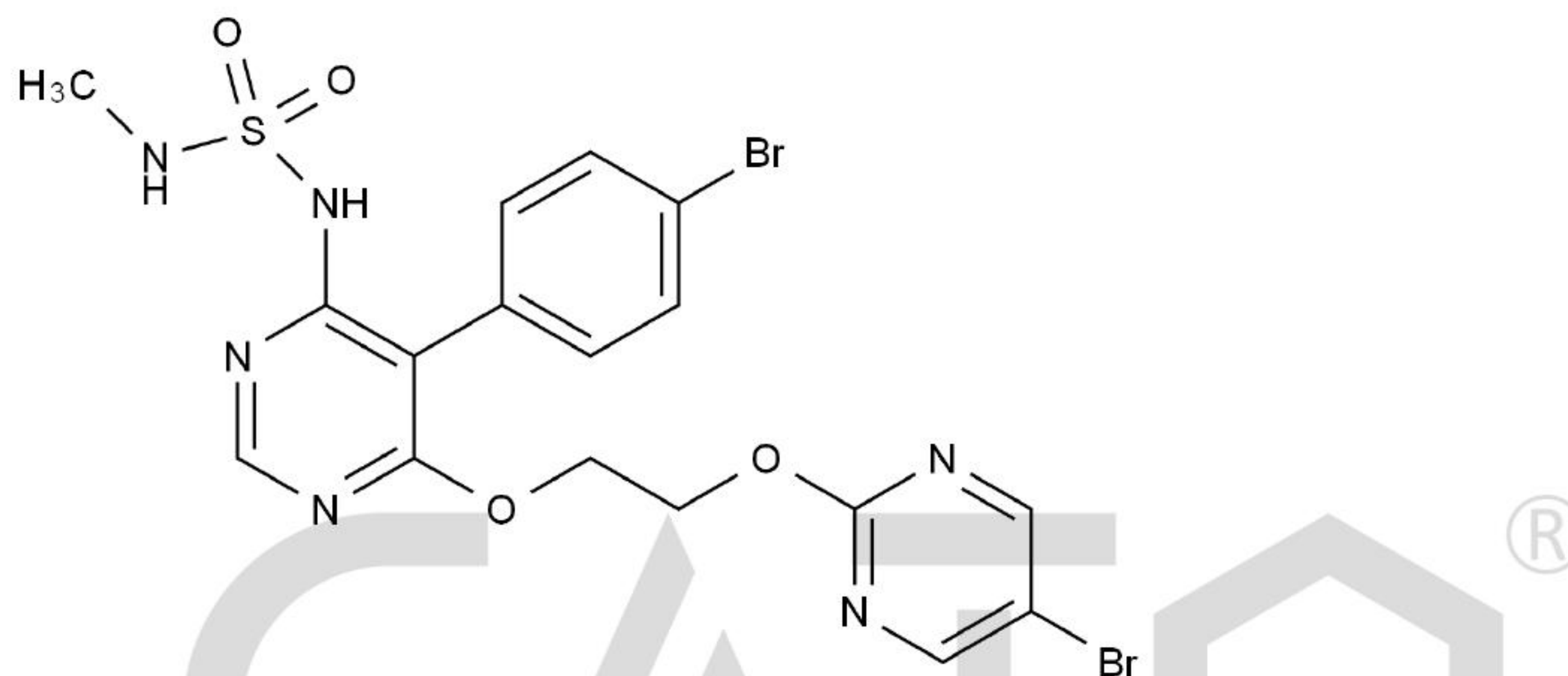


Certificate of Analysis

Reference Material

Product Name:	Macitentan Impurity 1	Catalogue Number:	C4X-11751
Chemical Name:	N/A	Lot Number:	0404-RE-0054
CAS Number:	441798-25-0	Expiry Date:	Mar 21, 2025
Molecular Formula:	C ₁₇ H ₁₆ Br ₂ N ₆ O ₄ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	560.22		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.949%
Water Content	Karl Fischer	0.69%
Assay		98.3%

Comment:

The calculation of the 100% 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:

Nacy

Reviewed by:

Xenia

Aporoved by General manager:

David

Date: Mar 22, 2022

Date: Apr 12, 2023

Date: Apr 12, 2023

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