Steps taken following Prequalification of [TB383 trade name]*

This document will only list changes endorsed by WHO Prequalification Team – Medicines that affect the WHOPAR.

Changes	WHOPAR parts affected	Date
Addition of FPP package size	3, 4, 5	6 July 2022
Addition of FPP manufacturing site	3	18 December 2023

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

Page 1 of 1