

Steps taken following Prequalification of [TB238 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	5 February 2014
Addition of embossing on the tablets	3, 4	5 February 2014
Addition of a primary packaging	3, 4, 5	3 March 2017
Product information updated with respect to sections 4 of the SmPC and PIL	3, 4	November 2018
Change in the address of the FPP supplier	3, 4, 5	19 June 2019
Requalification	1	30 September 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4, 5	November 2021

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