

Certificate of Analysis

Product Name: Gemcitabine hydrochloride

Catalog No.: 3259

Batch No.: 3

CAS Number: 122111-03-9

IUPAC Name: (+)-2'-Deoxy-2',2'-difluorocytidine hydrochloride

1. PHYSICAL AND CHEMICAL PROPERTIES

Batch Molecular Formula: C₉H₁₁F₂N₃O₄·HCl

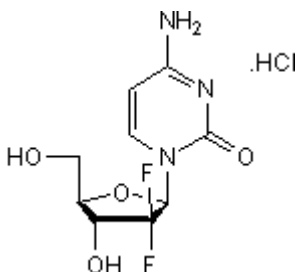
Batch Molecular Weight: 299.66

Physical Appearance: White solid

Solubility: water to 100 mM
DMSO to 20 mM

Storage: Desiccate at +4°C

Batch Molecular Structure:



2. ANALYTICAL DATA

HPLC: Shows 99.9% purity

¹H NMR: Consistent with structure

Mass Spectrum: Consistent with structure

Optical Rotation: [α]_D = +49.4 (Concentration = 1, Solvent = Water)

Microanalysis:

Carbon Hydrogen Nitrogen

	Carbon	Hydrogen	Nitrogen
Theoretical	36.07	4.04	14.02
Found	36.07	3.92	13.77

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IUPAC Name: (+)-2'-Deoxy-2',2'-difluorocytidine hydrochloride

Description:

Deoxycytidine analog that inhibits DNA synthesis. Metabolized to form gemcitabine triphosphate (dFdCTP) and gemcitabine diphosphate (dFdCDP). dFdCTD inhibits ribonucleotide reductase causing a reduction in cellular nucleotides. dFdCTP is incorporated in DNA resulting in DNA strand termination. Displays antitumor activity in vitro and in vivo.

Physical and Chemical Properties:

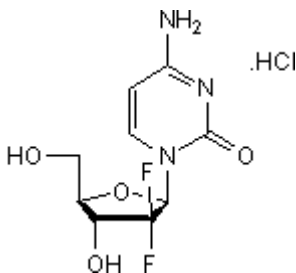
Batch Molecular Formula: C₉H₁₁F₂N₃O₄.HCl

Batch Molecular Weight: 299.66

Physical Appearance: White solid

Minimum Purity: >99%

Batch Molecular Structure:



Storage: Desiccate at +4°C

Solubility & Usage Info:

water to 100 mM

DMSO to 20 mM

Stability and Solubility Advice:

Some solutions can be difficult to obtain and can be encouraged by rapid stirring, sonication or gentle warming (in a 45-60°C water bath).

Information concerning product stability, particularly in solution, has rarely been reported and in most cases we can only offer a general guide. Our standard recommendations are:

SOLIDS: Provided storage is as stated on the product label and the vial is kept tightly sealed, the product can be stored for up to 6 months from date of receipt.

SOLUTIONS: We recommend that stock solutions, once prepared, are stored aliquoted in tightly sealed vials at -20°C or below and used within 1 month. Wherever possible solutions should be made up and used on the same day.

References:

Heinemann et al (1995) Gemcitabine: a modulator of intracellular nucleotide and deoxynucleotide metabolism. *Semin.Oncol.* **22** (Suppl. 11) 11. PMID: 7481839.

Plunkett et al (1995) Preclinical characteristics of gemcitabine. *Anticancer Drugs* **6** (Suppl. 6) 7. PMID: 8718419.

Hertel et al (1990) Evaluation of the antitumor activity of Gemcitabine (2',2'-Difluoro-2'-deoxycytidine). *Cancer Res.* **50** 4417. PMID: 2364394.

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