

Steps taken following prequalification of [MA078 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 shelf life of the FPP	4	15 January 2016
Requalification	1	21 March 2020
Deletion of a manufacturing site of the FPP	3	February 2023
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	June 2025

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

[#] Formerly known as Cipla Limited