

## Steps before prequalification

### I. BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2024 an application for [NT021 trade name]\* (NT021) to be assessed with the aim of including [NT021 trade name] in the list of prequalified medicinal products for broad-spectrum anthelmintic infections.

[NT021 trade name] 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

September 2022	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
September and October 2024	The assessment team reviewed the quality data and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
January 2025	The applicant's response letter was received.
January 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2025	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2025	The applicant's response letter was received.
May 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2025	The applicant's response letter was received.
July 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September and November 2025	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
November 2025	The applicant's response letter was received.

\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

November 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2025	Product dossier accepted (quality assurance)
19 December 2025	[NT021 trade name] was included in the list of prequalified medicinal products.

## II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacturer and Inspection status

#### Manufacturer of the finished product and responsible for batch release

Ipca Laboratories Limited  
Plot no. 255/1, Village Athal  
Silvassa 396 230  
U.T. of Dadra and Nagar Haveli and Daman and Diu  
India

#### Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

### 2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

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