

Steps taken following Prequalification of [TB179 trade name]*:

Changes	WHOPAR parts affected	Accepted on
Change in immediate packaging material and pack size of the FPP	3,4,5	December 2008
Change in pack size of the FPP	3,4,5	May 2010
Change in the shelf life of the FPP	4	December 2010
Change in the shelf life of the FPP	4	December 2011
Change in pack size of the FPP	3,4,5	August 2014
Change of pack size of the FPP	3,4,5	June 2015
Addition of a manufacturing and batch control testing site for the FPP	3	August 2015
Addition of a manufacturing and batch control testing site for the FPP	3	August 2018
Addition of primary packaging type	3,4,5	June 2019
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	March 2023
Addition of a FPP manufacturing site	3	March 2024

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