

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH106 trade name]*

Medroxyprogesterone acetate 104mg/0.65ml suspension for injection

[RH106 trade name], manufactured at Incepta Pharmaceuticals Ltd, Krishnapura, Sahabelishor Dhamrai, Dhaka, Bangladesh, was included in the WHO list of prequalified medicinal products used for long-term contraception in women on 01 October 2025.

[RH106 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(s) of [RH106 trade name] is Medroxyprogesterone acetate

The efficacy and safety of Medroxyprogesterone acetate is well established based on extensive clinical experience in its use for long-term 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 in reproductive health, the team of assessors advised that [RH106 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH106 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH106 trade name]:

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

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

Initial acceptance	Date	Outcome
Status on PQ list	01 October 2025	listed
Pharmaceutical quality	24 September 2025	MR
Bioequivalence	29 September 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	16 January 2025	MR
GCP/GLP (re-)inspection	17 January 2025	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 NA: not applicable, not available PQ: prequalification	