WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ciprofloxacin Tablets USP 250 mg[1]

International Nonproprietary Name (INN):
Ciprofloxacin (as hydrochloride)

Abstract

Ciprofloxacin Tablets USP 250 mg, manufactured at Unique Pharmaceutical Laboratories (Division of J. B. Chemicals & Pharmaceuticals Ltd) Panoli - 394 116 Bharuch, Gujarat, India was submitted to be considered for prequalification in 2018 when the product was licensed / registered in the USA and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 18 December 2018.

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 of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely 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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.

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°C.
The shelf-life at this storage condition is 48 months.

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (www.fda.gov/drugsatfda)

---

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility Throughout this WHOPAR the proprietary name is given as an example only.
[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

The English language version of the Patient Information Leaflet, the Summary of Product Characteristics and the labelling, as certified to be FDA approved texts, are included in this WHOPAR.

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Ciprofloxacin Tablets USP 250 mg are included here.

Ciprofloxacin Tablets USP 250 mg contains ciprofloxacin. Its WHO recommended use is for the treatment of HIV/AIDS related conditions.

The most frequent adverse reactions observed during treatment with ciprofloxacin were nausea, diarrhoea, liver function tests abnormal, vomiting, and rash.
The most frequent serious adverse effects of ciprofloxacin are tendinitis and tendon rupture, peripheral neuropathy, central nervous system effects, exacerbation of myasthenia gravis, hypersensitivity reactions, hepatotoxicity, *clostridium difficile*-associated diarrhoea, prolongation of the QT-interval and photosensitivity/phototoxicity.

The efficacy and safety profile of ciprofloxacin is well established based on the extensive clinical experience in the treatment and the management of bacterial infections.

Summary of Prequalification Status for Ciprofloxacin Tablets USP 250 mg

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list,	18 Dec 2018	listed		
Dossier Evaluation	30 Nov 2018	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.