

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[RH095 trade name]\***

Carbetocin 100 micrograms/mL solution for injection

[RH095 trade name], manufactured at Ferring Pharmaceuticals (China) Co., Ltd., Zhongshan City, Guangdong Province, People's Republic of China, and Steril-Gen Life Sciences Private Ltd., Mangalam Village, Villianur, Puducherry, India, was included in the WHO list of prequalified medicinal products for facilitating reproductive health on 4 July 2022.

[RH095 trade name] is indicated for the prevention of postpartum haemorrhage due to uterine atony. 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 [RH095 trade name] is carbetocin. The efficacy and safety of carbetocin have been established on the basis of clinical experience in the prevention of postpartum haemorrhage.

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 carbetocin in the prevention of postpartum haemorrhage, the team of assessors advised that [RH095 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH095 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [RH095 trade name]:**

Initial acceptance	Date	Outcome
Status on PQ list	04 July 2022	listed
Quality	20 June 2022	MR
Bioequivalence	28 June 2022	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	NA	NA
FPP	NA	NA
<b>GCP/GLP (re-)inspection</b>	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 NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.