

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



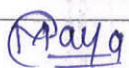
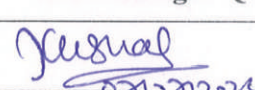
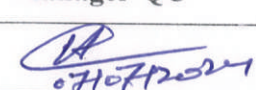
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QUALITY CONTROL
CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

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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 ₃ N ₅ O.	100.2 %

CONCLUSION: The Finish Product Sample Complies / ~~Does not comply~~ 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	 07/07/2024	 07/07/2024	 07/07/2024

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