



# ZEE LABORATORIES LTD

Behind 47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. :

Document No. : 252624680

Ref. STS No.	25417	Product Code	FG04062
Product Name	TAB. FLUCOZEE-400		
Generic Name	FLUCONAZOLE TABLETS I.P. 400MG		
Batch No.	425-1536	Date Of Sampling	22/07/2025
Batch Size	20000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	07/2025	Exp. Date	06/2028
A. R. No.	ZL25FG05634	Date Of Release	26/07/2025

S NO.	Tests	Specification	Results
1	Description	White colour, elongated, biconvex film coated tablets, scored on one side.	Complies
2	Identification	the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution	Complies
3	Average Weight of Tablet	915.0 mg $\pm$ 5.0 %	912.0 mg
4	Uniformity of Weight	Average weight of tablet $\pm$ 5.0 %.	-0.55% to + 0.54%
5	Disintegration Test	Not more than 30 minutes	01:15 Min
6	Dissolution (%)	Q. Not less than 80 % of the stated amount of Fluconazole	89% to 91 %
7	Related Substances	the area of any secondary peak is NMT1.0% the sum of areas of all the secondary peaks is NMT2.0%	Complies
8	Assay Each Film coated tablet contains Fluconazole I.P. 400 mg	NLT 90.0 % and NMT 110.0 % of the stated amount of Fluconazole,	96.8 %

**Remarks** The above sample complies/does not comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In house specification.

Particulars	Prepared By	Checked By	Approved By
Sign & Date	26/07/2025	22/07/2025	26/07/2025
Name:	Rajhveer	Dherent	Thakur Deen Singh
Designation:	Officer in Charge	Audit Manager	Q.C. Manager