

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	28 August 2009
Addition of FPP manufacturing site	3	01 April 2010
Addition of FPP manufacturing sites	3	19 October 2010
Addition of FPP manufacturing and testing site	3	02 December 2010
Change of tablet appearance	3, 4	21 April 2011
Change in the FPP storage conditions	3, 4, 5	03 June 2011
Change in the name of the FPP manufacturer	3	29 August 2014
Change in the shelf-life of the FPP involving extension	4	24 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 manufacturing site of the FPP	3	February 2023

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