WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH083 trade name][*]

Oxytocin 10 IU/mL Solution for Injection

[RH083 trade name], manufactured at Steril-Gene Life Sciences (P) Ltd, Villianur Commune, Puducherry, India, was included in the WHO list of prequalified medicinal products for facilitating reproductive health on 14 October 2019.

[RH083 trade name] is currently 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 (API) of [RH083 trade name] is oxytocin. The API is well established and documented for the management of labour and complications of pregnancy.

The efficacy and safety of oxytocin 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 oxytocin for women in reproductive health indications, the team of assessors advised that [RH083 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH083 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH083 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	**14 Oct 2019**	listed
Pharmaceutical quality	03 Oct 2019	MR
Bioequivalence	04 Oct 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	30 Jan 2019	MR*
FPP	11 June 2019	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