WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH048 trade name]*

Misoprostol 200 µg tablets

[RH048 trade name], manufactured at China Resources Zizhu Pharmaceutical Co., Ltd, Beijing, P.R. China, was included in the WHO list of prequalified medicinal products for the treatment of reproductive health conditions on 022 November 2016.

[RH048 trade name] is indicated for indicated for induction of labour, prevention of postpartum haemorrhage, induction of abortion (alone in combination with mifepristone or letrozole) and management of incomplete abortion or missed abortion & intrauterine fetal death (alone or in combination 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 [RH048 trade name] is misoprostol.

The efficacy and safety of misoprostol is well established based on extensive clinical experience in the treatment of induction of labour, prevention of postpartum haemorrhage, induction of abortion (alone in combination with mifepristone or letrozole) and management of incomplete abortion or missed abortion & intrauterine fetal death (alone or in combination with mifepristone).

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 [RH048 trade name] in reproductive health conditions, the team of assessors advised that [RH048 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH048 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH048 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 Nov 2016	listed
Quality	02 Nov 2016	MR
Bioequivalence	03 Nov 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 Jun 2021	MR
FPP	26 Oct 2018	MR
GCP	14 Jan 2014	MR
GCP/GLP (re-)inspection	NA	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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	13 September 2022

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