

Steps taken following prequalification of [TB230 trade name]*:

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

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP involving extension	4	December 2012
Change in the pack size of the FPP	3, 4, 5	November 2013
Change in the pack size of the FPP	3, 4, 5	March 2014
Change in the pack size of the FPP	3, 4, 5	August 2014
Addition of a FPP manufacturing and release testing site	3	June 2015
Change in the shelf life of the FPP involving extension	4	September 2017
Addition of a scoreline	3, 4	October 2017
Change in shelf-life of the FPP involving extension	4	April 2020
Requalification	1	18 December 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2,3,4	July 2021
General update of the WHOPAR to reflect the WHO guidelines and state of scientific knowledge.	4	January 2025
Addition of a packaging site for the FPP	3	May 2025

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