WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA753 trade name]*

Flucytosine 250 mg tablet

[HA753 trade name], manufactured at Mylan Laboratories Limited, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of fungal infections on 29 September 2021.

[HA753 trade name] is indicated for severe systemic fungal infections, particularly: candidiasis, cryptococcosis, chromoblastomycosis and certain forms of aspergillosis. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient(s) of [HA753 trade name] is flucytosine. The efficacy and safety of flucytosine is well established based on extensive clinical experience in the treatment of fungal infections.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of flucytosine in fungal infections, the team of assessors advised that [HA753 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA753 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA753 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 September 2021	listed
Pharmaceutical quality	1 September 2021	MR
Bioequivalence	8 September 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	8 July 2021	MR*
GCP (re-)inspection	NA	NA
GLP (re-)inspection	8 July 2021	MR*

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification