WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ritonavir Tablet USP, 100 mg [1]

Ritonavir 100 mg tablet

Ritonavir Tablet USP, 100 mg was submitted in 2022 by Cipla Limited. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for for the treatment of HIV/AIDS on 04 October 2022.
Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information (https://extranet.who.int/pqweb/medicine/4435)

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the approval by the U.S. FDA (https://www.fda.gov/), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Do not store above 25℃. Protect from moisture.
- The shelf-life at this storage condition is 24 months

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf

For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by U.S.FDA (Drugs@FDA: FDA-Approved Drugs https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (Abbreviated New Drug Application ANDA 202573)
In addition the "Patient Information" and the "Prescribing Information" are included in this WHOPAR.
This WHOPAR for Ritonavir Tablet USP, 100 mg is comprised of parts 2, 3, 4, 5 and 7.

Ritonavir Tablet USP, 100 mg contains the protease inhibitor ritonavir.
Its WHO recommended use is as a pharmacokinetic enhancer for the treatment of HIV/AIDS in combination with other antiretroviral products.
The efficacy and safety profile of ritonavir is well established based on the extensive clinical experience in the in the treatment of HIV/AIDS.

Summary of Prequalification Status for Ritonavir Tablet USP, 100 mg

Initial acceptance	**Date**	**Outcome**
Status on PQ list	04 October 2022	listed
Quality	September 2022	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.