

Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Ltd. submitted in 2013 an application for [RH038 trade name]* (RH038) to be assessed with the aim of including [RH038 trade name] in the list of prequalified medicinal products for contraception for women.

[RH038 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

March 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2013	The company's response letter was received.
Oct 2013	The additional quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2013	Product dossier accepted (quality assurance)
Nov 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
11 March 2014	[RH038 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, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Active tablets

Famy Care Limited, Unit II
Plot No. 1608-1609, G. I. D.C.
Sarigam, District Valsad
Gujarat, India.396155

Hormone inactive tablets

Famy Care Limited
Plot No. 20 & 21, Pharmez
Pharmaceutical Special Economic Zone (SEZ)
Sarkhej, Near Matoda, Village
Ahmedabad, India

Inspection status

API manufacturers not inspected for GMP, as these are innovator sites located within a Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) country.

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

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

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>