WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH032 trade name]*

(Levonorgestrel 750 micrograms Tablets)

[RH032 trade name], manufactured at Famy Care Ltd, Ahmedabad, India was included in the WHO list of prequalified products for emergency contraception for women on 14 June 2013.

[RH032 trade name] is indicated for emergency contraception. 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 (API) of [RH032 trade name] is levonorgestrel.
The efficacy and the safety profile of levonorgestrel are well established based on extensive clinical experience in emergency 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 levonorgestrel for emergency contraception, the team of WHO assessors accepted [RH032 trade name] for inclusion in the list of prequalified medicinal products.

Summary of prequalification status for [RH032 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 June 2013	listed
Quality	10 June 2013	MR
Bioequivalence	11 June 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	MR
FPP	30 November 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	11 February 2020

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.
† Formerly Famy Care Ltd then Jai Pharma Ltd.