WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH050 trade name]*

Oxytocin 10IU/ml Solution for injection

[RH050 trade name], manufactured at PT Sanbe Farma, Bandung, Indonesia, was included in the WHO list of prequalified medicinal products for facilitating reproductive health on 30 Jun 2017.

[RH050 trade name] is indicated for the management of labour, prevention and treatment of postpartum haemorrhage and for the management of complications of pregnancy. 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 [RH050 trade name] is oxytocin.

The efficacy and safety of oxytocin are well established based on extensive clinical experience in the management of labour and complications of pregnancy.

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 oxytocin for women in reproductive health indications, the team of assessors advised that [RH050 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH050 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH050 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	30 June 2017	listed
Pharmaceutical quality	19 October 2016	MR
Bioequivalence	NA	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	17 February 2017	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	04 July 2024