

**Steps taken following Prequalification of [HA389 trade name] \***

| <b>Changes</b>   | <b>WHOPAR parts affected</b> | <b>Accepted on</b> |
|--|------------------------------|--------------------|
| Inclusion of cross-scoring of the tablets              | 3, 4                         | 31 August 2010     |
| Change in the shelf life of the FPP                    | 4                            | 22 July 2011       |
| Change in the name of supplier and manufacturer of FPP | 3, 4, 5                      | 02 March 2016      |
| Change in the name of supplier and manufacturer of FPP | 3, 4, 5                      | 03 August 2018     |

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