

Certificate of Analysis

Reference Material & Standard

Product Name:	Gemcitabine-13C,15N2 Hydrochloride	Catalogue Number:	CCAD303806
Synonyms:	N/A	Lot Number:	1212-SA-7151
CAS Number:	1262897-74-4	Expiry Date:	Dec 11, 29
Molecular Formula:	N/A	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	N/A		

Chemical Structure: N/A

Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification:	LC&HNMR	Confirmed
Purity:	HPLC	98.498%
Uncertainty		±2.0%

Comment:

The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

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Reviewed by:

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Approved by General Manager:

David

Date: Dec 12, 25

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Directions:

1. *Intended use: This product is suitable for identification and quantification of the analyte(s), instrument calibration, method development and quality control in analytical and R&D applications. It is not intended for administration to humans or animals, and shall not be used to diagnose, treat or cure any diseases.*
2. *Minimum sample size: 1mg is recommended as the minimum sample size.*
3. *Metrological traceability: This product meets the requirements of ISO 17034 and is traceable to NMI through an unbroken chain of comparisons.*
4. *Instructions for handling and correct use: Handling in a well-ventilated place.*

Document Version:

Revision No.	Date	Reason for Revision
01	Dec 12, 25	First release.

