

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[CV001 trade name]*

Remdesivir 100mg powder for solution for injection

[CV001 trade name], manufactured at Hetero Labs Limited, Siddipet, Telangana State, India, was included in the WHO list of prequalified medicinal products for COVID-19 on 14 May 2025.

[CV001 trade name] is indicated for treatment of 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 of [CV001 trade name] remdesivir.

The efficacy and safety of remdesivir are well established based on extensive clinical experience in the treatment of 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 remdesivir in COVID-19, the team of assessors advised that [CV001 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [CV001 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [CV001 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	14 May 2025	listed
Pharmaceutical quality	30 April 2025	MR
Bioequivalence	04 May 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 December 2024	MR*
FPP	08 May 2025	MR*
GCP/GLP (re-)inspection	NA	NA
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.