

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Azithromycin tablets USP¹

Azithromycin 500mg film-coated tablets

Azithromycin tablets USP was submitted in 2024 by ACI HealthCare Limited to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of neglected tropical diseases on 10 April 2024.

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/nt019>

The “Procedure for prequalification of pharmaceutical products²” 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 United States 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 Applicant⁴.

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:

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

- Do not store above 25°C.
- The shelf-life at this storage condition is 36 months

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.

(<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215773> ANANDA 215773)

For details on the uses of this product, for relevant efficacy and safety information, see the prescribing information and the patient information as approved by US FDA.

The English language version of the prescribing information, the patient information and the labelling, as certified to be USFDA approved texts, are included in this WHOPAR.

This WHOPAR for Azithromycin tablets USP is comprised of parts 2, 3, 4, 5 and 7

For products for which the WHO recommended uses differ from those authorized by the reference authority additionally parts 3a, 4a and 5a are included.

Azithromycin tablets USP contains azithromycin.

Its WHO recommended use is for the management of neglected tropical diseases.

Summary of Prequalification Status for Azithromycin tablets USP

Initial acceptance	Date	Outcome
Status on PQ list	10 April 2024	listed
Quality	April 2024	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.