WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV016 trade name]*

Nirmatrelvir 150 mg tablets and ritonavir 100 mg tablets (co-blistered)

[CV016 trade name], manufactured at Zhejiang Huahai Pharmaceutical Co., Ltd, Xunqiao Linhai, Zhejiang, P.R.China, was included in the WHO list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) on 18 December 2023.

[CV016 trade name] is indicated for the treatment of 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 [CV016 trade name] are nirmatrelvir and ritonavir, each in separate tablets.

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 the treatment of coronavirus disease 2019, the team of assessors advised that [CV016 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV016 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV016 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	23 August 2023	MR
Bioequivalence	28 August 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 December 2023	MR*
FPP	30 October 2020	MR*
FPP	21 December 2023	MR*
GCP/GLP (re-)inspection	14 July 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.