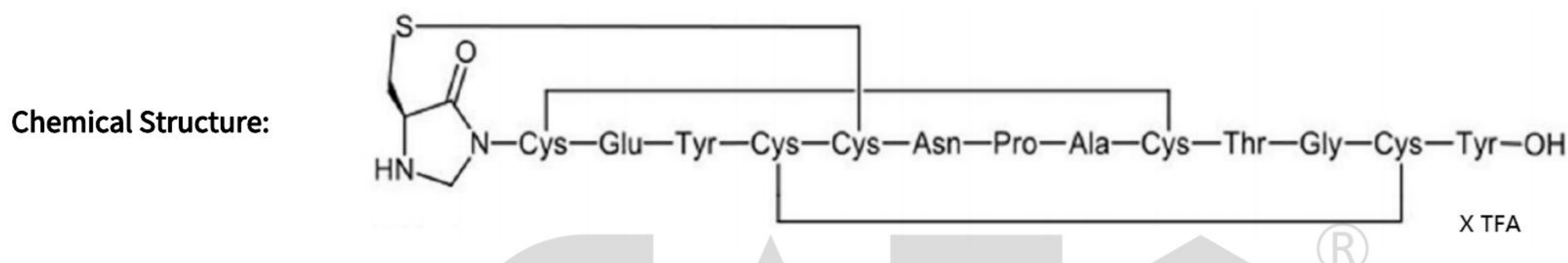


Certificate of Analysis

Reference Material & Standard

Product Name:	Cys1-Linaclotide Imidazolidione Impurity XTFA Salt	Catalogue Number:	C4X-21061
Synonyms:	N/A	Lot Number:	1221-RE-0058
CAS Number:	N/A	Expiry Date:	Dec 25, 2025
Molecular Formula:	C60H79N15O21S6 XC2HF3O2	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	1538.8 X114.0		



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	HRMS&CNMR&HNMR	Confirmed
Purity	HPLC	98.0111%
Water Content	Karl Fischer	4.00%
Residual Solvents	NMR	5.4% trifluoroacetic acid
Assay(Free base)		88.8%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (Free base)(%) = (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:

Koi

Reviewed by:

Lisa

Aporoved by General Manager:

David

Date: Dec 26, 2023

Date: Dec 26, 2023

Date: Dec 26, 2023

