WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH046 trade name]*

Levonorgestrel 1.5 mg tablets

[RH046 trade name] manufactured by Cipla Limited, Verna Goa, India was accepted by WHO and included in the WHO list of prequalified products for reproductive health on 9 July 2015.

[RH046 trade name] is indicated for emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. 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 [RH046 trade name] is the second-generation progestin (synthetic progestogen), levonorgestrel.

The efficacy and safety profile of [RH046 trade name] is well established based on extensive clinical experience in emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

On the basis of data submitted and public information on the use of [RH046 trade name] in reproductive health, the team of assessors advised that [RH046 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH046 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH046 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	09 July 2015	Listed
Quality	02 July 2015	MR
Bioequivalence	06 July 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 May 2012	MR
FPP	20 Nov 2013	MR*
GCP/GLP (re-)inspection	NA	NA

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

The table represents the status of relevant completed activities only.

Requalification	03 August 2021

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