

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company (ACI HealthCare Limited) submitted in 2024 an application for Azithromycin tablets USP¹ (NT019) to be assessed with the aim of including Azithromycin tablets USP in the list of prequalified medicinal products for the management of neglected tropical diseases.

Azithromycin tablets USP was assessed according to the ‘Procedure for Assessing the Acceptability, in principle, of Pharmaceutical Products for purchase by United Nations Agencies’ by the team of WHO assessors. The assessors are senior experts, mainly from National Authorities, invited by WHO to participate in the prequalification assessment process.

2. Steps taken in the evaluation of the product

March 2023	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2024	The company’s response letter was received.
April 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
10 April 2024	Azithromycin tablets USP was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

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