

Steps taken following Prequalification of [HA516 trade name]*

Changes	WHOPAR parts affected	Accepted on
Addition of manufacturing and quality control testing site for the FPP	3	13 June 2014
Change in the FPP primary packaging pack	3, 4	12 October 2016
Requalification	1	18 December 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	March 2020
Addition of manufacturing and quality control testing site for the FPP	3	06 April 2022

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