# CERTIFICATE OF ANALYSIS

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| **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.

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

# CERTIFICATE OF ANALYSIS

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|---|---|---|---|
| **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.

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

# CERTIFICATE OF ANALYSIS

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| **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.

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| 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 |
| | Total of other secondary peaks | Not more than 1.5 | 0.39 |
| 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 | 0.16 |
| 9. | 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 |