

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV022 trade name]*

Molnupiravir 200 mg capsules

[CV022 trade name], manufactured at Mylan Laboratories Limited, Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) on 23 May 2024.

[CV022 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 [CV022 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 [CV022 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV022 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV022 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	23 May 2024	listed
Pharmaceutical quality	10 May 2024	MR
Bioequivalence	17 May 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	09 October 2019	MR*
FPP	15 April 2021	MR*
GCP/GLP (re-)inspection	11 March 2022	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.