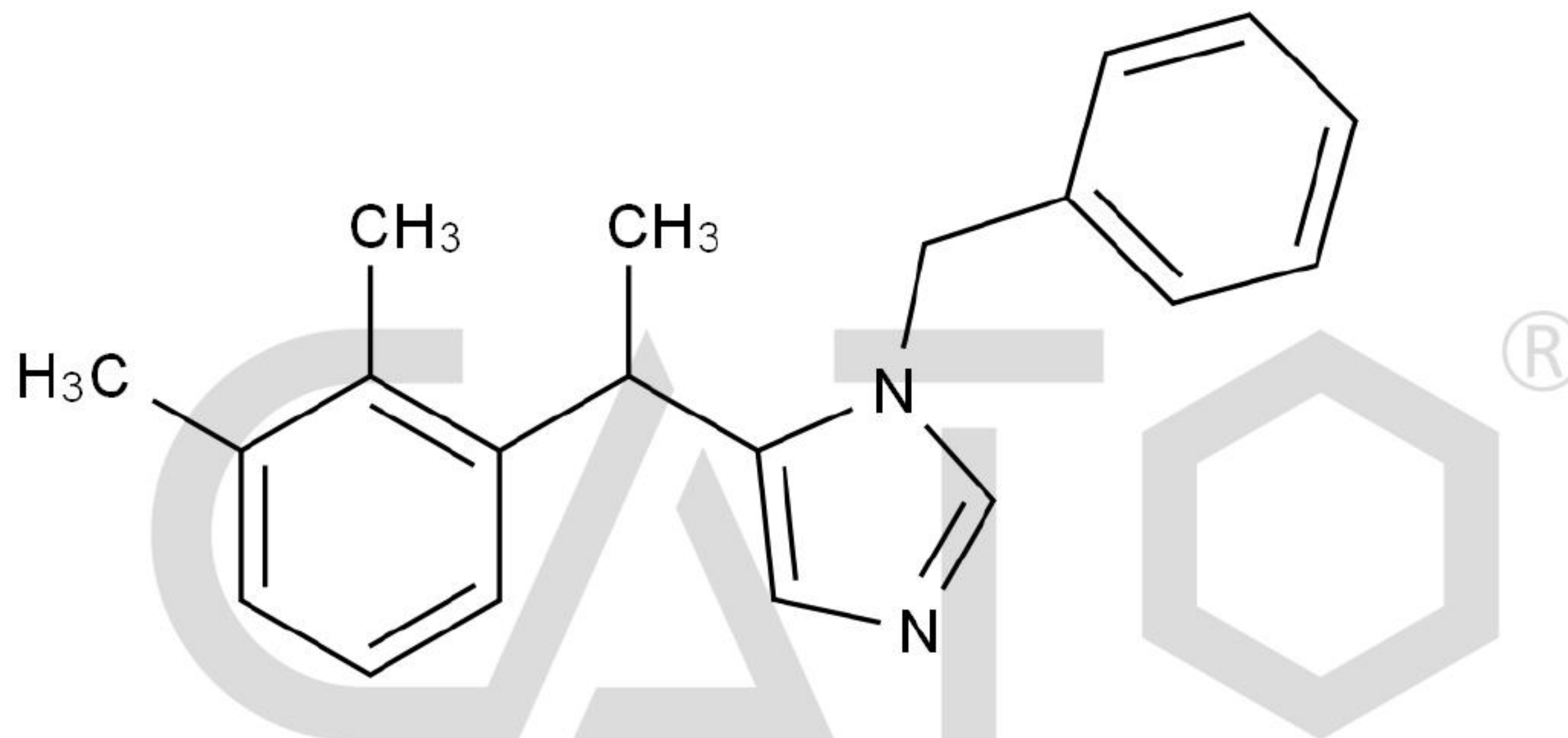


Certificate of Analysis

Reference Material & Standard

Product Name:	Dexmedetomidine Impurity 15	Catalogue Number:	C4X-123015
Synonyms:	Dexmedetomidine hydrochloride USP Impurity D	Lot Number:	0620-RE-0049
CAS Number:	2250242-52-3	Expiry Date:	Aug 20, 2029
Molecular Formula:	C20H22N2	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	290.40	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.120%
Water Content	Karl Fischer	0.12%
Assay		99.0%

Comment:

The calculation of the 100% 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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Aug 28, 2025

Date: Aug 28, 2025

Date: Aug 28, 2025

