Proficiency Testing Scheme for Pharmaceutical Quality Control Laboratories: East African Regional Experience rolled to the entire continent of Africa.

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INTRODUCTION

- In an effort to build African capacity for providing PT services in the pharmaceutical sector, the EAC Secretariat in cooperation with PTB (the German Metrology Institute) started to support Pharma R&D lab to become a regional PT provider for testing laboratories.
- PT is a valuable tool for Pharma testing laboratories to demonstrate testing competencies as a requirement for ISO/IEC 17025 accreditation.
- Participants in this scheme include NQCL of the NMRAs, pharmaceutical manufacturing QC labs, National bureau of Standards (NBS), universities and others within the EAC, neighboring countries and later rolled over the entire continent.

METHODOLOGY

- Planning and execution :ISO/IEC 17043:2010 Conformity requirement
- Statistical evaluation as per requirement ISO 13528
  - Determination of assigned value: consensus value from participants with target RSD set at 2.5 %.
  - Z-score –biased estimate of the results (mean value, assigned value and target RSD) + kernel density
    - **<2 = satisfactory; 2-3 = questionable; >3 = non satisfactory**
  - Cochran's test - checking for higher RSD
  - Grubbs' test – checking for outlying means

STEPS INVOLVED

1. Preparation of PT material and protocol
   - PT provider: homogeneity testing
2. Distribution of PT material and protocol to participants
   - PT provider: stability testing
   - Participants: sample analysis
3. Data analysis
   - Participants: send raw data
   - PT provider: statistical analysis
4. Preliminary PT report
5. Evaluation workshop: PT provider and participants
6. FINAL PT report

Table 1: **REGIONAL DISTRIBUTION OF PARTICIPANTS**

R/N	TANZANIA	KENYA	UGANDA	BURUNDI	RWANDA	OTHERS
4	6	2	4	1	2	3 (Congo DRC, Eritrea, Ethiopia)
5	6	4	1	1	2	1 (Ethiopia)
6	5	2	2	-	2	-
8	6	6	2	-	2	3 (2 Ethiopia and 1 Seychelles)
9	6	4	2	-	2	3 (1 Ethiopea, 1 Seychelles and 1 Germany)
10	5	2	2	-	1	7 (1 Congo DRC, 1 Seychelles, 2 Nigeria, 1 Burkina Fasso, 1 Zimbabwe and 1 Mali)

RESULTS

Table 2: EAC –PT SCHEME ROUNDS

Round	Test substance /strengths	Test Parameter	Method	Number of Lab	
				Registered	Responded
4	Paracetamol • S1-600mg • S2-400mg • S3- 500mg	Assay	UV-Absorbance	20	16
5	Quinine • S1-360mg • S2-195mg • S3- 300mg	Assay	Non-Aqueous Titration	16	15
6	Albendazole • S1-400mg	Assay	HPLC	15	12
7	Albendazole • S1-400mg	Dissolution	UV		
8	Metronidazole • S1-200 mg	Assay	Own Method	19	19
9	Co-trimoxazole • S1-480 mg	Assay and Dissolution	Own Method	22	17/16
10	Ciprofloxacin • S1-500 mg	Assay and Dissolution	Own method	36	17

EAC PT SCHEMES RESULTS

	Round 4	Round 5	Round 6	Round 8	Round 9 A	Round 9 D	Round 10 A	Round 10 D
Satisfactory	57.5	71.1	91.7	78.95	76.47	90.63	70.59	56.25
Questionable	12.9	13.4	0	5.3	8.82	3.13	5.88	31.25
Nonsatisfactory	29.6	15.5	8.3	15.8	14.71	9.38	23.53	12.50

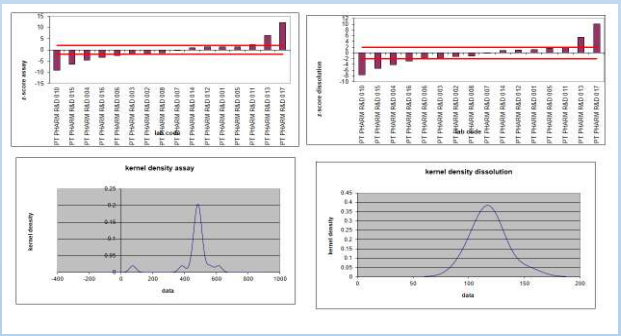

Figure showing PT round 10: ASSAY AND DISSOLUTION TESTING OF CIPROFLOXACIN TABLETS (500 mg)

CONCLUSION

- Six locally organized African PT schemes within pharma testing Labs
- A great opportunity for both the provider and participants to follow the lessons learned, which forms the ground for Continuous Quality improvements.
- The experience gained is helpful for further maintenance of the ISO/IEC 17043 accreditation status
- Appeals to African pharma testing labs to actively participate and demonstrate competence

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