

Steps taken following Prequalification of [TB354 trade name]*

Changes	WHOPAR parts affected	Accepted on
Addition of FPP pack size	3,4,5	21 August 2020
Change in the shelf-life of the FPP involving extension	4	21 August 2020
Change in the name and address of the FPP applicant	3,4,5	28 September 2020
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1,3,4	26 November 2021

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