

Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company P.T. Tunggal Idaman Abdi submitted in 2019 an application for [RH090 trade name]* (RH090) to be assessed with the aim of including [RH090 trade name] in the list of prequalified medicinal products for contraception in women.

[RH090 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

May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
February 2019	The applicant’s response letter was received.
March 2019	During the meeting of the assessment team the quality data and the additional safety and efficacy data were reviewed and further information was requested.
July 2019	The applicant’s response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2020	The applicant’s response letter was received.
April 2020	The additional quality data were reviewed and further information was requested.
May 2020	The applicant’s response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant’s response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	The applicant’s response letter was received.
September 2020	The applicant’s response letters were received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2020	The applicant’s response letters were received.

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

November 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
December 2020 + March 2021	The additional quality data were reviewed and further information was requested.
March 2021	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 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.
May 2021	The applicant's response letter was received.
June 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2021	Product dossier accepted (quality assurance)
01 July 2021	[RH090 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

PT Tunggal Idaman Abdi
Jl. Jend. Ahmad Yani No.7
Jakarta 13230
Indonesia

Inspection status

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

A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements

2. Conditions or restrictions regarding supply and use

<To be decided by the national medicines regulatory authority in accordance with national legislation.>

Further information is available at:

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