

Steps taken following Prequalification of [MA064 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 FPP quality control testing site	3	August 2009
Addition of FPP manufacturing site	3	April 2010
Addition of FPP manufacturing sites	3	October 2010
Addition of FPP manufacturing and testing site	3	December 2010
Change of tablet appearance	3, 4	April 2011
Change in the FPP storage conditions	3, 4, 5	June 2011
Change in the name of the FPP manufacturer	3	August 2014
Change in the FPP shelf-life involving extension	4	September 2015
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	January 2020
Deletion of a FPP manufacturing site	3	February 2023
Deletion of FPP manufacturing sites	3	October 2024
Change in the name of a FPP manufacturing site	3	October 2024

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