

Format No.: KBPL/QC/030/F03-01			
Product Name	VORICONAZ 200 Injection		
Generic Name	Voriconazole Injection IP 200 mg per vial		
Batch No.	K10824008	A.R. No.	FP/09/24/00028
Mfg. Date	Sep-2024	Sampling Quantity	65 vials
Exp. Date	Aug-2026	Sampling Date	18/09/2024
Batch Size	10000 vials	Date of Analysis	18/09/2024
Pack Quantity	NA	Date of Release	03/10/2024
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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.	6.2
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 %)	0.077 %
		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 %)	0.229 %
5.	Uniformity of weight	Only for information.	3.4 gm
6.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container	21 particles per container
	≥ 25 µm	NMT 600 no. of particles per container	0 particle per container



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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.	101.4 %

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

Function	Prepared By	Reviewed By	Approved By
Name	Vinod Patel	Kushal Deshmukh	Avnish Kumar
Designation-Department	Sr. Officer-QC	Asst. Manager-QC	Manager-QC
Sign & Date	<i>Vinod</i> 03/10/2024	<i>Kushal</i> 03/10/2024	<i>Avnish</i> 03/10/2024

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