

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[RH031 trade name]\***

Levonorgestrel 1.5 mg tablets

[RH031 trade name], manufactured at Famy Care Limited, Ahmedabad, Gujarat, India, was included in the WHO list of prequalified medicinal products for emergency contraception on 21 October 2013.

[RH031 trade name] is currently indicated for emergency contraceptive to prevent pregnancy following unprotected intercourse or a known or suspected contraceptive failure. 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 of [RH031 trade name] is levonorgestrel.

The efficacy and safety 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, the team of assessors advised that [RH031 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH031 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [RH031 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	21 October 2013	listed
Pharmaceutical quality	10 October 2013	MR
Bioequivalence	10 October 2013	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	NA	MR
FPP	06 September 2012	MR
<b>GCP/GLP (re-)inspection</b>	18 October 2012	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	

<b>Requalification</b>	31 March 2020
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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

† Formerly Famy Care Ltd then Jai Pharma Ltd then Mylan Laboratories Ltd