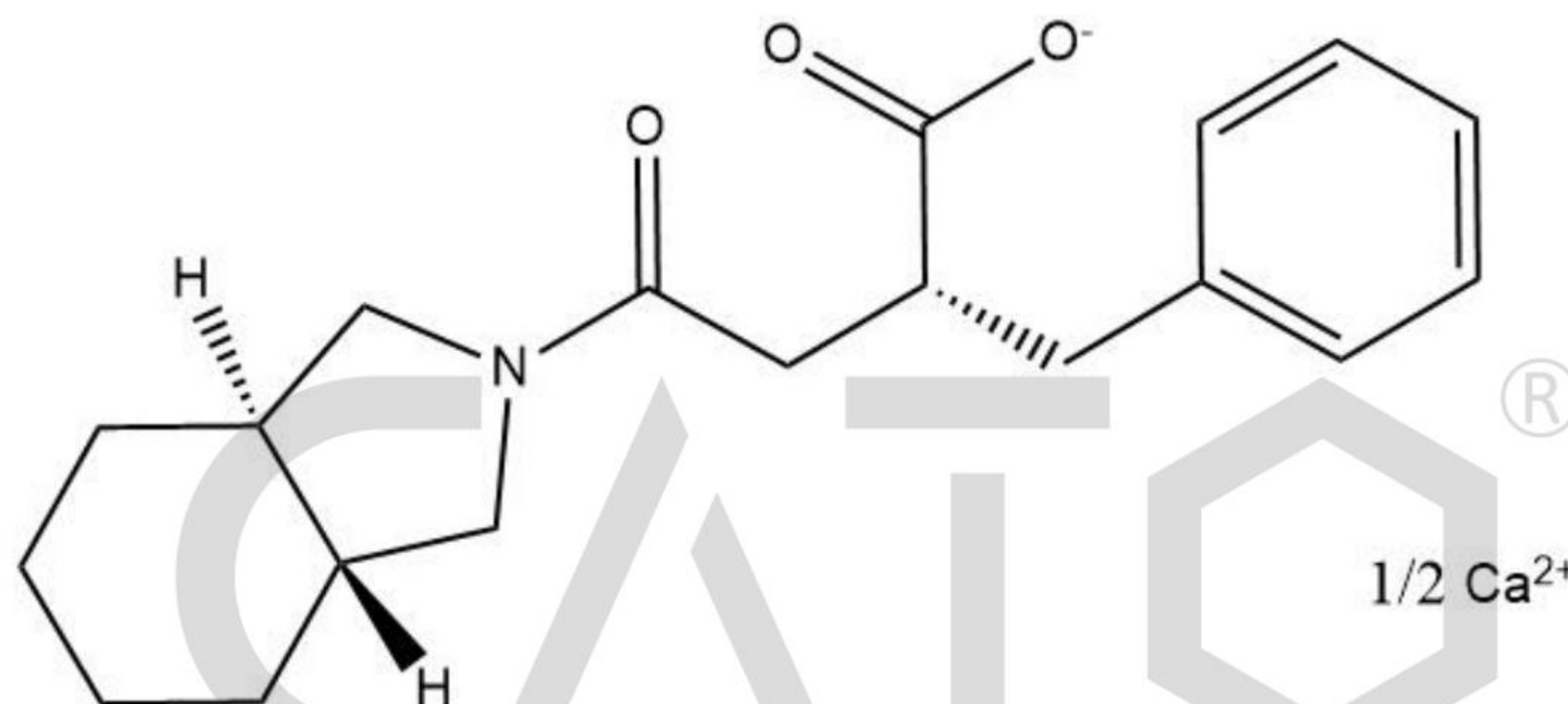


Certificate of Analysis

Reference Material & Standard

Product Name:	Mitiglinide Impurity 5	Catalogue Number:	C4X-11615
Synonyms:	N/A	Lot Number:	0923-RC-0026
CAS Number:	N/A	Expiry Date:	Sep 08, 2024
Molecular Formula:	2*C ₁₉ H ₂₄ NO ₃ Ca	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	314.40 0.5*40.08	Shipping Condition:	Shipping at Room Temperature

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	97.6870%
Water Content	Karl Fischer	6.6%
Residual Solvents	NMR	Not detected in NMR
Specific Rotation		[α] _D 20.0(c=0.35,CH ₃ OH)/-48.9°
Assay		91.2%

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:

Debia

Reviewed by:

Cady

Approved by General Manager:

David

Date: Sep 23, 2021

Date: Sep 26, 2021

Date: Sep 26, 2021

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