Pyrazinamide Tablets

External Quality Control Program (EQCP)—Phase II, Step X / Version 2: 26-Oct-2012 / English

	Methodology: *USP 35-NF 30* Page 4488
M	**RS Information:** USP Pyrazinamide RS (lot, open, exp., etc.)
GC	**RS Handling:** Handling according to label specifications
GLP	**Visual Inspection:** List specifications (sample name, dosage, lot, etc.)

	Dissolution:
GLP	Dissolution Instrument Qualification *Date* :
M	Medium Prep: water
M	Vessel Vol: 900 mL
M	Apparatus 2: 50 rpm
GC	Instrument Level Check
GC	Shaft Check
GC	Paddle Check
GC	Paddle Height Check
M	Time: 45 min
GC	Vessel temperature: 37.0 +/- 0.5 ºC
GLP	Thermometer Calibration *Date* :
GLP	Balance Qualification *Date* :
GLP	Balance Calibration *Date* :
M	Standard Sol Prep: (both working and control RS)
GLP	Spectrophotometer Qualification *Date* :
GLP	Verify RS work vs. RS Cont Solution
GC	Appropriate Sampling Time: (withdraw sample within time constraints)
M	Test Sol Prep:
M	Samples Filtered:
M	Blank Prep:
M	UV Wavelength:
GLP	Correct Blank for UV Readings
GLP	Correct Reading Technique
M	Calculations of Results: NLT 75% (Q)

	Assay:
GLP	Balance Qualification *Date* :
GLP	Balance Calibration *Date* :
GLP	pH Meter Qualification *Date* :
GLP	pH Meter Calibration *Date* :
GLP	Thermometer Calibration *Date* :
M	Mobile Phase Prep:
M	Mobile Phase Filtering and Degassing Information
M	Standard Sol Prep: (both working and control RS)
GLP	Verify RS work vs. RS Control Solution
M	System Suitability Sol Prep:
M	Assay Sol Prep:
M	Assay Sol Filtering Information
	Chromatographic system:

GLP	HPLC Instrument Qualification *Date* :
M	UV Wavelength:
M	Column Specs:
M	Flow Rate:
M	Injection Vol:
	System Suitability:
M	Column Efficiency:
M	Tailing Factor:
M	Resolution:
GLP	Injection Sequence: (bracketed and replicate injections)
GLP	Injection of Blank
M	Calculations of Results: 93.0 - 107.0%
M	Use of USP Formula

	References:
M	Indicates information that is required by the *USP 35-NF 30* Pirazynamide Tablets Monograph
GN	Indicates information that is required by the *USP 35–NF 30* General Notices
GC	Indicates information that is required by a specific General Chapter in the *USP 35–NF 30*
GLP	Indicates information that is required by Good Laboratory Practices

Laboratory Groups—General Classification Guidelines

- EQCP's Step X to focus on two compendial tests: Dissolution and Assay

- In Step X, the participating laboratories are expected to:
  - Satisfactorily perform the two selected tests following all relevant monograph procedures.
    Please, refer to the above spreadsheet for a list of minimum requirements to consider when conducting the tests and documenting the results.
  - Report complete and correct results, including original data and calculations.
    Please, submit results according to the routine forms/procedures in place in the laboratory, including a copy of the lab notebook records and chromatograms.

- In Step X, classification of the participating laboratories in different performance levels (Groups I, II and III, in decreasing order) will be based on:
  - Evaluation and interlaboratory comparison of the dissolution and assay results for Pyrazinamide Tablets submitted by the participating laboratories.
  - Overall performance of each and all the participating laboratories as transpired in the records provided by the participating laboratories.