WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV014 trade name]*

Molupiravir 200 mg capsules

[CV014 trade name], manufactured at Aurobindo Pharma Limited (Unit III), Bachupally Mandal, Medchal-Malkajgiri District,Telangana State, India, was included in the WHO list of prequalified medicinal products for the treatment of Covid-19 on 18 December 2023.
[CV014 trade name] is indicated for Covid-19. 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 [CV014 trade name] is molnupiravir

The efficacy and safety of molnupiravir are established based on clinical experience in the treatment of COVID-19.

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 molnupiravir in Covid-19, the team of assessors advised that [CV014 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV014 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV014 trade name]:

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	18 December 2023	listed
Quality	01 August 2023	MR
Bioequivalence	11 August 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 November 2022	MR*
FPP	04 December 2023	MR
GCP/GLP (re-)inspection	03 February 2023	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

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