

Steps taken following Prequalification of [HA444 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	01 December 2010
Change in the desiccant of the FPP	3, 4	19 April 2011
Change in the name of the supplier and manufacturer of the FPP	3, 4, 5	18 October 2011
Inclusion of alternate screw cap closure for packaging of the FPP	3, 4	04 February 2013
Addition of manufacturing and quality control testing site for the FPP with change in batch size	3	03 July 2013
Change in the pack size of the FPP	3, 4, 5	27 February 2015
Change in desiccant	3, 4	27 March 2015
Change of FPP primary packaging	3, 4	12 July 2016
Change in the name and/or address of the supplier of the FPP	3, 4, 5	01 March 2017
Requalification	1	09 April 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific	1, 3, 4	25 January 2023

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

Formerly known as 'Matrix Laboratories Limited'