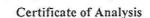
## Mac-chem Products (India) Pvt Ltd Quality Control Department





| 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.)                      |   |                            |
| а  | 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)<br>(BP/PH.EUR.)     |   |                            |
| a  | Impurity A (Uracil Arabinoside)                  | Not more than 0.15%   | 0.068%                     |
| b  | Unspecified impurities                           | Not more than 0.05%   | BDSL                       |
| С  | Total impurities                                 | Not more than 0.3%  | 0.068%                     |
| 10 | Assay (By Potentiometry)<br>(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)<br>(ICH) (IH)        |   |                            |
| а  | Methanol   | Not more than 3000 ppm  | 91 ppm                     |
| ь  | Acetone  | Not more than 5000 ppm  | Not detected               |
| С  | 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

Checked By : Pravin Dhole

Approved By : Sunil Bhosale

Designation

: Sr. Officer - QC

Designation : Asst. Manager - QC

Designation

Date

: Manager - QC

: 25/03/2025

Date

: 25/03/2025

Date

25/03/2025

Office: 208, Town Centre, Andheri-Kurla Road, Andheri (E), Mumbai - 400059, INDIA. T.: +91 224093 9000

Factory: N-211/2/10, Tarapur MIDC, Boisar, Dist. Palghar, Pin - 401506, INDIA. T.: +91 7770016606 / 7770016607 / 02525 661120

www.macchemgroup.com

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