WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH052 trade name][*]

Mifepristone 200 mg tablets

[RH052 trade name], manufactured at China Resources Zizhu Pharmaceutical Co. Limited, Chaoyang District, Beijing, P.R. China, was included in the WHO list of prequalified medicinal products for reproductive health in women on 15 August 2016

[RH052 trade name] is currently indicated for induction of abortion, management of missed abortion and intrauterine fetal death. 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 [RH052 trade name] is mifepristone, a progesterone receptor modulator.

The efficacy and safety of mifepristone are well established based on extensive clinical experience in the treatment of abortion, management of missed abortion and intrauterine fetal death.

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 mifepristone, the team of assessors advised that [RH052 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH052 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH052 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.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 August 2016	listed
Pharmaceutical quality	19 May 2016	MR
Bioequivalence	21 June 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 October 2015	MR
FPP	28 January 2016	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	**17 February 2023**