

Steps taken following prequalification of [TB158 trade name]*

Changes	WHOPAR part affected	Accepted on
Change of immediate packaging material and pack size of the FPP	3, 4, 5	25 May 2010
Change of FPP primary packaging type	3, 4	09 June 2015
Addition of a manufacturing site for the FPP	3	04 February 2016
Change of FPP primary packaging type	3, 4, 5	19 April 2018
Change in the FPP excipients	3, 4	19 April 2018
Inclusion of additional pack presentation	3, 4, 5	14 August 2018
Change in shelf-life of the FPP involving extension	4	08 September 2018
Addition of FPP pack size	3,4	14 April 2021

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