

Steps taken following Prequalification of [TB154 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change of the FPP secondary packaging material	3, 4	12 December 2008
Addition of FPP manufacturing and quality control testing site	3	12 March 2009
Change of the FPP primary packaging type	3, 4, 5	24 February 2015
Change in the FPP shelf-life	4	24 February 2015
Change in the FPP pack size	3, 4, 5	1 July 2015
Addition of FPP manufacturing site	3	26 August 2015
Requalification	1	25 October 2017
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	April 2022

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