

## **Certificate of Analysis**

HCI

#### **Reference Material**

#### **Product name**

1-[(2RS)-2-[(5-Bromo-2-chlorothiophen-3-yl)methoxy]-2-(2,4 -dichlorophenyl)ethyl]-1H-imidazole Hydrochloride

**Product code** MM1307.07-0025 **CAS** number not listed

Molecular weight 503.07

Molecular formula  $C_{16}H_{12}BrCl_3N_2OS$ 

Lot number 1028448

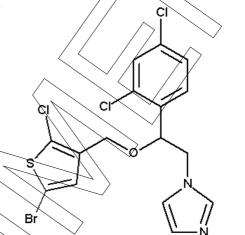
**Appearance** off-white solid

Melting point (DSC)

188 °C

Long-term storage

2 to 8 °C, dark



Assay "as is' **98.8 %** 

Date of shipment:

13 Sep 2019

Producer confirms that this reference makerial (RM) meets the specification detailed on this Certificate of Analysis for one year from the date of shipment, provided the substance is stored under the recommended conditions unopened in the original container.

Date of Release: Release by: Product Release Dr. Sabine Schröder u¢kenwalde, 03 Sep 2019



#### **Product information**

For laboratory use only. Not suitable for human or animal consumption.

Before usage of the RM, it should be allowed to warm to room temperature. No drying required, as the certified value is already corrected for the content of water and other volatile materials.

The product quality is controlled by regularly performed quality control tests (retests).

#### **Further content**

Identity

Assay

Final result

Revision table

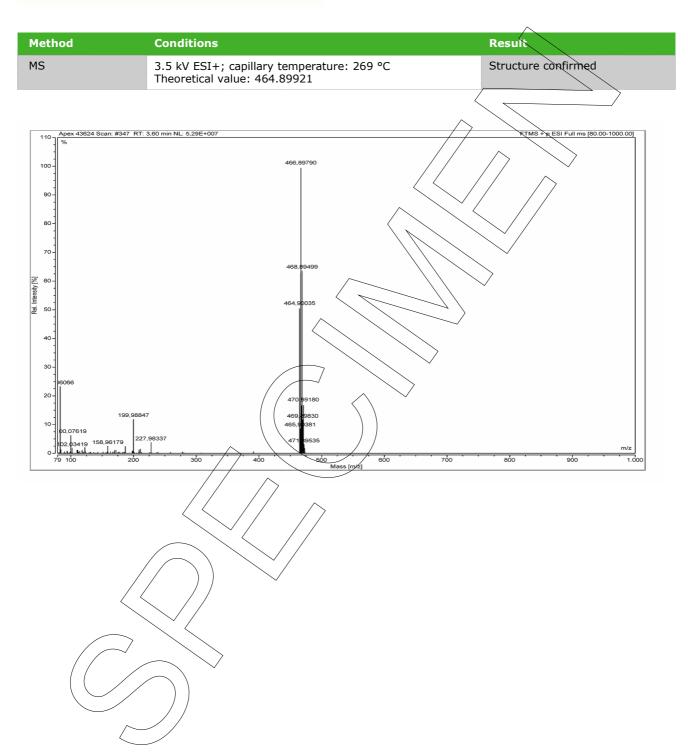


### **Identity**

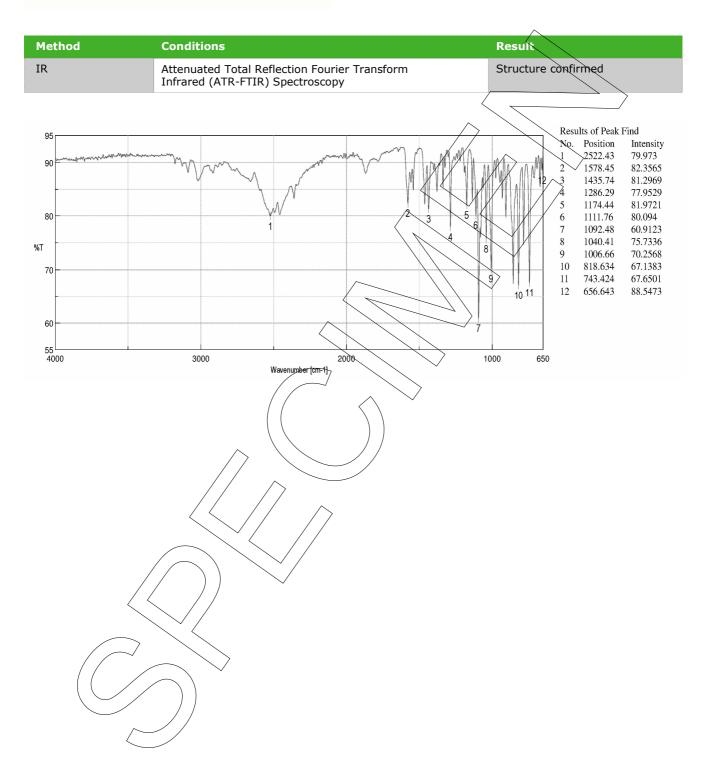
The identity of the reference material was established by following analyses.













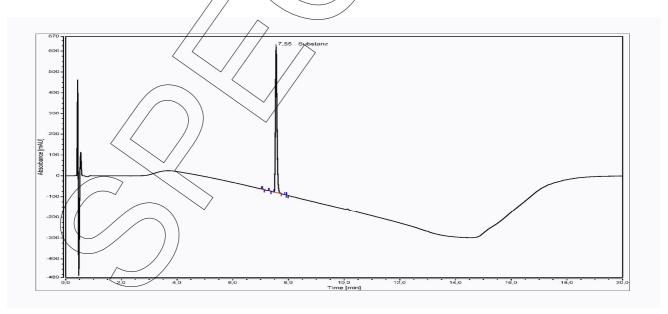
#### **Assay**

The assay of the reference material was assessed by following analyses.

#### Purity by High Performance Liquid Chromatography (HPLC)

HPLC Conditions:	
Column	Cortecs UPLC C18/+; 1.6 µm, 75 x 2.1 mm
Column temperature	40 °C
Detector	DAD, 200 nm
Injector	Auto 1.00 μl; 0.233 mg/ml in Methanol
Flow rate	0.5 ml/min
Phase A	Water, 0.1 % HCOOH
Phase B	Acetonitrile, 0.1 % HCOOH
Gradient program	0-1 min A/B 98/2
	1-11 min A/B to 2/98
	11-13 min A/B 2/98
	13-15 min A/B to 98/2
	15-20 min A/B 98/2 (v/v)

HPLC chromatogram and peak table



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Area percent repo			
Pk #	Retention time	Area	Area %
1	7.067	0.1316	0.28
2	7.313	0.0767	0.17
3	7.553	46.1560	99.39
4	7.863	0.0208	0.04
5	7.940	0.0539	0.12
Totals		46.439	100.00

The content of the analyte was determined as ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %. System peaks were ignored in calculation.

Result (n = 3) 99.38 %; SD = 0.02 %

#### **Volatile content**

Water content		
Method	/Kar	I Fischer zitration
Result (n = 3)	0.5	4 %, SD = 0.02/%

# Residual solvents Method Property (No significant amounts of residual solvents were detected (< 0.05 %).



#### **Final result**

Assay "as is":

98.84 %

The assay "as is" is assessed by 100% method (mass balance) and is equivalent to the assay based on the not anhydrous and not dried substance respectively.

The calculation of the 100% method follows the formula:

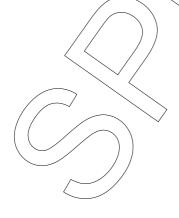
Assay (%) = (100 % - volatile contents (%)) \* 
$$\frac{\text{Purity (\%)}}{100 \%}$$

Volatile contents are considered as absolute contributions and purity is considered as relative contribution. Inorganic residues are excluded by additional tests.

#### **Revision table**

Revision	Date	Reason	for revision			
00	03 Sep 2019	Release	of the Certifical	te of A	Analysis - initial version	

Product warranties for the RM are set out in the terms and conditions of purchase.



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