

Steps taken following Prequalification of Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets* :

Changes	Product information affected	Accepted on
Submission of new or updated CEP for Ethambutol HCl API		25 March 2011
Change in the batch size of the finished product		19 April 2011
Change in test procedure for Ethambutol HCl API		16 May 2011
Change in the batch size of the finished product		03 August 2012
Change in the specification of Isoniazid API		25 October 2012

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.