Proficiency Testing Scheme for Pharmaceutical Lab: East African Regional Experience

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PHARM R&D LAB, MUHAS TANZANIA

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
**PROFICIENCY TESTING SCHEMES**

- **PT**: evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.
- There are three types of laboratory examination
  - Quantitative tests: statistical analysis
  - Qualitative tests: Descriptive, statistical analysis not necessary
  - Interpretive: “PT item” is the test result (descriptive morphology)
- **Uses of PT results**
  - Accreditation bodies
  - Other parties eg customers, subcontracting mandate
  - Regulatory bodies

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• Internal benefits of Interlaboratory comparisons:
  ❖ determine the performance of individual labs for specific tests or measurements and to monitor labs’ continuing performance
  ❖ Identify problems in labs and initiate remedial actions through root cause analysis
In an effort to build regional 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 laboratory, to become a regional PT provider for pharmaceutical testing laboratories - 2013.

Pharm R&D: Formulation development and Drug Testing capability

Planning and execution are based in the ISO/IEC 17043:2010 Conformity requirement where the statistical evaluation as per requirement ISO/IEC 13528 using z-score and excluding outliers with Cochran's and Grubbs' test.
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

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### EAC - PT SCHEME ROUNDS

<table>
<thead>
<tr>
<th>Round</th>
<th>Test substance /strengths</th>
<th>Test Parameter</th>
<th>Method</th>
<th>Number of Lab Registered</th>
<th>Number of Lab Responded</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Paracetamol</td>
<td>Assay</td>
<td>UV-Absorbance</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>(S1-600mg, S2-400mg and S3-500mg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Quinine</td>
<td>Assay</td>
<td>Non-Aqueous Titration</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>(S1-360mg, S2-195mg and S3-300mg)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6</td>
<td>Albendazole</td>
<td>Assay</td>
<td>HPLC</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>S1-400mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Albendazole</td>
<td>Dissolution</td>
<td>UV</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>S1-400mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Metronidazole</td>
<td>Assay</td>
<td>Own Method</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>S1-200 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Co-trimoxazole</td>
<td>Assay and Dissolution</td>
<td>Own Method</td>
<td>20</td>
<td>On going</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## DISTRIBUTION OF THE PARTICIPANTS BY TYPES

<table>
<thead>
<tr>
<th>R/N</th>
<th>NQCL</th>
<th>INDUSTRY</th>
<th>UNIVERSITY</th>
<th>NBS</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>4</td>
<td>7</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>8</td>
<td>3</td>
<td>0</td>
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</tr>
<tr>
<td>6</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>8</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>R/N</th>
<th>TANZANIA</th>
<th>KENYA</th>
<th>UGANDA</th>
<th>BURUNDI</th>
<th>RWANDA</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>6</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3 (Congo DRC, Eritrea, Ethiopia)</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1 (Ethiopia)</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>-</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>-</td>
<td>2</td>
<td>3 (Ethiopia and Seyshels)</td>
</tr>
</tbody>
</table>
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### Trend of the poor performing labs in ROUND 4-8

<table>
<thead>
<tr>
<th>Lab code</th>
<th>Round 4</th>
<th>Round 5</th>
<th>Round 6</th>
<th>Round 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>03</td>
<td>Not Participated</td>
<td>Satisfactory</td>
<td>Unsatisfactory</td>
<td>Questionable</td>
</tr>
<tr>
<td>11</td>
<td>Unsatisfactory</td>
<td>Satisfactory</td>
<td>Not participated</td>
<td>Unsatisfactory</td>
</tr>
<tr>
<td>13</td>
<td>Satisfactory</td>
<td>Satisfactory</td>
<td>Not participated</td>
<td>Unsatisfactory</td>
</tr>
<tr>
<td>16</td>
<td>Not participated</td>
<td>Not participated</td>
<td>Not participated</td>
<td>Unsatisfactory</td>
</tr>
</tbody>
</table>
Possible causes of deviations

- Each participant with Z-score $\geq 2$ need to perform a root cause analysis.
Evaluation and training workshop

• Preliminary PT report is sent to participating labs
• Poor performing lab to do investigation/root cause analysis
• Feedback evaluation workshop and training

Certificate of participation and successful completion
CONCLUSION

- Five locally organized EAC PT scheme within pharma testing Labs
- Participation is good but variable with laboratories
- This external quality assurance tool provides a competence assessment opportunity for the participant towards quality system improvement.
- The experience gained is useful for the further preparation towards ISO/IEC 17043 accreditation.
- Therefore it is encouraged for more testing laboratories to engage in this scheme
How to register for Round 9

• Visit our website

https://pharmrd.muhas.ac.tz/proficiency/register
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How to register for Round 9

FEES AND PAYMENTS
1. Assay Only without workshop (60 USD)
2. Dissolution Only without workshop (80 USD)
3. Assay or Dissolution + workshop (120 USD)
4. Both Assay and Dissolution + workshop (160 USD)

Total fee payable: Should be selected from 1 to 4

Samples will only be dispatched to labs that have submitted the application form and the proof of payment.

BANKING DETAILS
ACCOUNT NAME: MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
BANK: NATIONAL BANK OF COMMERCE (NBC)
BRANCH: MUHIMBILI BRANCH
ACCOUNT NO.: 012105003692
BRANCH CODE: 00010002
AKNOWLEDGEMENT

• PTB
• EAC secretariat
• ALL Participants from testing labs
• MUHAS
• AUDA-NEPAD