



Mac-chem Products (India) Pvt Ltd

Quality Control Department

Certificate of Analysis

Product Name	Cytarabine	Batch No.	CYD0220005
Pharmacopoeia	BP/Ph.Eur.	Batch Qty.	75.25 KGS
CAS. No.	147-94-4	Approved On	12/06/2020
Mfg. Date	May 2020	TO. No.	TO2100538
Retest Date	NA		
Exp. Date	Apr 2025		

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	215.00°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.	+157.04°
7	Sulfated ash (BP/Ph.Eur.)	Not more than 0.5 %	0.08%
8	Loss on drying (at 60° for 3 hours) (BP/Ph.Eur.)	Not more than 1.0 %.	0.34%
9	Related substances (By HPLC) (BP/Ph.Eur.)		
a	Impurity A	Not more than 0.15%	0.106%
b	Unspecified impurities	Not more than 0.05%	0.038%
c	Total impurities	Not more than 0.3%	0.144%
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.	99.73%
11	Residual solvents (By GCHS) (ICH) (IH)		
a	Methanol	Not more than 3000 ppm	92 ppm
b	Acetone	Not more than 5000 ppm	Not detected
c	Isopropyl alcohol	Not more than 5000 ppm.	9 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

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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 : Ramool Chaudhari

Designation : Sr. Executive - QC

Date : 10/09/2020

Checked By : Sachin Gapat

Designation : Asst. Manager - QC

Date : 10/09/2020

Approved By : Ankush Dalvi

Designation : Dy. Manager - QC

Date : 10/09/2020

