









Registered Address: Chemicea Pharmaceuticals Pvt Ltd, Platinum Springs,

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CERTIFICATE OF ANALYSIS

Analysis Date: Sep 2022 Re-test Date: Aug 2025

Product Name: Gemcitabine EP Impurity B

Identification:

Chemical Name: 4-Amino-1-((2S,4R,5R)-3,3-difluoro-4-hydroxy-5-(hydroxymethyl)tetrahydrofuran-2-yl)pyrimidin-2(1H)-

one

Synonyms : Gemcitabine α -anomer

CAS Number : 95058-85-8

CAT Number : CP-G7002

Molecular Formula : C9H11F2N3O4

Molecular Weight : 263.20

Batch Number : CHEM-GEM-B

Storage Condition : Tightly closed, Inert atmosphere at 2 to 8° C

Shipping condition : All Products are stable to be shipped at room temperature, if specific condition required it is

mention in the COA

Analytical Information:

Sr. No.	Test	Result
1)	Description	White Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	95.09%
5)	H1NMR	Confirm to structure
6)	13CNMR	Confirm to structure



Prepared and Reviewed By

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Ms Priyanka Salunkhe (Manager QC Analytical) **Approved By**



Ms Rohini Gagare (QA Head)

Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions.