

WHO Prequalification Programme  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[RH054 trade name]\***

Estradiol valerate /Norethisterone enantate 5mg/50mg/mL Solution for Injection

[RH054 trade name], manufactured at Bayer de México, Ixtaczoquitlán, Veracruz, Mexico was included in the WHO list of prequalified medicinal products for hormonal contraception for women on 30 July 2020.

[RH054 trade name] is indicated for hormonal contraception for women. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients of [RH054 trade name] are estradiol valerate and norethisterone enantate.

The efficacy and safety of estradiol valerate and norethisterone enantate are well established based on extensive clinical experience in hormonal contraception for women.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of estradiol valerate and norethisterone enantate for hormonal contraception for women, the team of assessors advised that [RH054 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH054 trade name] in the list of prequalified medicinal products.

**Summary of Prequalification Status for [RH054 trade name]:**

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	30 July 2020	listed
Quality	22 July 2020	MR
Bioequivalence	23 July 2020	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
APIs	NA	NA
FPP	12 October 2018	MR
<b>GCP/GLP (re-)inspection</b>	NA	NA

MR: meets requirements

NA: not applicable, not available

The table represents the status of relevant completed activities only.

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