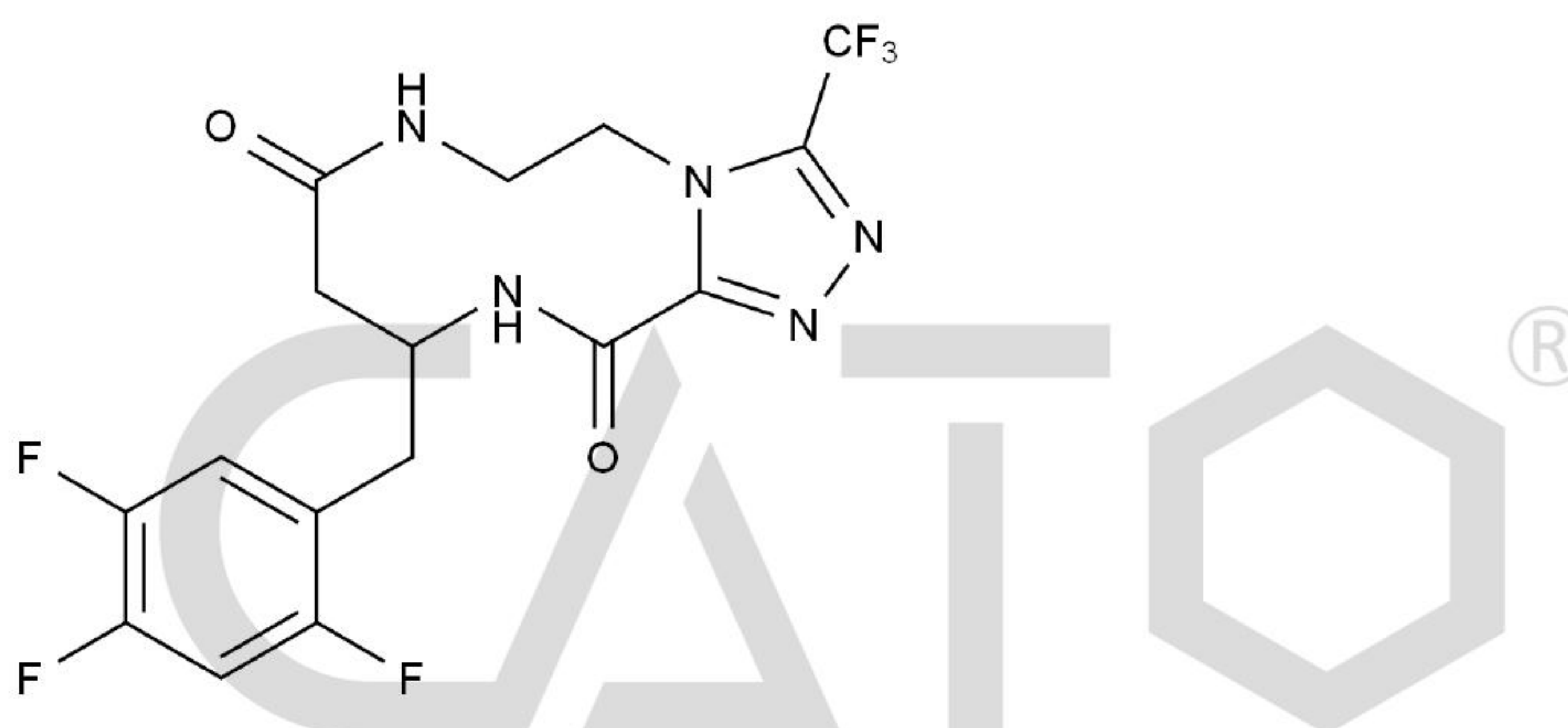


Certificate of Analysis

Reference Material & Standard

Product Name:	Sitagliptin Tablets EP Impurity FP-B	Catalogue Number:	C4X-114466
Synonyms:	N/A	Lot Number:	0428-RG-0088
CAS Number:	2805078-75-3	Expiry Date:	Apr 27, 2028
Molecular Formula:	C ₁₆ H ₁₃ F ₆ N ₅ O ₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	421.30	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.126%
Residue on Ignition	TGA	0.2083%
Loss on Drying	TGA	0.0201%
Assay		98.9%

Comment:

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

Assay (%) = (100% - Residue on Ignition - Loss on Drying) * Purity HPLC (%) / 100%

Residue on Ignition and Loss on Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Apr 29, 2025

Date: Apr 29, 2025

Date: Apr 29, 2025



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