

ZESS PHARMA

Quality Healthcare • Windsor Paradise, 2E-1054, Raj Nagar Ext., Ghaziabad, UP – 201017

Testing Laboratory: Central QA & NABL Accredited Analytical Division

OFFICIAL QA
RELEASE

COA-ZP-2410-01

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Zesstrac 100mg Capsule	Batch Number	ZP-ITR100-2410
Generic Formulation	Itraconazole Capsules IP 100mg	Dosage Form	Hard Gelatin Capsule
Manufacturing Date	10/2024	Expiry Date	09/2026
Pharmacopoeia Standard	Indian Pharmacopoeia (IP)	Batch Size	50,000 Capsules
Date of Analysis	18/10/2024	Date of Release	20/10/2024
Manufacturing Unit	Unit II, Pharma Industrial Zone, Solan (HP) • WHO-GMP Compliant Facility		

#	Test Parameter	Pharmacopoeial Specification	Observed Result	Verdict
1	Description	Size '0' hard gelatin capsule with white pellets	Complies	PASSED
2	Identification (HPLC)	Retention time matches Reference Standard	Conforms	PASSED
3	Average Net Fill Weight	420.0 mg ± 5.0% (399.0 mg – 441.0 mg)	421.3 mg	PASSED
4	Uniformity of Dosage Units	Acceptance Value (AV) ≤ 15.0	AV = 3.2	PASSED
5	Dissolution (45 min)	Not less than 75% of label claim	84.6%	PASSED
6	Assay (Itraconazole)	90.0% – 110.0% of declared amount	99.82%	PASSED
7	Related Substances	Total Impurities ≤ 1.0%	0.18%	PASSED
8	Microbial Contamination	TAMC ≤ 1000 cfu/g; Pathogens absent	< 50 cfu/g; Absent	PASSED
9	Heavy Metals	Within permissible limit (≤ 10 ppm)	< 5 ppm	PASSED

QUALITY ASSURANCE RELEASE OPINION

The tested sample of **Zesstrac 100mg Capsule (Batch No: ZP-ITR100-2410)** complies with the standards and analytical specifications of the **Indian Pharmacopoeia (IP)**. The product meets all safety, identity, strength, and quality parameters, and is hereby **APPROVED AND RELEASED**.

Quality Control Analyst
QC Lab In-charge



Head – Quality Assurance
Zess Pharma QA Head