

PAN AMERICAN DRUG REGULATORY HARMONIZATION

External Quality Control Program for the Official Medicine Control Laboratories (EQCP)

Following on the External Quality Control Program for the Official Medicine Control Laboratories (EQCP) that the Pan American Health Organization/World Health Organization (PAHO/WHO) has been implementing since 2001 with the assistance of the U.S. Pharmacopeia (USP), we would like to inform you that this year we will have the Tenth Phase of the EQCP with PYRAZINAMIDE tablets.

For the Tenth Phase of the EQCP, please find attached:

- Sample: PYRAZINAMIDE tablets, 130 units
- 2 vials of USP Reference Standard PYRAZINAMIDE 200 mg Lot # HOG198; USP Certificate and MSDS.
- Material monograph: PYRAZINAMIDE tablets USP 35/NF 30 (2012) page 4488
- Analysis Report form
- The list of requirements to be considered/completed

In the Tenth Phase of the EQCP, unlike previous phases of the program, the performance evaluation of participating laboratories will focus on two compendial tests: assay and dissolution. Please, submit complete results according to the routine forms/procedures in place in your laboratory, including a copy of the lab notebook records. If deviations or changes to the monograph procedures occur, please, explain them and provide pertinent results and comments.