

Steps taken following Prequalification of [HA498 trade name]*:

This document will only list changes endorsed by WHO that affect the WHOPAR.

Changes	WHOPAR parts affected	Accepted on
Change in the package size(s) of FPP	3, 4, 5	23 July 2016
Change in the FPP film coat	3, 4	26 January 2017
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	April 2020
Addition of FPP manufacturing and testing site	3	16 July 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	October 2024

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