

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV024 trade name]*

Nirmatrelvir+Ritonavir 150 mg+100 mg tablets

[CV024 trade name], manufactured at Mylan Laboratories Limited, Sinnar, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) on 19 December 2024.

[CV024 trade name] is currently indicated for treatment of coronavirus disease 2019 (COVID-19) in adults who do not require supplemental oxygen and whose disease is at higher risk for progressing to severe 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 ingredients of [CV024 trade name] are nirmatrelvir and ritonavir.

The efficacy and safety of nirmatrelvir and ritonavir are well established based on extensive clinical experience in the treatment of coronavirus disease 2019 (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 nirmatrelvir and ritonavir in coronavirus disease 2019 (COVID-19), the team of assessors advised that [CV024 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV024 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV024 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	19 December 2024	listed
Pharmaceutical quality	12 December 2024	MR
Bioequivalence	13 December 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 January 2024	MR
API	17 July 2024	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		