# KWALITY PHARMACEUTICALS LIMITED

1-A,INDUSTRIAL AREA, RAJA KA BAGH,TEHSIL NURPUR,KANGRA-176201 (INDIA)

## DEPARTMENT : QUALITY CONTROL

## FINISHED PRODUCT COA

| | | | |
|---|---|---|---|
| **Product Name** | Ifosfamide For Injection USP 1000 mg/vial | **A. R. Number** | KPH/21/FPO/153 |
| **Batch Number** | OL0241 | **Sample Received on** | 07/09/2021 |
| **Date of Mfg.** | 09/2021 | **Batch Size** | 1200 Vials |
| **Date of Exp.** | 08/2024 | **Specification No.** | KPL/SPC/IN/074-03 |
| **Date of Analysis** | 07/09/2021 | **Date of Release** | 07/10/2021 |

| Sr. No | Test | Specification | Result |
|---|---|---|---|
| 1. | **Description** | | |
| | **Before reconstitution** | White to off white cake filled in clear moulded glass vial USP Type I. | White cake filled in clear moulded glass vial USP Type I. |
| | **After reconstitution** | A clear colourless solution should be produced after reconstitution with water for injection. | A clear colourless solution is produced after reconstitution with water for injection. |
| 2. | **Identification** | | |
| | **By TLC** | The $R_f$ value of the principal spot obtained from the test solution corresponds to that obtained from the standard solution. | Complies |
| | **By HPLC** | As in assay; the retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation, both relative to the internal standard. | Complies |
| 3. | **pH** | 4.0 to 7.0 | 5.479 |
| 4. | **Reconstitution Time** | NMT 2 min. | 30 seconds |
| 5. | **Completeness and clarity of solution** | The solution should be clear and colorless after reconstitution and it should not significantly less clear than an equal volume of diluents. | Complies |
| 6. | **Uniformity of Dosage Units** | For L1 Stage, AV = NMT 15 and For L2 Stage, AV= NMT 25 | AV=10.39 |
| 7. | **Bacterial Endotoxins Test** | NMT 0.125 IU/ mg | Less than 0.124 IU/mg |
| 8. | **Sterility** | Should be sterile | Complies |
| 9. | **Particulate Matter** | For 10µm to less than 25 µm – NMT 6000 particles | 1113 particles |

| | | | | | |
|---|---|---|---|---|---|
| Prepared By Sign./Date | 13/06/24 | Reviewed By Sign./Date | 13/06/24 | Approved By Sign./Date | 13/06/24 |
| Name | Anil Pathania | Name | Narender Jamwal | Name | Brijesh Pandey |
| Designation | Sr. Executive | Designation | Sr. Manager | Designation | Sr. Manager |

# KWALITY PHARMACEUTICALS LIMITED

1-A,INDUSTRIAL AREA , RAJA KA BAGH,TEHSIL NURPUR,KANGRA-176201
(INDIA)

**DEPARTMENT : QUALITY CONTROL**

**FINISHED PRODUCT COA**

| | | | |
|---|---|---|---|
| **Product Name** | Ifosfamide For Injection USP 1000 mg/vial | **A. R. Number** | KPH/21/FPO/153 |
| **Batch Number** | OL0241 | **Sample Received on** | 07/09/2021 |
| **Date of Mfg.** | 09/2021 | **Batch Size** | 1200 Vials |
| **Date of Exp.** | 08/2024 | **Specification No.** | KPL/SPC/IN/074-03 |
| **Date of Analysis** | 07/09/2021 | **Date of Release** | 07/10/2021 |

| Sr. No | Test | Specification | | Result |
|---|---|---|---|---|
| | | For 25µm or greater – NMT 600 particles | | 10 particles |
| **10.** | **Water Determination** | Not more than 0.3 % | | 0.1766% |
| **11.** | **Assay:-Each vial contains-** | | | |
| | **Active Ingredient** | **Label Claim** | **Limit** | **Result** |
| | **Ifosfamide USP** | 1000 mg | 90.0% to 110.0% | 1016.70 mg (101.7%) |

**Remarks:** In the opinion of undersigned the product complies/~~does not comply~~ with ~~IP/BP~~/USP/In House specification.

| | | | | | |
|---|---|---|---|---|---|
| Prepared By Sign./Date | 13/06/24 | Reviewed By Sign./Date | 13/06/24 | Approved By Sign./Date | 13/06/24 |
| Name | Anil Pathania | Name | Narender Kumar | Name | Bishwajit Pandit |
| Designation | Sr. Executive | Designation | Sr. Manager | Designation | Sr. Manager |