Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited, Hyderabad, Telangana, India submitted in 2021 an application for [NT011 trade name]* (NT011) to be assessed with the aim of including [NT011 trade name] in the list of prequalified medicinal products for schistosoma infections.

[NT011 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 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2021	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
March 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
March and April 2021	The quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November and December 2021	The additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
May 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March and June 2022	The additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

July 2022	Product dossier accepted (quality assurance)
23 August 2022	[NT011 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

Hetero Labs Limited, Unit-V
Survey No. 439, 440, 441 & 458,
TSIIC-Formulation SEZ, Polepally Village,
Jadcherla (Mandal), Mahaboob Nagar District
Telangana State,
India – 509 301

Inspection status

The sites were inspected through desk review and found to be in compliance with WHO requirements for GMP.

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

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products