

Steps taken following Prequalification of [TB178 trade name]*:

Changes	WHOPAR parts affected	Accepted on
Change of immediate packaging material and pack size of the FPP	3, 4, 5	01 December 2008
Change of pack size of the FPP	3, 4, 5	07 May 2010
Addition of a break line to the tablets	3, 4	01 July 2010
Change in the shelf life of the FPP	4	03 December 2010
Change in the shelf life of the FPP	4	09 December 2011
Change of pack size of the FPP	3, 4, 5	19 August 2014
Addition of a manufacturing and batch control testing site for the FPP	3	24 August 2015
Addition of primary packaging type	3, 4, 5	25 June 2019
Requalification	1	30 July 2019
Replacement of an excipient with another comparable excipient	3, 4	12 May 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	01 March 2023

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