

Certificate of Analysis

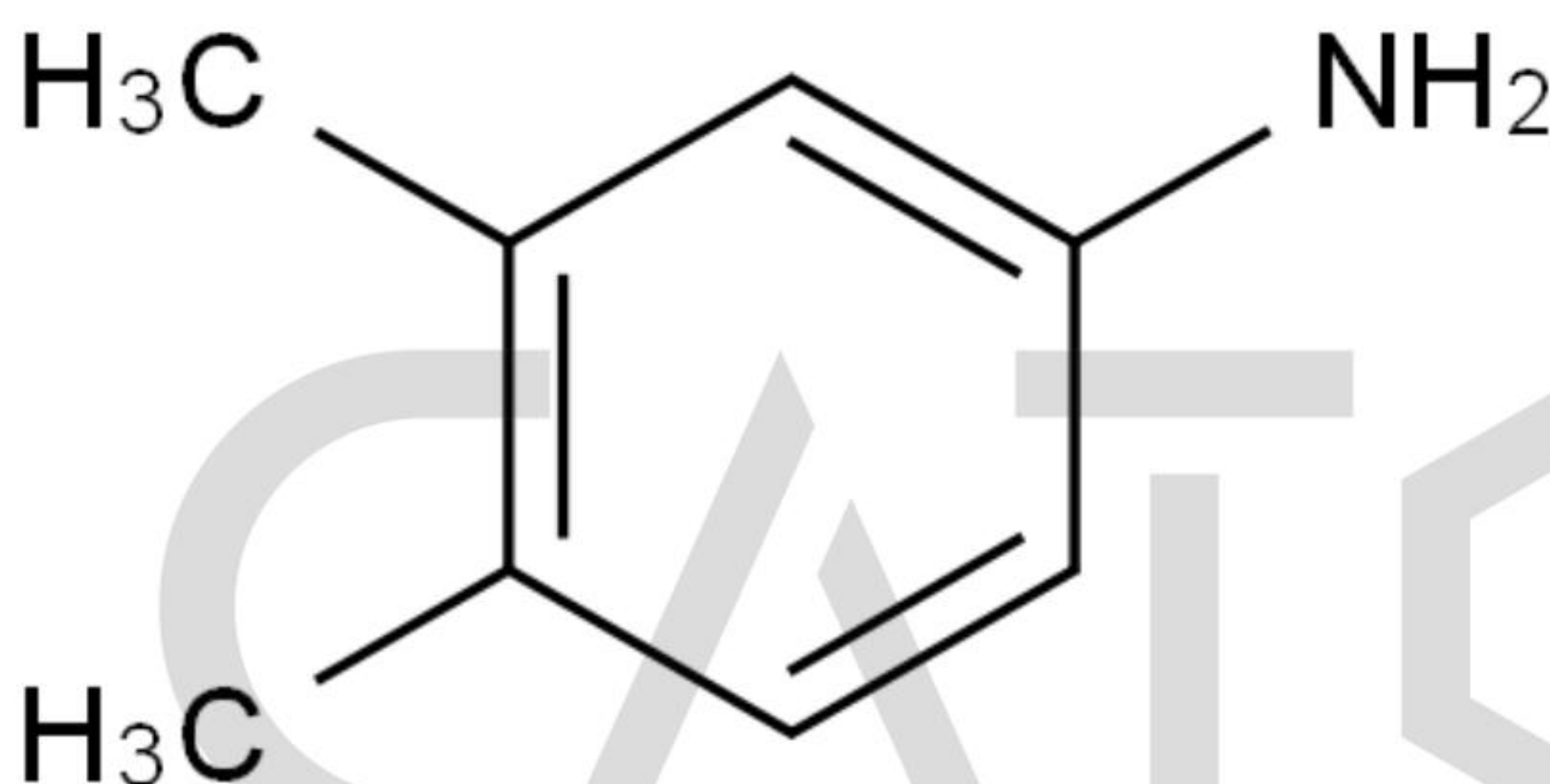
Reference Material & Standard

Product Name:	Dexmedetomidine Impurity 55	Catalogue Number:	C4X-123055
Synonyms:	3,4-Dimethylaniline	Lot Number:	0423-RC-0011
CAS Number:	95-64-7	Expiry Date:	Apr 21, 2030
Molecular Formula:	C ₈ H ₁₁ N	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	121.18	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Crystalline Solid
Identification	GCMS&IR&HNMR	Confirmed
Purity	HPLC	99.9196%
Water Content	Karl Fischer	0.2405%
Assay		99.7%

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: Apr 22, 2026

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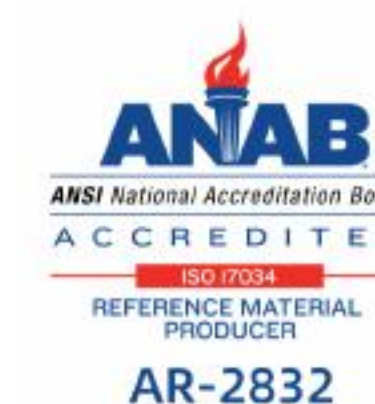
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