

Steps taken following prequalification of [TB351 trade name]* :

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

Changes	WHOPAR parts affected	Date
Change in the shelf life of the FPP involving extension	4	November 2019
Addition of a primary packaging type	3,4	May 2020
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge.	2 ,3, 4	January 2022
General update of the WHOPAR to reflect the current WHO guidelines and state of scientific knowledge.	3, 4	May 2023

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