

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

AmBisome Liposomal Amphotericin B 50mg
Powder for Concentration for Dispersion for Infusion¹

Liposomal Amphotericin B 50mg Powder for Concentration for Dispersion for Infusion

AmBisome Liposomal Amphotericin B 50mg Powder for Concentration for Dispersion for Infusion 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.

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/pqweb/medicine/3894>)

The “Procedure for prequalification of pharmaceutical products²” 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 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 Applicant⁴.

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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs March2016_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs%20March2016_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 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 in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (<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 HPRAs <https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=Liposomal%20Amphotericin%20B&field=>

This WHOPAR for AmBisome Liposomal Amphotericin B 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.

The efficacy and safety profile of liposomal amphotericin B is well established based on the extensive clinical experience in the treatment fungal infections.

Summary of Prequalification Status for AmBisome Liposomal Amphotericin B

Initial acceptance	Date	Outcome
Status on PQ list	19 June 2018	listed
Quality	24 May 2018	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.