

Steps taken following Prequalification of [RH013 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	15 December 2011
Change in the name and/or address of a manufacturer of the FPP	3	16 September 2015
Change in the name of the supplier of the FPP	3, 4, 5	20 November 2015
Change in the name and address of the applicant/supplier and manufacturer of the FPP	3, 4, 5	21 February 2017
Requalification 31 October 2019	1	31 October 2019
Addition of FPP manufacturing and testing site	3	14 April 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2,3,4,5	November 2021

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