

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH056 trade name]*

Misoprostol 200 µg tablets

[RH056 trade name], manufactured at Acme Formulation Pvt. Limited, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for reproductive health in women on 27 April 2016.

[RH056 trade name] is indicated for induction of labour at term, for prevention of postpartum haemorrhage when oxytocin is not available, for incomplete abortion as well as spontaneous and induced abortion (preferably with mifepristone). 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 [RH056 trade name] is misoprostol.

The efficacy and safety of misoprostol is well established based on extensive clinical experience in women for the indicated 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 misoprostol for reproductive health in women, the team of assessors advised that [RH056 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH056 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH056 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	27 April 2016	Listed
Quality	12 April 2016	MR
Bioequivalence	18 April 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	08 July 2014	MR
FPP	14 August 2015	MR
GCP/GLP (re-)inspection	16 March 2016	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 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.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.