

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : FLUCONAZOLE	Grade : IP
Batch No : FLFPS0340425	Date of Analysis : 10.05.2025
Quantity : 50.0 g	AR. Number : AR/FP/25/043
Date of manufacture : April 2025	Expiry/Retest Date : September 2027

S. No.	Test	Specification	RESULTS
1.	Description	A white or almost white, Crystalline powder.	White Crystalline powder
2.	Solubility	Freely soluble in methanol	Complies
3.	Identification by : A. IR	Determine by infrared absorption spectrophotometry Compare the spectrum with that obtained with fluconazole RS or with the spectrum of fluconazole.	Complies
	B. UV	When examined the range 200 nm to 350 nm ,a 0.025% w/v solution in methanol shows absorption maxima at about 266 nm and 261nm.	Complies
4.	Appearance of Solution	A 5.0 % w/v solution in methanol is clear and colorless	Complies
5.	Related Substances by HPLC (% w/w)		
	Impurity peak at RRT about 0.6	Not more than 1.0	0.25
	Fluconazole impurity A	Not more than 0.2	0.01
	Fluconazole impurity C	Not more than 0.2	Not detected
	Fluconazole impurity B	Not more than 0.1	0.01
	Any other secondary peak	Not more than 0.1	0.05
	Total of other secondary peaks	Not more than 1.5	0.46
6.	Iron (ppm)	Not more than 20	Less than 20
7.	Sulphated Ash (% w/w)	Not more than 0.1	0.08
8.	Loss on drying (% w/w) (at 105°C for 3 hours)	Not more than 0.5	0.20
9.	Assay by Potentiometry (% w/w) (on the dried basis)	Not less than 98.5 and Not more than 101.5	99.7

Note: The material is Complies as per the above specifications.

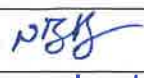
Prepared by:		Checked by:		Approved by:	
Date:	24/06/2025	Date:	24/06/2025	Date:	24/06/2025

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : FLUCONAZOLE	Grade : IP
Batch No : FLFPS0350425	Date of Analysis : 10.05.2025
Quantity : 50.0 g	AR. Number : AR/FP/25/044
Date of manufacture : April 2025	Expiry/Retest Date : September 2027

S. No.	Test	Specification	RESULTS
1.	Description	A white or almost white, Crystalline powder.	White Crystalline powder
2.	Solubility	Freely soluble in methanol	Complies
3.	Identification by : A. IR	Determine by infrared absorption spectrophotometry Compare the spectrum with that obtained with fluconazole RS or with the spectrum of fluconazole.	Complies
	B. UV	When examined the range 200 nm to 350 nm ,a 0.025% w/v solution in methanol shows absorption maxima at about 266 nm and 261nm.	Complies
4.	Appearance of Solution	A 5.0 % w/v solution in methanol is clear and colorless	Complies
5.	Related Substances by HPLC (% w/w)		
	Impurity peak at RRT about 0.6	Not more than 1.0	0.29
	Fluconazole impurity A	Not more than 0.2	0.01
	Fluconazole impurity C	Not more than 0.2	Not detected
	Fluconazole impurity B	Not more than 0.1	0.01
	Any other secondary peak	Not more than 0.1	0.07
	Total of other secondary peaks	Not more than 1.5	0.50
6.	Iron (ppm)	Not more than 20	Less than 20
7.	Sulphated Ash (% w/w)	Not more than 0.1	0.07
8.	Loss on drying (% w/w) (at 105°C for 3 hours)	Not more than 0.5	0.26
9.	Assay by Potentiometry (% w/w) (on the dried basis)	Not less than 98.5 and Not more than 101.5	99.5

Note: The material is Complies as per the above specifications.

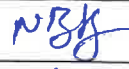
Prepared by:		Checked by:		Approved by:	
Date:	24/06/2025	Date:	24/06/2025	Date:	24/06/2025

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : FLUCONAZOLE	Grade : IP
Batch No : FLFPS0360425	Date of Analysis : 10.05.2025
Quantity : 50.0 g	AR. Number : AR/FP/25/045
Date of manufacture : April 2025	Expiry/Retest Date : September 2027

S. No.	Test	Specification	RESULTS
1.	Description	A white or almost white, Crystalline powder.	White Crystalline powder
2.	Solubility	Freely soluble in methanol	Complies
3.	Identification by : A. IR	Determine by infrared absorption spectrophotometry Compare the spectrum with that obtained with fluconazole RS or with the spectrum of fluconazole.	Complies
	B. UV	When examined the range 200 nm to 350 nm, a 0.025% w/v solution in methanol shows absorption maxima at about 266 nm and 261nm.	Complies
4.	Appearance of Solution	A 5.0 % w/v solution in methanol is clear and colorless	Complies
5.	Related Substances by HPLC (% w/w)		
	Impurity peak at RRT about 0.6	Not more than 1.0	0.23
	Fluconazole impurity A	Not more than 0.2	0.01
	Fluconazole impurity C	Not more than 0.2	Not detected
	Fluconazole impurity B	Not more than 0.1	0.01
	Any other secondary peak	Not more than 0.1	0.06
	Total of other secondary peaks	Not more than 1.5	0.44
6.	Iron (ppm)	Not more than 20	Less than 20
7.	Sulphated Ash (% w/w)	Not more than 0.1	0.07
8.	Loss on drying (% w/w) (at 105°C for 3 hours)	Not more than 0.5	0.24
9.	Assay by Potentiometry (% w/w) (on the dried basis)	Not less than 98.5 and Not more than 101.5	100.3

Note: The material is Complies as per the above specifications.

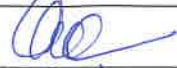
Prepared by:		Checked by:		Approved by:	
Date:	24/06/2025	Date:	24/06/2025	Date:	24/06/2025

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT: FLUCONAZOLE IP (Working Standard)			
Working Standard Batch No : FLZFLWS0010125		Date of Analysis	: 29.01.2025
Quantity : 100.0 mg		AR. Number	: AR/FP/25/002
Date of manufacturing : January 2025		Valid up to	: December 2025
Source Batch No. : FLC-FL/24/019		Reference Standard (B.No./Lot No)	: IPRSF009

S. No.	Test	Specification	RESULTS
1.	Description	A white or almost white, Crystalline powder.	White Crystalline powder
2.	Solubility	Freely soluble in methanol	Complies
3.	Identification by : A. IR	Determine by infrared absorption spectrophotometry Compare the spectrum with that obtained with fluconazole RS or with the spectrum of fluconazole.	Complies
	B. UV	When examined the range 200 nm to 350 nm ,a 0.025%w/v solution in methanol shows absorption maxima at about 266 nm and 261nm.	Complies
4.	Appearance of Solution	A 5.0 %w/v solution in methanol is clear and colorless	Complies
5.	Related Substances by HPLC (% w/w)		
	Impurity peak at RRT about 0.6	Not more than 1.0	0.23
	Fluconazole impurity A	Not more than 0.2	0.03
	Fluconazole impurity C	Not more than 0.2	ND
	Fluconazole impurity B	Not more than 0.1	ND
	Any other secondary peak	Not more than 0.1	0.03
6.	Total of other secondary peaks	Not more than 1.5	0.39
	Iron (ppm)	Not more than 20	Less than 20
	Sulphated Ash (% w/w)	Not more than 0.1	0.07
	Loss on drying (% w/w) (at 105°C for 3 hours)	Not more than 0.5	0.16
	Assay by Potentiometry (% w/w) (on the dried basis)	Not less than 98.5 and Not more than 101.5	100.2

Note: The material is Complies as per the above specifications.

Prepared by:		Checked by:		Approved by:	
Date:	24/06/2025	Date:	24/06/2025	Date:	24/06/2025