

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2020 an application for [HA761 trade name]* (HA761) to be assessed with the aim of including [HA761 trade name] in the list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection in adults and children weighing 35 kg or more.

[HA761 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

July 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September 2020	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2020	The applicant’s response letter was received.
January 2021	The applicant’s response letter was received.
January 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
February 2021	The applicant’s response letter was received.
January and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested
March 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2021	The applicant’s response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
July 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2022	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2023	The applicant’s response letter was received.
March and April 2023	The additional quality data were reviewed and further information was requested.

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

May 2023	Between the meetings of the assessment team the response letter was received. The additional quality data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
July 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2023	Product dossier accepted (quality assurance)
02 September 2023	[HA761 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

Micro Labs Limited

Plot No S-155 to S-159 & N1, Phase III & Phase IV,

Verna Industrial Estate,

Verna, Goa, 403 722, India

Inspection status

The FPP manufacturing site was inspected and found to be in compliance with WHO requirements for GMP.

The manufacturer of one of the APIs was not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

The GMP compliance of one of the API manufacturers was accepted based on WHO desk assessment.

The sites inspected were found to be in compliance with WHO requirements for 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>