

Good Manufacturing Practices Assessments of Anti-Tuberculosis Medicine Manufacturers

Paonta Sahib and Guargon, India

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Trip Report

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Executive Summary

Mr. Toledo and Ms. Derry traveled to India to perform Good Manufacturing Practices (GMP) assessments of Akorn India Pvt. Ltd and Medicamen Biotech Ltd. These assessments were performed using the World Health Organization (WHO) inspection procedures approach for auditing the manufacture of pharmaceuticals. The assessment revealed that the firms have the systems in place as well as the capabilities, facilities, infrastructure, knowledge, and skills necessary to manufacture finished anti-tuberculosis (TB) pharmaceutical products. All the non-compliances and opportunities for improvement observed during the assessments are listed in full confidential reports for the manufacturers.

In addition to the assessments, a meeting was held with Simpex to discuss their Levofloxacin dossier status and the technical assistance that PQM can offer the company in the process of obtaining WHO prequalification (PQ).

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- PQM administrative staff and editors

ACRONYMS

CAPA	Corrective and Preventive Action
CMO	Contract Manufacturing Organization
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
PAS	Para-Aminosalicylic Acid
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
TA	Technical Assistance
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

Tuberculosis (TB) is a global concern, and PQM has actively contributed to the USAID strategic objective of “increased use of effective interventions to reduce the threat of infectious diseases, including tuberculosis” (P.E.1.2 -TB). PQM assists countries to implement anti-TB medicine quality monitoring, and in 2008, began providing technical assistance (TA) to interested companies on the preparation of medicine dossiers they submit to the World Health Organization (WHO) with their "Expressions of Interest" for the WHO Prequalification (PQ) Program.

Purpose of Trip

The purposes of the trip were to conduct Good Manufacturing Practices (GMP) assessments of Akorn, Abbott’s contract manufacturing organization (CMO), and Medicament, Kilitch’s CMO. In addition, PQM held a meeting with Simpex to discuss the status of their Levofloxacin dossier.

Source of Funding

This trip was funded by USAID through Core TB and Maternal and Child Health (MCH).

Overview of Activities

Manufacturer	Products	Status	Next Steps
Akorn	Capreomycin Finished Pharmaceutical Product (FPP)	Assessed facilities in Paonta Sahib. The assessment revealed that the firm has the systems in place as well as the capabilities, facilities, infrastructure, knowledge, and skills necessary to manufacture third-line anti-TB FPP. A confidential report was sent to Abbott for corrective and preventive action (CAPA) plan implementation.	PQM will continue to support Abbott in the WHO PQ process. PQM will review Abbott’s dossier by Q3.
Medicament	Zinc sulfate tablets	Assessed facilities in Guargon. The assessment revealed that the firm has the systems in place as well as the capabilities, facilities, infrastructure, knowledge, and skills necessary to manufacture Zinc tablets. A confidential report was sent to Medicament for CAPA implementation.	PQM will continue supporting Medicament in the WHO PQ process. PQM has reviewed the dossier, and it will be submitted to WHO by Q2.
Simpex	Levofloxacin FPP Terizidone FPP Prothionamide FPP PAS FPP	Met with Simpex representative to discuss Levofloxacin project status and provide clarifications regarding dossier compilation guidelines. Validation batches had started for Levofloxacin and other projects will follow after Levofloxacin is completed.	PQM will continue to support Simpex regarding project readiness. The Levofloxacin dossier will be submitted to WHO by Q3.

Conclusion

This visit to India was successful, with two baseline GMP assessments for two manufacturers completed and a meeting about current and future collaboration held with a third company. All three companies plan to submit dossiers to WHO in the coming year.