

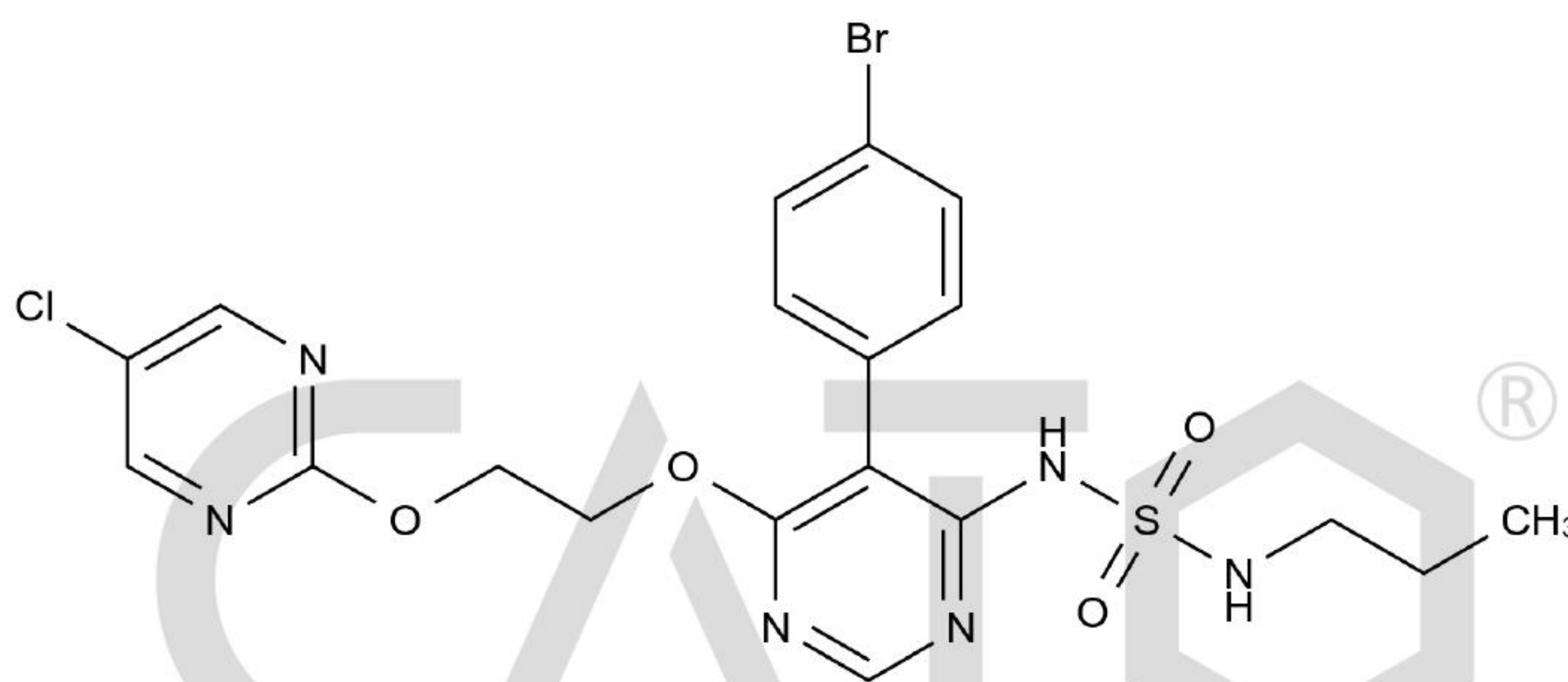
Certificate of Analysis

Reference Material & Standard

Product Name:	Macitentan Impurity N1	Catalogue Number:	C1874651
Synonyms:	N/A	Lot Number:	0113-RG-0109
CAS Number:	2443747-63-3	Expiry Date:	Jan 05, 2028
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	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.679%
Water Content	Karl Fischer	0.35%
Residual Solvents	NMR	Not detected in NMR
Assay		99.3%

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:

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Reviewed by:

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Approved by General Manager:

David

Date: Jan 13, 2025

Date: Jan 13, 2025

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