WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH035 trade name]*

Ethinylestradiol and levonorgestrel 30 µg/150 µg tablets

[RH035 trade name] manufactured at Famy Care Ltd, Sarigam, Gujarat, India, was included in the WHO list of prequalified medicinal products for contraception for women on 21 October 2013.

[RH035 trade name] is indicated for contraception 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 [RH035 trade name] are the synthetic hormones ethinylestradiol and levonorgestrel. The pack also includes 7 inactive tablets.

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 (SmPC).

On the basis of data submitted and public information on the use of ethinylestradiol and levonorgestrel in contraception for women, the team of assessors advised that [RH035 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH035 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH035 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.
**Formerly known as Famy Care Ltd

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**21 Oct 2013**	**listed**
Pharmaceutical quality	19 Sept 2013	MR
Bioequivalence	03 Oct 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	09 Sept 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	6 May 2020	MR