WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Freya 21[1]

Desogestrel/Ethinylestradiol 0.15mg/0.03mg Tablets

Freya 21 was submitted in 2013 by Famy Care Ltd, India. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for contraception for women on 14 August 2013.
After prequalification the applicant changed to Mylan Laboratories Limited, India.

Information on the site(s) involved in the manufacture of the product and the APIs is available at the products listing information: *https://extranet.who.int/pqweb/medicine/4003*

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 Canadian Medical Products Agency *"https://www.hc-sc.gc.ca/"* 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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_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 not store above 30°C.
- The shelf-life at this storage condition is 24 months

For details on the uses of this product, for relevant efficacy and safety information, see the product monograph as approved by Health Canada https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=88154 (Submission Control No.: 226394)

This WHOPAR for Freya 21 is comprised of parts 2, 5 and 7.

Freya 21contains the synthetic hormones desogestrel and ethinylestradiol. Its recommended use is for contraception for women.

The efficacy and safety profile of desogestrel and ethinylestradiol is well established based on the extensive clinical experience in female contraception.

Summary of Prequalification Status for Freya 21

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 August 2013	listed
Quality	09 August 2013	MR
PQ: prequalification MR: meets requirements		

Requalification	11 November 2022

The table represents the status of relevant completed activities only.