

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV021 trade name]*

Molnupiravir 200 mg Capsules

[CV021 trade name], manufactured at Cipla Limited, Verna Industrial Estate, Verna, Salcette, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) on 18 December 2023.

[CV021 trade name] is indicated for treating non-severe COVID-19 in adults who are at high risk of their disease becoming severe. 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 of [CV021 trade name] is molnupiravir.

The efficacy and safety of molnupiravir are well established based on extensive 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 [CV021 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV021 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV021 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
Pharmaceutical quality	27 November 2023	MR
Bioequivalence	05 December 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 August 2020	MR*
FPP	22 March 2019	MR
GCP/GLP (re-)inspection	23 March 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.