

Steps taken following prequalification of [TB134 trade name]

Changes	WHOPAR parts affected	Date
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
Addition of FPP manufacturing site	3	09 July 2023
Requalification	1	20 September 2023.
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	July, 2026