

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

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