

Assessment of response to position paper "WHO response to the USFDA warning letter issued to Mylan Laboratories Ltd, Nashik"

WHO Prequalification Team (WHO-PQT) refers to the publication of the [response](#), dated 4 May 2017, to the USFDA warning letter for Mylan Laboratories Limited, Nashik site, dated 3 April 2017. Based on the response received from Mylan Nashik site, WHO-PQT hereby provides an update as follows.

WHO/PQT has requested Mylan Laboratories Limited, Nashik site to provide an impact assessment of the inspection observations for the WHO prequalified products, manufactured at the Nashik site. The impact assessment report confirmed that:

- For all 22 products (21 prequalified, 1 under assessment) respective analytical methods were validated before being transferred to Nashik site. Respective procedures for transfer of analytical methods (from R&D side) and procedure for method transfer (Nashik) were revised. It was confirmed that all method validations were completed prior to release of commercial WHO product. There was no impact identified on WHO prequalified products.
- All the Out of Specifications (OOS) related to products under the WHO prequalification process were handled appropriately.
- All critical parameters from equipment used to manufacture products under the WHO prequalification process were recorded in the Batch Manufacturing Record (BMR) and relevant logbooks.

The company performed a simulation study to demonstrate that no data was lost due to unplugged or disconnected equipment power cord. An independent evaluation was also done, which confirmed that no data or audit trails were deleted.

It was confirmed that there were no complaints received for any of the WHO prequalified products from June 2015 to present date.

Based on the above impact assessment, WHO-PQT concludes that the observations in the USFDA warning letter, do not raise concerns regarding the quality of the WHO prequalified products. Mylan Laboratories Limited, Nashik site shall be inspected by WHO-PQT in due course. Further updates shall be provided, if required.

The prequalification status of the prequalified products from Mylan remains unchanged.