kaliberr

# QUALITY CONTROL
# CERTIFICATE OF ANALYSIS
# (FINISHED PRODUCT)

| Format No.: KBPL/QC/030/F03-01 | | | |
|---|---|---|---|
| **Product Name** | **VORICONAZ 200 mg** | | |
| **Generic Name** | **Voriconazole Injection IP 200 mg per vial** | | |
| **Batch No.** | K10824005 | **A.R. No.** | FP/06/24/00012 |
| **Mfg. Date** | Jun-2024 | **Sampling Quantity** | 65 vials |
| **Exp. Date** | May-2026 | **Sampling Date** | 13/06/2024 |
| **Batch Size** | 5000 vials | **Date of Analysis** | 13/06/2024 |
| **Pack Quantity** | NA | **Date of Release** | 27/06/2024 |
| **Ref. Spec. No.** | FP/SPC/0024-00 | **Page No.** | Page 1 of 2 |
| **Pack Size/Type** | 1 Combipack | | |

| Sr. No. | Test | Specification | Result |
|---|---|---|---|
| 1. | **Description** | A white powder or cake. | A white cake. |
| 2. | **pH** | 5.0 -7.0. | 6.5 |
| 3. | **Identification** | | |
| | **By Assay** | The principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. | Complies |
| 4. | **Related substances (By HPLC)** | Area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (c) (0.5 %) | Not detected |
| | | Sum of areas of all the secondary peaks is not more than 4 times the area of the principal peak in the chromatogram obtained with reference solution (c) (2.0 %) | Not detected |
| 5. | **Uniformity of weight** | Only for information. | 3.1 gm |
| 6. | **Particulate Matter** | | |
| | **≥ 10 µm** | NMT 6000 no. of particles per container | 267 particles per container |
| | **≥ 25 µm** | NMT 600 no. of particles per container | 3 particles per container |

Kaliberr BioScience Pvt. Ltd.

kaliberr

# QUALITY CONTROL
# CERTIFICATE OF ANALYSIS
# (FINISHED PRODUCT)

| Format No.: KBPL/QC/030/F03-01 | | | |
|---|---|---|---|
| **Product Name** | **VORICONAZ 200 mg** | | |
| **Generic Name** | **Voriconazole Injection IP 200 mg per vial** | | |
| **Batch No.** | K10824005 | **A.R. No.** | FP/06/24/00012 |
| **Mfg. Date** | Jun-2024 | **Sampling Quantity** | 65 vials |
| **Exp. Date** | May-2026 | **Sampling Date** | 13/06/2024 |
| **Batch Size** | 5000 vials | **Date of Analysis** | 13/06/2024 |
| **Pack Quantity** | NA | **Date of Release** | 27/06/2024 |
| **Ref. Spec. No.** | FP/SPC/0024-00 | **Page No.** | Page 2 of 2 |
| **Pack Size/Type** | 1 Combipack | | |

| | | | |
|---|---|---|---|
| 7. | **Bacterial Endotoxins** | Not more than 0.1 Endotoxins Unit per mg of voriconazole. | Less than 0.1 Endotoxins Unit per mg |
| 8. | **Sterility** | Should be sterile. | Sterile |
| 9. | **Assay (By HPLC)** | Not less than 90.0 % and not more than 110.0 % of the stated amount of voriconazole, $C_{16}H_{14}F_3N_5O$. | 100.2 % |

**CONCLUSION:** The Finish Product Sample Complies / ~~Does not complies~~ as per ~~IH~~/IP/~~BP/USP~~ Specification.

| Function | Prepared By | Reviewed By | Approved By |
|---|---|---|---|
| Name | Maya Sirsat | Kushal Deshmukh | Avnish Kumar |
| Designation-Department | Executive-QC | Asst. Manager-QC | Manager-QC |
| Sign & Date | Maya 07/07/2024 | Kushal 07/07/2024 | 07/07/2024 |

Kaliberr BioScience Pvt. Ltd.

Registered Office
Survey No. 12/1, Plot No. 23,
Tipre Colony, Camp Road, Malegaon
Dist.: Nashik, Pin Code: 423203
Maharashtra, India

Plant Address:
Survey No. 444/1, Koshimba Road,
Khadki, Lakhmapur, Tal: Dindori,
Dist.: Nashik, Pin Code: 422202
Maharashtra, India

Kaliberr BioScience Pvt. Ltd.