

**Steps taken following Prequalification of [TB243 trade name]\***

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

Changes	WHOPAR parts affected	Accepted on
Change in the FPP shelf-life involving extension	4	15 February 2013
Addition of FPP pack size	3, 4, 5	27 March 2014
Addition of FPP pack size	3, 4, 5	10 August 2015
Addition of FPP manufacturing and testing site	3	25 August 2015
Addition of FPP manufacturing site	3	7 October 2015
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge.	1,3,4	09 July 2022
Change in the FPP shelf-life involving extension	4	06 October 2022
Change in the FPP shelf-life involving extension	4	16 May 2025

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