	Nixi Laboratories Pvt. Ltd. **VPO: Mouza Ogli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)**

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	Voriconaz 200	**AR. No.**	NL/LYP/FG/25/076
Generic Name	Voriconazole Injection IP 200 mg		
Mother Batch No.	L25GD001	**Reference**	IP
Child Batch No.	L25GD001C	**Batch Size**	2100 Vials
Mfg. Date	02/2025	**Exp. Date**	01/2027
Specification No.	QC/LYP/FG/STS/005	**Standard Test Procedure No.**	QC/LYP/FG/STS/005
Quantity Sampled	45 Vials	**Sampling Date**	20/02/2025
Release Date	06/03/2025		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	**Description**	A white colour cake free from foreign particles filled in clear glass tubular vial, plugged with grey rubber stopper and sealed with flip off aluminum seal	A white colour cake free from foreign particles filled in clear glass tubular vial, plugged with grey rubber stopper and sealed with flip off aluminum seal
2.	**Identification: By Liquid Chromatography (HPLC)**	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies
3.	**Average filled Weight**	Filled weight ± 10%	3282.88 mg
4.	**Uniformity of filled weight**	Average filled weight ± 10%	-4.80% to +2.14%
5.	**pH**	5.0 to 7.0	6.06
6.	**Particulate matter**		
	Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles: Equal to or greater than 10µm Equal to or greater than 25µm	 NMT 6000 particles/container NMT 600 particles/container	 235.0 particles/Container 5.0 particles/Container
7.	**Related substances**		
	Any secondary impurity Sum of all secondary impurities	NMT 0.50% NMT 2.00%	0.015% 0.021%
8.	**Sterility**	Should be complies	Complies
9.	**Bacterial Endotoxins**	Not more than 1.5 EU/mg of Voriconazole (for intravenous	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	**Ganesh Jaiswal**	**Meenakshi Panday**	**Aditya Singh**
Signature			
Date	06/03/25	06/03/25	06/03/25

Nixi Laboratories Pvt. Ltd. QC APPROVED

	Nixi Laboratories Pvt. Ltd. **VPO: Mouza Ogli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)**

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	Voriconaz 200	**AR. No.**	NL/LYP/FG/25/076
Generic Name	Voriconazole Injection IP 200 mg		
Mother Batch No.	L25GD001	**Reference**	IP
Child Batch No.	L25GD001C	**Batch Size**	2100 Vials
Mfg. Date	02/2025	**Exp. Date**	01/2027
Specification No.	QC/LYP/FG/STS/005	**Standard Test Procedure No.**	QC/LYP/FG/STS/005
Quantity Sampled	45 Vials	**Sampling Date**	20/02/2025
Release Date	06/03/2025		

		infusion).	
10.	**Assay:** Each lyophilized vial contains: Voriconazole IP 200 mg	180.00 mg to 220.00 mg (90.00 % to 110.00 %)	212.97 mg (106.48 %)

Result: The above sample **COMPLIES / ~~DOES NOT COMPLY~~** as per Specification No- QC/LYP/FG/STS/005.

Conclusion: In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / ~~IS NOT STANDARD QUALITY~~** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

	ANALYSED BY	**CHECKED BY**	**APPROVED BY**
Name	**Ganesh Jaiswal**	**Meenakshi Panday**	**Aditya Singh**
Signature			
Date	06/03/25	06/03/25	06/03/25

Nixi Laboratories Pvt. Ltd. QC APPROVED Mouza Ogli Kala-Amb (H.P.)