

Steps taken following prequalification of [TB315 trade name]*:

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

Changes	WHOPAR parts affected	Date
Change in the shelf life of the FPP involving extension	4	September 2017
Change in the shelf-life of the FPP (as packaged for sale) involving: extension	4	February 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4, 5	July 2021
Requalification	1	15 August 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1, 2, 3, 4, 5	February 2024
Addition of FPP pack size	3, 4, 5	30 May 2024
General update of the WHOPAR to reflect the current WHO guidelines and state of scientific knowledge.	4	January 2025
Change in the FPP appearance	3, 4	14 March 2025

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