

## Certificate of Analysis.

### Rivaroxaban secondary standard, certified reference material (CRM).

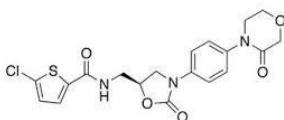
Product code:	<b>BS16154.</b>
Description:	<b>Rivaroxaban secondary standard, certified reference material (CRM).</b>
Synonym:	<b>(S)-5-Chloro-N-[[2-oxo-3-[4-(3-oxomorpholino)phenyl]oxazolidin-5-yl]methyl]thiophene-2-carboxamide.</b>
Pack:	<b>1 gm.</b>
CAS NO.:	<b>366789-02-8.</b>
Mol. Weight:	<b>435.88 g/mol.</b>
Mol. Formula:	<b>C<sub>19</sub>H<sub>18</sub>ClN<sub>3</sub>O<sub>5</sub>S.</b>
MDL Number:	<b>MFCD11974010.</b>
Melting Point:	<b>232 °C.</b>
Boiling Point:	<b>732.6 °C</b>
Density:	<b>1.460 g/cm<sup>3</sup>.</b>
Solubility:	<b>Soluble in DMSO.</b>
Storage:	<b>Store at 2-8°C Refrigerator.</b>
Batch No:	<b>Sample.</b>
Manufacture Date:	<b>Lot specific.</b>
Expiry Date:	<b>3 years.</b>

Test	Specification	Measured Values
Appearance:	White to Light yellow powder to crystal.	<b>Lot specific.</b>
Identification by NMR:	Confirms to the structure.	<b>Lot specific.</b>
Identification by MASS:	Confirms to the structure.	<b>Lot specific.</b>
Identification by IR:	Confirms to the structure.	<b>Lot specific.</b>

#### Comparative Purity:

Test	In-house LOT (Lot specific)	USP LOT (Lot specific)
Purity by HPLC:	<b>Lot specific.</b>	<b>Lot specific.</b>

Please Note: - This material is only for laboratory purpose and not for human consumption.



#### Certification & Traceability:

This product was manufactured, processed and/or certified under a quality management system that is complies with ISO 17034:2016 and ISO/IEC 17025:2017. This standard has been gravimetrically



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prepared Using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.

All standard components used in the manufacture of this product are pre-qualified and verified before use. Tests were performed for capacity, readability, repeatability and linearity.

This product is manufactured, packaged, stored, and shipped in accordance with good manufacturing practices that is certified to WHO-GMP. The uncertainty associated with each certified value represents the expanded uncertainty at the 95% confidence level using a coverage factor of  $k=2$ .

**Instructions for handling and correct use:** The internal pressure of the container may be slightly different from the atmospheric pressure at the users location. Open slowly and carefully to avoid dispersion of the material.

#### Validity Period:

Briti Scientific standards ensures the accuracy of this product for 5 years from the manufacture date given above, provided the instructions for use are followed.

#### Quality Certifications:

This product was prepared under a quality management system that is Complies with the following:

**ISO 17034:2016:** Reference Materials Producer, CGI Certificate No. WGMP/22N2594 – General Requirements for the Competence of Reference Material Producers.

ISO 17034 references additional requirements specified in ISO Guide 31 and ISO Guide 35.

**ISO/IEC 17025:2017:** Chemical Testing, CGI Certificate No. UG/23N256- General Requirements for the Competence of Testing and Calibration Laboratories

**ISO 9001:2015 Certified:** Quality Management Systems, CGI Certificate No. QMS/23N258.

**WHO-GMP Certified:** Good Manufacturing Practices, CGI Certificate No. WGMP/22N2594.

#### Homogeneity:

This product was determined to be homogenous by procedures consistent with the requirements of ISO 17034 and ISO Guide 35. Replicate samples of the finished solution were analysed to confirm its homogeneity, in accordance with internal procedures for the assessment of homogeneity and stability.





### Health and Safety Information:

Refer to the Safety Data Sheet (SDS), which can be obtained at [www.britisscientific.com](http://www.britisscientific.com).

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