

Steps taken following Prequalification of [HA549 trade name]¹

Changes	WHOPAR parts affected	Accepted on
Change in the package size involving additional number of units in a package	3, 4, 5	25 August 2017
Change in shelf-life of the FPP involving extension	4	10 October 2017
Addition of FPP manufacturing and quality control testing site	1, 3, 6, 7	20 October 2017
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	March 2023

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
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