WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV024 trade name]*

Nirmatrelvir+Ritonavir 150mg+100mg tablets

[CV024 trade name], manufactured at Mylan Laboratories Limited, Sinnar, Nashik - 422 113, 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 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