WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

P-Aminosalicylic acid 5.52 g powder[1]

International Nonproprietary Name (INN):
P-Aminosalicylic acid, 5.52 g powder for oral solution

Abstract

P-Aminosalicylic acid 5,52 g powder, manufactured at Joint-Stock Company "Olainfarm", Latvia, was submitted to be considered for prequalification in 2010 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified products for treatment of tuberculosis on 22 March 2011.

The "Procedure for Assessing the Acceptability, in principle, of Pharmaceutical Products for purchase by United Nations Agencies"[2] defines specific evaluation mechanisms for multisource (generic) products approved by regulatory authorities, which apply similarly stringent standards for quality, safety and efficacy as those recommended by WHO.
The prequalification of this product is based on the approval by a stringent regulatory authority (in line with the "Guideline on Submission of Documentation for Prequalification of Multisource (generic) Finished Pharmaceutical Products (FPPs) approved by Stringent Regulatory Authorities (SRAs) in the regions of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)").
Hence, no assessment of the data underlying this approval has been undertaken within WHO Prequalification Programme.
This prequalification is based on the approval by the Latvian Authority "Zāļu Valsts aģentūra".
Based on the above, this WHOPAR refers for parts 6 and 8 (scientific discussion and steps taken following prequalification) to the information available at the approving stringent regulatory authority.

P-Aminosalicylic acid 5.52 g powder contains para-aminosalicylic acid and is indicated for the treatment of tuberculosis in combination with other active agents. It is most commonly administered to patients with multi-drug resistant tuberculosis (MDR-TB) or extremely drug-resistant tuberculosis (XDR-TB) or in situations when therapy with isoniazid and rifampicin is not possible due to resistance and/or intolerance. When P-Aminosalicylic acid 5.52 g powder is added to the treatment regimen in patients with proven or suspected drug resistance, it should be accompanied by at least one and preferably two other new agents to which the Mycobacterium is known or expected to be susceptible.

Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which is a company authorized English translation of the Latvian "Zāļu apraksts" and can be found in this WHOPAR. The most recent Latvian product information can be found at: http://www.zva.gov.lv

[1] Trade names are not prequalified by WHO. This is under local Drug Regulatory Authority's responsibility.
Throughout this WHOPAR the proprietary name is given as an example only.
[2] *http://whqlibdoc.who.int/trs/WHO_TRS_948_eng.pdf*

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for P-Aminosalicylic acid 5.52 g powder are included here.

Summary of Prequalification Status for P-Aminosalicylic acid 5.52 g powder

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	22 March 2011	listed				
Dossier Evaluation						
Quality	14 March 2011	MR				
Bioequivalence	NA	NA				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	NA	NA				
FPP	NA	NA				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available