

**Steps taken following prequalification of [TB177 trade name] \*:**

This document will only list changes that affect the WHOPAR and are endorsed by Prequalification Team – Medicines.

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Date</b>
Addition of a manufacturing and quality control testing site of the FPP	3	December 2011
Addition of a pack size of the FPP	3, 4, 5	April 2013
Change in the shelf-life of the FPP involving reduction	4	November 2015
Change in the corporate address of the supplier of the FPP	3, 4, 5	July 2016
Deletion of packaging type and sizes	3, 4, 5	November 2019
Requalification	1	06 May 2020
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	December 2023