

Steps taken following prequalification of [MA099 trade name]*:

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

Changes	WHOPAR parts affected	Date
Change in the pack size of the FPP	3, 4, 5	September 2014
Addition of primary packaging of the FPP	3,4	August 2015
Change in the pack size of the FPP	3, 4,5	February 2017
Change in the name and/or address of the supplier of the FPP	3, 4,5	March 2017
Change in the pack size of the FPP	3, 4,5	February 2019
Change in shelf-life of the FPP involving extension	4	April 2019
Change in the pack size of the FPP	3, 4,5	August 2019
Addition of packaging and batch control testing site of the FP	3	March 2020
Requalification	1	17 May 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1, 2, 3, 4, 5	March 2023
Supplementary bioequivalence data	6a	23 November 2017

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