

Mac-chem Products (India) Pvt Ltd
Quality Control Department
Certificate of Analysis

MAC

Product Name	Cytarabine	Batch No.	CYD0225003
Pharmacopoeia	BP/Ph.Eur.	Batch Qty.	82.06 KGS
CAS. No.	147-94-4	Approved On	25/03/2025
Mfg. Date	Mar 2025	TO. No.	TO2503086
Exp. Date	Feb 2030		

NO	TESTS	SPECIFICATIONS	RESULTS
1	Appearance (BP/Ph.Eur.)	A white or almost white, crystalline powder.	A white crystalline powder
2	Solubility (BP/Ph.Eur.)	Freely soluble in water, Practically insoluble in ethanol (96 percent) and in methylene chloride	Complies
3	Identification (BP/Ph.Eur.)		
a	By Infrared absorption	Test infrared spectrum of the sample should concordant with the infrared spectrum of the Cytarabine working/reference standard obtained in same manner.	Complies
4	Melting point (BP/Ph.Eur.)	Melts at about 215°C	214.50°C
5	Appearance of solution (BP/Ph.Eur.)	The solution should be clear and not more intensely coloured than reference solution Y5	Complies
6	Specific optical rotation (BP/Ph.Eur.)	Between + 154.0° to + 160.0° on dried substance.	+155.36°
7	Sulfated ash (BP/Ph.Eur.)	Not more than 0.5 %	0.06%
8	Loss on drying (at 60° for 3 hours) (BP/Ph.Eur.)	Not more than 1.0 %.	0.37%
9	Related substances (By HPLC) (BP/Ph.Eur.)		
a	Impurity A (Uracil Arabinoside)	Not more than 0.15%	0.068%
b	Unspecified impurities	Not more than 0.05%	BDSL
c	Total impurities	Not more than 0.3%	0.068%
10	Assay (By Potentiometry) (BP/Ph.Eur.)	Not less than 99.0 per cent and not more than the 101.0 per cent, calculated with reference to the dried substance.	100.70%
11	Residual solvents (By GCHS) (ICH) (IH)		
a	Methanol	Not more than 3000 ppm	91 ppm
b	Acetone	Not more than 5000 ppm	Not detected
c	Isopropyl alcohol	Not more than 5000 ppm.	15 ppm
d	1,4 Dioxane	Not more than 380 ppm.	Not detected
12	Bacterial Endotoxin test (IH)	Not more than 0.07 EU/mg	Less than 0.07 EU/mg
13	Microbial enumeration test (IH)		
a	Total aerobic microbial counts	Not more than 100 cfu/g	Less than 10 cfu/g
b	Total combined yeast and mould count	Not more than 10 cfu/g	Less than 10 cfu/g

Remark : The Product complies the prescribed standards of quality as per BP/Ph.Eur. Specification.

Storage Condition : Store in airtight containers, protected from light, not exceeding 30°C.

Prepared By : Mayuri Wade
 Designation : Sr. Officer - QC
 Date : 25/03/2025

Checked By : Pravin Dhole
 Designation : Asst. Manager - QC
 Date : 25/03/2025

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 Designation : Manager - QC
 Date : 25/03/2025

