

**Steps taken following prequalification of [TB178 trade name]\*:**

This document will only list changes endorsed by WHO that affect the WHOPAR.

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Date</b>
Change of immediate packaging material and pack size of the FPP	3, 4, 5	December 2008
Change of pack size of the FPP	3, 4, 5	May 2010
Addition of a break line to the tablets	3, 4	July 2010
Change in the shelf life of the FPP	4	December 2010
Change in the shelf life of the FPP	4	December 2011
Change of pack size of the FPP	3, 4, 5	August 2014
Addition of a manufacturing and batch control testing site for the FPP	3	August 2015
Addition of primary packaging type	3, 4, 5	June 2019
Requalification	1	18 July 2025
Replacement of an excipient with another comparable excipient	3, 4	May 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	March 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	July 2025

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