

Steps taken following prequalification of [HA424 trade name] *:

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

Changes	WHOPAR parts affected	Date
Addition of FPP manufacturing and testing site	3	June 2013
Addition of FPP manufacturing site	3	March 2019
Requalification	1	May 2019
Update of the WHOPAR to reflect new safety information, the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1, 2, 3, 4, 6	June 2023
Change in the FPP shelf-life involving extension	4	March 2024
Addition of FPP manufacturing site	3	December 2025

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