

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH084 trade name]*

Medroxyprogesterone acetate 150 mg/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 the treatment of contraception on 05 February 2020.

[RH084 trade name] is currently indicated for 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 Medroxyprogesterone acetate.

The efficacy and safety of medroxyprogesterone acetate are well established based on extensive clinical experience in the treatment 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, 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]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
Status on PQ list	05 February 2020	Listed
Pharmaceutical quality	08 January 2020	MR
Bioequivalence	13 January 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	27 July 2017	MR
GCP/GLP (re-)inspection	29 September 2017	MR
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

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