WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH013 trade name][*]

Ethinylestradiol/levonorgestrel 30 micrograms/150 micrograms tablets

[RH013 trade name], manufactured at Senador Laboratories Private Limited, Sarigam, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of reproductive health conditions on 29 September 2011.

[RH013 trade name] is indicated in women for contraception and may also protect women against gynaecological conditions that respond to an oestrogen-progestogen combination. 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 [RH013 trade name] are ethinylestradiol and levonorgestrel.

The efficacy and safety of ethinylestradiol and levonorgestrel are well established based on extensive clinical experience in contraception and management of reproductive health conditions.

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 tuberculosis, the team of assessors advised that [RH013 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH013 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH013 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	29 September 2011	Listed
Pharmaceutical quality	21 July 2010	MR
Bioequivalence	13 August 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	09 September 2011	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

Requalification	31 October 2019	MR

MR: meets requirements

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
[1]Formerly known as Mylan Laboratories Limited.
[2] Mylan Laboratories Limited formerly known as Famy Care Ltd