

Steps taken following Prequalification of [RH048 trade name]*:

No variations with impact on the WHOPAR accepted by PQP at this moment.

Changes	WHOPAR parts affected	Accepted on
Requalification	1	13 September 2022
Change in the product information to reflect current WHO guidelines and state of scientific knowledge	3, 4, 5	November 2022

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