

Mac-chem Products (India) Pvt Ltd

Quality Control Department

Certificate of Analysis

MAC

MAC-CHEM PRODUCTS
(INDIA) PVT. LTD.

Product Name	Cytarabine	Batch No.	CYT0217009
Pharmacopoeia	BP/Ph.Eur.	Batch Qty.	36.44 KGS
CAS. No.	147-94-4	Approved On	03/10/17
Mfg. Date	Sep 2017	TO. No.	TO1803907
Retest Date	NA		
Exp. Date	Aug 2021		

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, very slightly soluble in alcohol and in methylene chloride.	Complies
3	Identification (BP/Ph.Eur.)		
a	By U.V. Spectrophotometer	The Solution should show an absorption maximum at 281 nm. The specific absorbance at the maximum should be between 540 and 570	Complies
b	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
c	By TLC	The principal spot in the chromatogram obtained with test solution (b) should be similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	Complies
4	Melting point (BP/Ph.Eur.)	Melts at about 215°C	213.2°C
5	Appearance of solution (BP/Ph.Eur.)	The solution should be clear and not more intensely coloured than reference solution Y ₅	Complies
6	Specific optical rotation (BP/Ph.Eur.)	Between + 154.0° to + 160.0° on dried basis.	+156.07°
7	Sulfated ash (BP/Ph.Eur.)	Not more than 0.5 %	0.19%
8	Loss on drying (at 60° for 3 hours) (BP/Ph.Eur.)	Not more than 1.0 %.	0.58%
9	Related substances (By TLC) (BP/Ph.Eur.)	Not more than 0.5 %	Less than 0.5%
10	Assay (Potentiometry) (BP/Ph.Eur.)	Not less than 99.0 per cent and not more than the equivalent of 100.5 per cent of 4-amino-1-β-D-arabinofuranosylpyrimidin-2(1H)-one, calculated with reference to the dried substance.	99.97%
11	Residual solvents (By GCHS) (ICH) (IH)		
a	Methanol	Not more than 3000 ppm	89 ppm
b	Acetone	Not more than 5000 ppm	BDL
c	Isopropyl alcohol	Not more than 5000 ppm.	32 ppm
d	1,4 Dioxane	Not more than 380 ppm.	BDL

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www.macchemgroup.com

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Remark : The Product complies the prescribed standards of quality as per BP/Ph.Eur. specification No. FPSTP00006-06

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

Prepared By : Tukaram Badhe	Checked By : Mrunali Patil	Approved By : Pinank Raval
Designation : Executive - QC	Designation : Sr. Executive - QC	Designation : Asst. Manager - QC
Date : 18/10/2017	Date : 18/10/2017	Date : 18/10/2017



Date: 21/12/2017

TO WHOMSOEVER IT MAY CONCERN

Name of Product: **Cytarabine**

We, **Mac- Chem Products (India) Pvt. Ltd.**, hereby declare and certify that during packing of our product **Cytarabine** no silica gel bags have been put inside the packing.

For M/ac-Chem Products (I) Pvt. Ltd.,

Grey 21/12/2017.
Name : Mr. R. Prem kumar

Designation : Asst. Manager - QA

Company seal:

