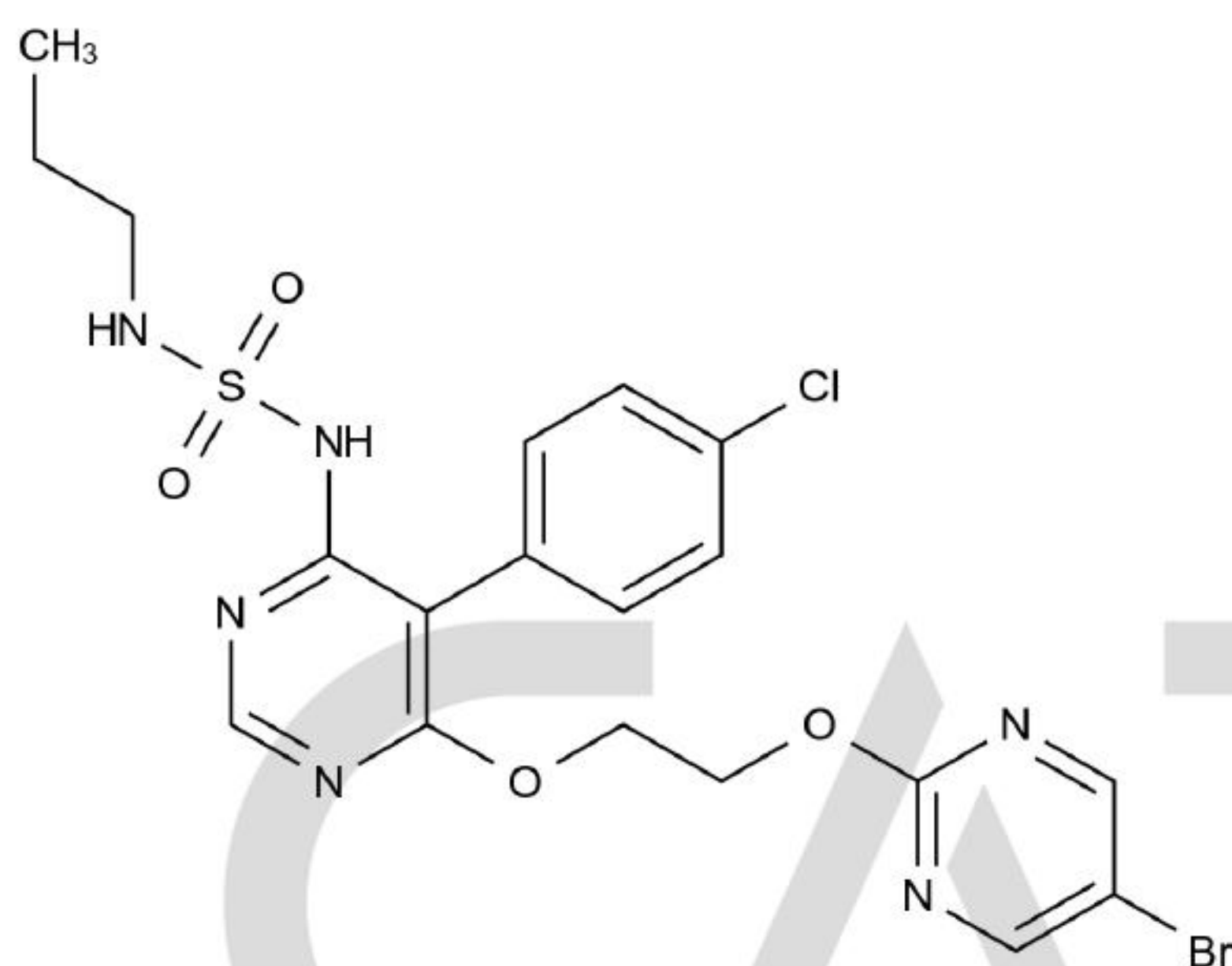


Certificate of Analysis

Reference Material & Standard

Product Name:	Macitentan Impurity 35	Catalogue Number:	C4X-117535
Synonyms:	N/A	Lot Number:	0106-RG-0100
CAS Number:	441798-36-3	Expiry Date:	Apr 14, 2027
Molecular Formula:	C ₁₉ H ₂₀ BrClN ₆ O ₄ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	543.82		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.669%
Water Content	Karl Fischer	0.12%
Residual Solvents	NMR	Not detected in NMR
Assay		99.5%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Jan 06, 2025

Date: Jan 07, 2025

Date: Jan 07, 2025

