

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 shelf-life of the FPP (as packaged for sale) involving: extension of shelf-life	4	06 October 2022

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