WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

AmBisome Liposomal Amphotericin B 50mg Powder for Concentrate for Dispersion for Infusion [1]

Liposomal Amphotericin B 50 mg powder for concentrate for dispersion for infusion

AmBisome was submitted in 2018 by Gilead Sciences International Ltd. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 19 June 2018.

The Marketing Authorization Holder changed from Gilead Sciences International Ltd., Cambridge, UK to Gilead Sciences Ireland UC, Cork, Ireland.in September 2018.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/ha705

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 Team: Medicines (PQTm), is based on the approval by the Irish "Health Products Regulatory Authority" (https://www.hpra.ie/) 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 in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

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

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

Based on the submitted stability data 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 Do not store above 25°C. Avoid excursions above 30°C.
- The shelf-life at this storage condition is 48 months

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

https://www.hpra.ie/homepage/medicines

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet as approved by the Irish HPRA:

https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=Liposomal%20Amphotericin%20B&field=

License number PA2322/001/001

This WHOPAR for AmBisome is comprised of parts 2, 5 and 7.

AmBisome Liposomal Amphotericin B contains liposomal amphotericin B. Its WHO recommended use is for the treatment of systemic mycotic infections and of visceral leishmaniasis in HIV/AIDS infected patients.

Summary of Prequalification Status for AmBisome Liposomal Amphotericin B 50 mg Powder for Concentrate for Dispersion for Infusion

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	19 June 2018	listed	18 November 2024	listed
Dossier Evaluation	May 2018	MR	November 2024	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.