1. Formerly Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd at the time of prequalification

WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV020 trade name]*

Nirmatrelvir 150 mg + ritonavir 100 mg film-coated tablets Co pack

[CV020 trade name], manufactured at Yaopharma Co., Ltd, Yubei District, Chongqing, China, was included in the WHO list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) on 04 September 2024.

[CV020 trade name] is indicated for the 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 ingredient(s) of [CV020 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 [CV020 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV020 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV020 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	04 September 2024	listed
Pharmaceutical quality	30 August 2024	MR
Bioequivalence	01 September 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 July 2023	MR
API	14 December 2023	MR
FPP	08 December 2023	MR
GCP/GLP (re-)inspection	15 June 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 NA: not applicable, not available PQ: prequalification	

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