WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ciprofloxacin Tablets USP 500 mg[1]

Ciprofloxacin (as hydrochloride) 500 mg film-coated tablets

Ciprofloxacin Tablets USP 500 mg was submitted in 2019 by Unique Pharmaceutical Laboratories, Mumbai to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 11 June 2019.

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/prequal/medicines/ha738

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 American "Food and Drug Administration" (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 30°C.
- The shelf-life at this storage condition is 48 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/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval. http://www.fda.gov/drugsatfda

For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by USFDA:
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=076639
An English language version of the Medication Guide and the Prescribing Information as certified to be FDA approved texts, is included in this WHOPAR.

This WHOPAR for Ciprofloxacin is comprised of parts 2, 3, 4, 5 and 7.

Ciprofloxacin contains ciprofloxacin (as hydrochloride). Its WHO recommended use is for treatment of bacterial infections in HIV/AIDS patients.

Summary of Prequalification Status for Ciprofloxacin Tablets USP 500 mg

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	11 June 2019	listed	19 May 2025	listed
Dossier Evaluation	May 2019	MR	May 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.