

Steps taken following prequalification of [TB334 trade name]*:

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

Changes	WHOPAR parts affected	Date
Change in the FPP shelf-life involving extension	4	April 2019
Addition of FPP pack size	3, 4,5	May 2019
Addition of FPP manufacturing and testing site	3	May 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3,4	March2021
Change in the FPP shelf-life involving extension	4	February 2023
Requalification	1	06 November 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3,4	January 2024
Change in the FPP shelf-life involving extension	4	August 2025
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	July 2026

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