

Steps taken following Prequalification of [MA100 trade name]*

This document will only list changes endorsed by WHO Prequalification Team – Medicines that affect the WHOPAR.

Changes	WHOPAR parts affected	Date
Addition of primary packaging of the FPP	3, 4	29 August 2015
Change in the name and/or address of the supplier of the FPP	3, 4, 5	01 March 2017
Change in the shelf-life of the FPP involving extension	4	14 April 2019
Addition of FPP manufacturing site	3	20 January 2020
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	May 2021
General update of the WHOPAR to reflect the current WHO guidelines and state of scientific knowledge	3, 4	March 2023
Requalification	1	March 2023
Supplementary bioequivalence data	6a	22 September 2017

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