WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH096 trade name]*

Ethinylestradiol/Levonorgestrel 30 µg/150µg film-coated tablets

[RH096 trade name], manufactured at HLL Lifecare Limited, (A Government of India Enterprise), Kanagala, Karnataka, India, was included in the WHO list of prequalified medicinal products for female contraception on 9 December 2022.

[RH096 trade name] is indicated as an oral combined hormonal contraceptive (CHC) agent 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 [RH096 trade name] are ethinylestradiol and levonorgestrel.

The efficacy and safety of ethinylestradiol and levonorgestrel are well established based on extensive clinical experience in female contraception.

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 ethinylestradiol and levonorgestrel, the team of assessors advised that [RH096 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH096 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH096 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	9 December 2022	listed
Pharmaceutical quality	16 May 2022	MR
Bioequivalence	24 May 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 October 2018	MR
FPP	25 February 2022	MR
GCP/GLP (re-)inspection	3 June 2022	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.