Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Renata PLC submitted in 2025 an application for [RH108 trade name]* (RH108) to be assessed with the aim of including [RH108 trade name] in the list of prequalified medicinal products for contraception for women.

[RH108 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 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2024	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2025	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and June 2025	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2025	The applicant's response letter was received.
July 2025	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2026	The applicant's response letter was received.
January and March 2026	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2026	The applicant's response letter was received.
March 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2026	Product dossier accepted (quality assurance)
23 March 2026	[RH108 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Renata PLC

Rajendrapur Potent Product Facility,

Noyapara, Bhawal Mirzapur,

Rajendrapur,

Gazipur 1700 Bangladesh

Inspection status

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

APIs supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

Not inspected for GLP /GCP. Previous site inspections by WHO were acceptable.

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