

Steps taken following Prequalification of [TB334 trade name] *

Changes	WHOPAR parts affected	Accepted on
Change in the FPP shelf-life involving extension	4	09 April 2019
Addition of FPP pack size	3, 4,5	11 May 2019
Addition of FPP manufacturing and testing site	3	11 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	March 2021
Change in the FPP shelf-life involving extension	4	February 2023
Requalification	1	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

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