WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV012 trade name]*

Nirmatrelvir 150mg tablets + Ritonavir 100mg tablets USP Co pack

[CV012 trade name], manufactured at Hetero Labs Limited, Jeedimetla, Hyderabad, Telangana, India was included in the WHO list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) on 25 December 2022.

[CV012 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 [CV012 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 [CV012 trade name] in coronavirus disease 2019 (COVID-19) the team of assessors advised that [CV012 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV012 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV012 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 December 2022	listed
Quality	24 December 2022	MR
Bioequivalence	12 December 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 August 2019	MR*
API	31 August 2020	MR*
FPPs	26 August 2019	MR*
FPP	05 October 2020	MR*
GCP/GLP (re-)inspection	15 December 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

The table represents the status of relevant completed activities only.

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