



CERTIFICATE OF ANALYSIS
Gemcitabine Hydrochloride

TEST	SPECIFICATION	RESULT
Description	White or almost white crystalline powder	Conforms
Identification A	Infrared Absorption	Conforms
Identification B	Meets the requirements of the tests for Chloride	Conforms
Specific optical rotation	Between +43° and +50°	+48°
Residue on ignition	Not more than 0.1%	0.07%
Heavy metal	Not more than 0.001%	Conforms
PH	2.0-3.0	2.6
Cytosine	≤0.1	0.01%
α-anomer	≤0.1	0.01%
Total impurities	≤0.2	0.09%
Assay	Between 97.5% to 101.5%	99.9%

CONCLUSION: Conform to USP28