Steps taken following prequalification of [TB134 trade name]ⁱ

Changes	WHOPAR parts affected	Accepted on
Change in the FPP shelf-life involving extension	4	01 May 2012
Addition of FPP package size	3, 4, 5	02 July 2015
Addition of FPP manufacturing site	3	07 July 2015
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	23 March 2021
Addition of FPP manufacturing site	3	09 July 2023

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