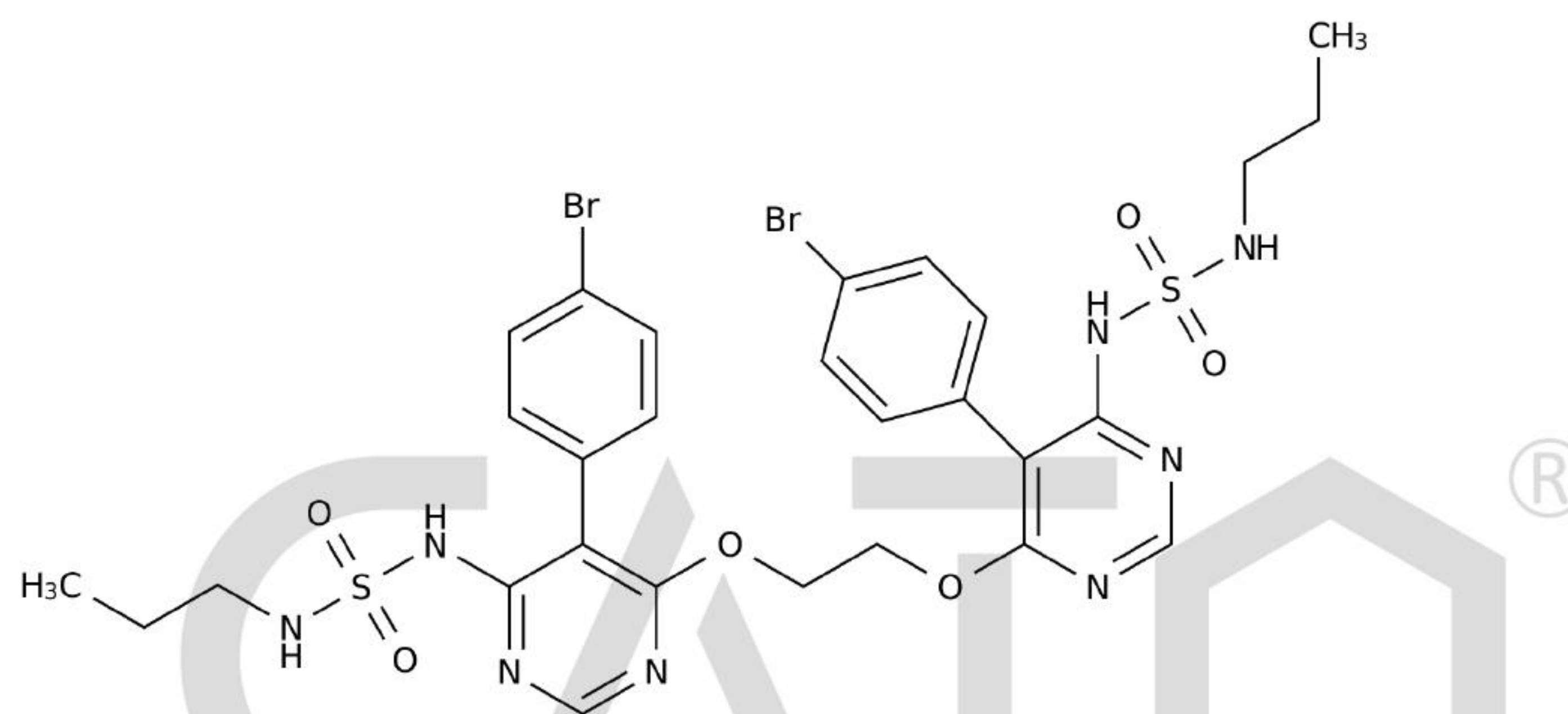


Certificate of Analysis

Reference Material & Standard

Product Name:	Macitentan Impurity 13	Catalogue Number:	C4X-117513
Synonyms:	N/A	Lot Number:	1121-RE-0025
CAS Number:	2089065-77-8	Expiry Date:	Nov 26, 2026
Molecular Formula:	C ₂₈ H ₃₂ Br ₂ N ₈ O ₆ S ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	800.54		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&UV&HNMR	Confirmed
Purity	HPLC	97.686%
Water Content	Karl Fischer	0.35%
Residual Solvents	NMR	Not detected in NMR
Assay		97.3%

Comment:

The calculation of the 100% 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:

Koi

Reviewed by:

Lisa

Aporoved by General Manager:

David

Date: Nov 27, 2023

Date: Nov 27, 2023

Date: Nov 27, 2023

