



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

NAFDAC Public Assessment Report (NAPAR)

Flucytosine 500 mg tablets

Flucytosine 500 mg

A4-102035

Oxus Pharma Limited

This report reflects the scientific assessment for the approval of Flucytosine tablets. The product was licenced in March 2026.

PART 1: ABSTRACT

Flucytosine tablets, manufactured at Macleods Pharmaceuticals Limited, Pithampur, Pradesh, India, was granted marketing authorization by NAFDAC for the treatment of susceptible fungal infections on 31 March 2026.

Flucytosine is indicated for treatment of susceptible fungal 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 flucytosine 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 flucytosine 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 flucytosine has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Flucytosine tablets	Flucytosine 500 mg	Uncoated tablet White, round, uncoated tablets. They are biconvex (rounded on top and bottom). The tablets are debossed (stamped into) with 'K' and '24' separated by break-line on one side and plain on other side	Round, opaque white plastic (HDPE) bottle containing 100 tablets. The bottle has a white, childproof plastic (polypropylene) screw cap	1 x 100 tablet

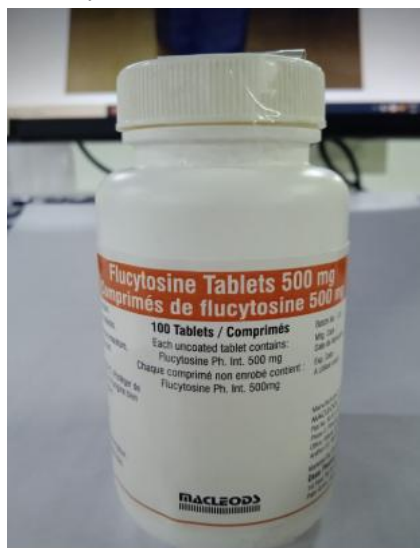
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

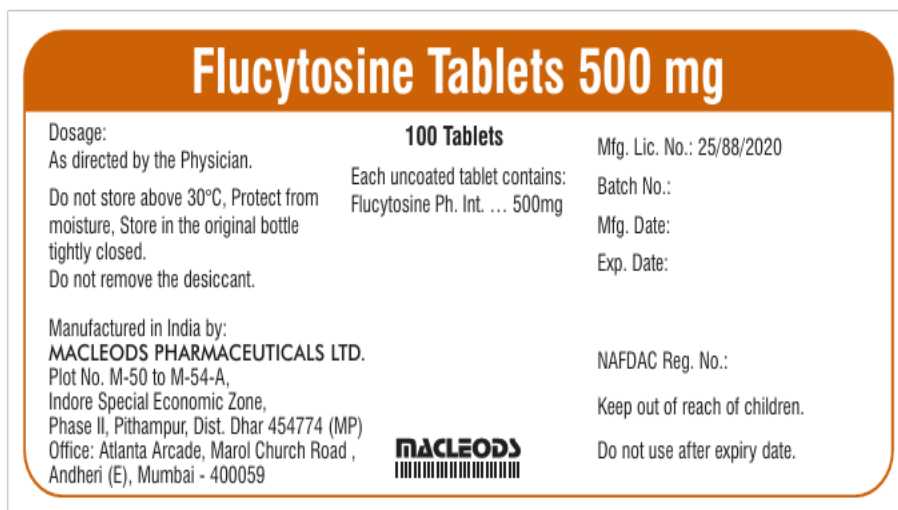
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Flucytosine 500 mg tablets

5.1.2 Therapeutic indication

Flucytosine is indicated for the treatment of serious fungal infections of susceptible organisms

5.1.3 Applicant

Oxus Pharma Limited, 20 Ogunaike Street, off Shipeolu Street, Palm Grove, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Uncoated tablet

White, round, uncoated tablets. They are biconvex (rounded on top and bottom). The tablets are debossed (stamped into) with 'K' and '24' separated by break-line on one side and plain on other side

5.1.5 Storage

Do not store above 30°C. Protect from moisture, Store in the original bottle tightly closed. Do not remove the desiccant.

5.1.6 Shelf life

5.1.7 Product presentation

Round, opaque white plastic (HDPE) bottle containing 100 tablets. The bottle has a white, childproof plastic (polypropylene) screw cap.

5.2 Drug Substance

5.2.1 Manufacturer

Flucytosine is manufactured by Macleods Pharmaceuticals Limited, Plot No. 2209, GIDC Industrial Estate, At and Post Sarigam Taluka: Umbergaon City: Valsad Gujarat, India.

The API specifications are pharmacopoeial and in-house based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of flucytosine tablets include maize starch, povidone K, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate, 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

Macleods Pharmaceuticals Limited, Plot No.50 to 54A, SEZ, Phase II, Pithampur, Dist.: Dhar Madhya Pradesh, 454774, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Ancotil 500 mg tablets manufactured by Laboratoires Pierre Fabre Médicament, France.

The product is manufactured by dry mixing, wet granulation, sieving, lubrication, compression, and packing. All the manufacturing processes were validated.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Ancotil tablets (Laboratoires Pierre Fabre Médicament) and Flucytosine tablets. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include description, identification, friability, disintegration test, dissolution test and microbial enumeration test. 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 12 months and 'Do not store above 30°C. Protect from moisture, Store in the original bottle tightly closed. Do not remove the desiccant' has been accepted.

5.6 Conclusion

Based on the assessment of data submitted on quality, safety and efficacy, the benefit–risk profile of flucytosine tablets was acceptable for the following indication: 'for the treatment of serious fungal infections of susceptible organisms' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Oxus Pharma Limited, 20 Ogunaik Street, off Shipeolu Street, Palm Grove, Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of flucytosine.

The following are the steps for registration

August 2024	Date of receipt of application
March 2026	Date of conclusion of assessment
February 2026	Date of inspection
31 March 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of flucytosine tablets.