

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

**[RH084 trade name]\***

Medroxyprogesterone acetate 150mg/mL suspension for injection

[RH084 trade name], manufactured at Incepta Pharmaceuticals Limited, Dhaka, Dhamrai, Bangladesh, was included in the WHO list of prequalified medicinal products for contraception in women on 05 February 2019.

[RH084 trade name] is indicated for long term contraception in 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 ingredient of [RH084 trade name] is the synthetic hormone medroxyprogesterone acetate. The API is well established and documented for long term female contraception.

The efficacy and safety profile of medroxyprogesterone acetate is well established based on extensive clinical experience of contraception in 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 medroxyprogesterone acetate for contraception in women, the team of assessors advised that [RH084 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH084 trade name] in the list of prequalified medicinal products.

**Summary of Prequalification Status for [RH084 trade name]:**

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	05 February 2020	Listed
Quality	08 January 2020	MR
Bioequivalence	13 January 2020	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	NA	NA
FPP	27 July 2017	MR
<b>GCP/GLP (re-)inspection</b>	29 September 2017	MR

MR: meets requirements

NA: not applicable, not available

The table represents the status of relevant completed activities only.

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