

Steps taken following prequalification of [TB230 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	08 December 2012
Change in the pack size of the FPP	3, 4, 5	24 November 2013
Change in the pack size of the FPP	3, 4, 5	27 March 2014
Change in the pack size of the FPP	3, 4, 5	06 August 2014
Addition of manufacturing and release testing site for the FPP	3	09 June 2015
Change in the shelf life of the FPP	4	12 September 2017
Addition of a scoreline	3, 4	26 October 2017
Change in shelf-life of the FPP involving extension	4	03 April 2020
Requalification	1	18 December 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of	2,3,4	July 2021

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