



KAMLAAMRUT PHARMACEUTICAL LLP.
(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Inrad, Ta-
Kadi, Dist.-Mehsana, Gujarat, 382715, India)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name : Fluconazole in Sodium Chloride Injection USP
Product Name : FLUGYL

Batch No. :AC2335001	A.R. No. : KAPL/FP/25/AC2335001
Batch Size :3500Ltrs	Quantity sampled :25 NOS
Fill Volume :100ml	Received Date :12/11/25
Mfg. Date :10/2025	Testing Date :12/11/25
Exp. Date :09/2028	Completion Date :30/11/25

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear & colorless Solution Confirms	A clear & almost colourless solution essentially free from visible particles.	USP Monograph
2.0	Identification by HPLC	 Confirms	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, obtained as directed in the assay.	USP Monograph (621)
3.0	pH	5.80 Confirms	Between 4.50 to 7.00	In-House
4.0	Organic Impurity			
	For Non polar Impurity	Largest unknown nonpolar impurity: 0.07 % Total unknown nonpolar impurities:0.20%	Largest unknown nonpolar impurity: NMT 0.1% Total unknown nonpolar impurities: NMT 0.5%	USP Monograph
	For polar Impurity	Largest unknown polar impurity : N.D. Total unknown polar impurities :N.D. Total unknown polar and nonpolar impurities:0.20%	Largest unknown polar impurity - 0.1% Total unknown polar impurities - 0.5% Total unknown polar and nonpolar impurities - 1.0%	USP Monograph



KAMLAAMRUT PHARMACEUTICAL LLP.
(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-
Kadi, Dist.-Mehsana, Gujarat, 382715, India)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name : Fluconazole in Sodium Chloride Injection USP

Product Name : FLUGYL

Batch No. :AC2335001	A.R. No. : KAPL/FP/25/AC2335001
Batch Size :3500Ltrs	Quantity sampled :25 NOS
Fill Volume :100ml	Received Date :12/11/25
Mfg. Date :10/2025	Testing Date :12/11/25
Exp. Date :09/2028	Completion Date :30/11/25

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
5.0	Extractable volume	102.00ml Confirms	The volume is not less than the nominal volume.	USP Monograph
6.0	Particulate matter for 100 ml nominal volume			
	For $\geq 10\mu$	23.33 Particles per container	NMT 6000 particles per container	USP Monograph (788)
	For $\geq 25\mu$	1.67 Particles per container	NMT 600 particles per container	
7.0	Assay of Sodium Chloride	0.8959%W/V 99.54%	Between 95.00% to 105.00% of the label claim. (Labelclaim:0.9%w/v)	USP Monograph
8.0	Assay of Fluconazole (By HPLC)	0.2072%W/V 103.59%	Between 90.00% to 110.00% of the label claim. (Labelclaim:0.2%w/v)	USP Monograph (621)
9.0	Bacterial Endotoxins	<0.208EU/mg Confirms	NMT 0.416EU/mg	USP Monograph (85)
10.0	Sterility	Sterile Confirms	It must be sterile	USP Monograph (71)

Remarks: The finish product **Confirms** with the defined specifications.

	Analysed by	Checked by	Verified by
Signature	<i>S. V. Patel</i>	<i>Baldev Makwana</i>	<i>Shashin Upadhyay</i>
Date	30/11/25	30/11/25	30/11/25
Name	Sahil Patel	Baldev Makwana	Shashin Upadhyay
Designation	Q.C. Analyst	Q.C. Executive	Asst Q.A. Manager

Revision No.: 01	Issue Date: 23/11/24	Eff. Date: 25/11/24	Page No. : 2 / 2
------------------	----------------------	---------------------	------------------