

### Steps taken following Prequalification of [HA598 trade name]<sup>1</sup>

This document will only list changes endorsed by WHO that affect the WHOPAR.

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Accepted on</b>
Change in the shelf-life of the FPP involving extension	4	02 July 2016
Change in the shelf-life of the FPP involving extension	4	01 December 2017
Change in the shelf-life of the FPP involving extension	4	27 March 2019
Change in the address of the FPP supplier	3, 4, 5	19 June 2019
Addition of FPP manufacturing and testing site	3	13 November 2019
Requalification	1	8 March 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	November 2023

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<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.