



National Agency for Food & Drug Administration & Control (NAFDAC)

NAFDAC Public Assessment Report (NAPAR)

Fluconazole 150 mg Capsules

Fluconazole 150 mg

A4-101929

Arepharm and Agrovat Limited

This report reflects the scientific assessment for the approval of Fluconazole capsules. The product was licenced in February 2026.
--

PART 1: ABSTRACT

Fluconazole capsules manufactured at Impulse Pharmaceutical Private Limited, Tarapur, Maharashtra State, India, was granted marketing authorization by NAFDAC for the treatment of susceptible fungal infections on 24 February 2026.

Fluconazole is indicated for the treatment and prevention of fungal and yeast infections which includes, vaginal yeast infections, oral thrush, mucosal infections, and other serious candida or cryptococcal infections.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of fluconazole capsules by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of fluconazole have been shown in part 2 of this report. The summary of product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of fluconazole has been presented in part 5 of this report.

The detailed steps taken to approve Fluconazole capsules by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of fluconazole capsules.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Fluconazole 150 mg capsules	Fluconazole 150 mg	Hard gelatin capsule Hard gelatin capsules with an opaque green cap and an opaque white body. They contain white powder.	Alu-Alu foil blister cards, each containing 10 capsules. Available in cartons of 1 x 10 capsules	1 x10 capsules

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Fluconazole 150 mg capsules

5.1.2 Therapeutic indication

Fluconazole is indicated for the treatment and prevention of fungal and yeast infections which includes, vaginal yeast infections, oral thrush, Mucosal infections, and other serious candida or cryptococcal infections.

5.1.3 Applicant

Arepharm and Agrovat Limited, No 46/47 Haco House, Igbo Road, Kano State, Nigeria.

5.1.4 Pharmaceutical form

Hard gelatin capsule

Hard gelatin capsules with an opaque green cap and an opaque white body. They contain white powder.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Hard gelatin capsules with an opaque green cap and an opaque white body. They contain white powder.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient, fluconazole capsule is manufactured by Aarti Drugs Limited. Plot No. W- 60 (B), 61 (B), 62 (B), 71 (B), 72 (B), 73 (B), M.I.D.C., Tarapur, Tal. - Palghar, Dist.: Thane – 401 506, Maharashtra, India.

The API specifications are pharmacopeial based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

Other ingredients used in the formulation of Fluconazole capsules include lactose monohydrate BP, sodium starch glycolate USP, purified Talc BP, magnesium stearate BP, colloidal anhydrous silica BP, and EHG capsule size`2` IH, cap-green and body-white, all being controlled by acceptable specifications. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

The drug product is manufactured by Impulse Pharmaceutical Private Limited, J-201, J-202/1, MIDC Tarapur, Boisar, Dist-Palghar 401 506 Maharashtra State, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to produce a safe, effective, stable, and high-quality product that consistently delivers the intended therapeutic effect as the reference product, Syscan 150 capsule manufactured by Torrent Pharmaceuticals Limited, India.

The manufacturing method used were sifting, blending, encapsulation and packing. All the manufacturing processes were validated.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Syscan 150 capsule (Torrent Pharmaceuticals Limited) and fluconazole capsules. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include identification by TLC and HPLC, uniformity of net content, average weight of net content, disintegration time, dissolution test, related substances, assay and microbial contamination. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and 'Do not store above 30°C' storage condition has been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Fluconazole capsules was acceptable for the following indication: for the treatment and prevention of fungal and yeast infections which includes, vaginal yeast infections, oral thrush, mucosal infections, and other serious candida or cryptococcal infections and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Arepharm and Agrovat Limited, No. 46/47 Haco House, Igbo Road, Kano State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of fluconazole 150 mg capsules.

The following are the steps for registration

August 2025	Date of receipt of application
February 2025	Date of conclusion of assessment
September 2025	Date of inspection
24 February 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of fluconazole capsules.