WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Dapsone Tablets, USP 100 mg[1]
International Nonproprietary Name (INN):
Dapsone

Abstract

Dapsone Tablets, USP 100 mg, manufactured at Jacobus Pharmaceutical Company, Inc. was submitted to be considered for prequalification in 2014 when the product was licensed / registered in USA and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 13 Jan 2015.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely "Food and Drug Administration" of the United States of America (http:// www.fda.gov), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"[3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme. However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.
WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

"Do not store above 30°C.
Keep the blister pack in the outer carton in order to protect from light.
The shelf-life at this storage condition is 24 months."

Based on the above, this WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (www.fda.gov/drugsatfda FDA Application No. 086842, last accessed May 2017).

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[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf

[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf
https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

The English language version of the Prescribing Information (analogues to the Summary of Product Characteristics) and the labelling, as certified to be FDA approved texts, are included in this WHOPAR.
The Patient Information Leaflet (part 3 of the WHPOAR) is neither available on the reference stringent regulatory authority website nor has it been submitted by the supplier.

Parts 2a, 2b, 4, 5 and 7 of the WHOPAR for Dapsone Tablets, USP 100 mg are included here.

Dapsone Tablets, USP 100 mg contains dapsone.
According to the WHO "Essential Medicines and Health Products Information Portal" (https://3c.web.de/mail/client/dereferrer?redirectUrl=http%3A%2F%2Fapps.who.int%2Fmedicinedocs%2Fen%2Fd%2FJs2215e%2F9.12.html) its WHO recommended use is for the treatment and prophylaxis of toxoplasmosis (*Pneumocystis* pneumonia) in HIV/AIDS patients.

The most frequent adverse events observed during treatment with dapsone were nausea, vomiting, anorexia and headache.
The most serious adverse effects of dapsone are hepatitis, psychosis, haemolysis, methaemoglobinaemia, and aplastic anaemia; and serious cutaneous hypersensitivity reactions including Stevens-Johnson syndrome and peripheral neuropathy with motor loss.

The efficacy and safety profile of dapsone is well established based on the clinical experience in the treatment of HIV related condition as detailed above.

Summary of Prequalification Status for Dapsone Tablets, USP 100 mg

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	13 Jan 2015	listed		
Dossier Evaluation	22 Dec 2014	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.