

Steps taken following Prequalification of [TB189 trade name]*:

Changes	WHOPAR parts affected	Accepted on
Requalification	1	03 August 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2,3, 4	October 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3,4,5	October 2025

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