WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH093 trade name][*]

Ethinylestradiol/levonorgestrel 30 µg/150 µg sugar-coated tablets + placebo film-coated tablets

[RH093 trade name], manufactured at Renata Limited, Rajendrapur Potent Product Facility, Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur 1700, Bangladesh, was included in the WHO list of prequalified medicinal products for female contraception on 22 February 2024.

[RH093 trade name] is indicated in women for contraception and it may also protect women against gynaecological conditions. 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 [RH093 trade name] are ethinylestradiol and levonorgestrel.

The efficacy and safety of ethinylestradiol and levonorgestrel are well established based on extensive clinical experience in the treatment of 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 in female contraception, the team of assessors advised that [RH093 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH093 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH093 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	22 February 2024	listed
Pharmaceutical quality	25 January 2024	MR
Bioequivalence	06 February 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 October 2018	MR
FPP	16 July 2022	MR
GCP/GLP (re-)inspection	09 June 2023	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