

Steps taken following Prequalification of [TB334 trade name] *

Changes	WHOPARparts affected	Accepted on
Change in the shelf-life of the FPP 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	March2021
Change in the shelf-life of the FPP (as packaged for sale) 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

*TradenamesarenotprequalifiedbyWHO.Thisisthenationalmedicinesregulatoryauthority'sresponsibility.