QARSHI
RESEARCH INTERNATIONAL Pvt. Ltd.
PROFICIENCY TESTING SCHEME
Pharmaceuticals
(ISO / IEC 17043:2010)

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The 1st and only ISO 17043 Accredited Proficiency Testing Provider By PNAC & TURKAK in Pakistan

INTRODUCTION:

Qarshi is a leading indigenous organization in Pakistan with a large number of National / International Accreditation and Certifications which includes

1. ISO/IEC 9001
2. ISO/IEC14001
3. HACCP
4. Halal
5. Organic Cultivation
6. PCP (Pakistan Center of Philanthropy)
7. ISO/IEC 17025 and
8. ISO/IEC 17043 accreditation (PNAC)
9. ISO/IEC 17043 accreditation (TURKAK)
10. ISO 17020 accreditation (PNAC)

Qarshi is playing a very active part in supporting Pakistan's business growth including exports, employment generating and contribution to national exchequer in the form of taxes. At the same time Qarshi Foundation is also contributing in the social sector through its continuous support in the field of health, education and environment friendly activities.

Qarshi Research International Pvt. Ltd.

QRI is an independent business unit within Qarshi Organization with the aim of providing quality testing & proficiency testing (PT) services through its internationally recognized accredited laboratories facilities located at Hattar Industrial Estate, Haripur, KPK, Pakistan.

QRI has been pioneer in the field of quality assurance in compliance with international standards in Pakistan. QRI was the first accredited organization in Pakistan that achieved accreditation in compliance with ISO/IEC 17025 from Norwegian Accreditation (an apex accreditation body in Norway) in 2004 covering the scope of physical, chemical and microbiology testing.

Subsequently the accreditation of QRI's testing laboratories was granted by the national accreditation body PNAC (Pakistan National Accreditation Council) in 2004.

QRI achieved yet another milestone in the accreditation history of Pakistan by becoming the first organization that achieved accreditation status as Proficiency Testing Provider (PTP) by PNAC and TURKAK in compliance with the requirements of ISO/IEC 17043.

Why it is necessary to participate in Proficiency Testing (PT) scheme?

Participation in appropriate PT scheme is not only one of the essential tools for the external evaluation of the performance and reliability of the testing results but it also fulfills one of the requirements of the accreditation standard ISO/IEC 17025, in order to demonstrate impartial comparability of results. Participation in PT provides the laboratories an excellent opportunity to demonstrate their performance.

QRI contribution in the history of PT Scheme in Pakistan

In 2006 PNAC conducted the very first PT program in Pakistan with the collaboration of QRI. In this PT program, QRI contributed with sampling, bottling, labeling, homogeneity and stability studies. This exercise proved to be successful. In the subsequent years, QRI conducted its own PT program based upon the successful venture with PNAC. Organizing PT programs in Pakistan by QRI was need of the time as there was no such program available in Pakistan and the laboratories in Pakistan seeking accreditation from PNAC were obliged to participate in appropriate PT programs operated by foreign based organizations.

QRI not only facilitates the laboratories in their quest to be accredited by PNAC in Pakistan but also supports the state to save foreign exchange by providing indigenous PT schemes. In addition, participating in PT organized by QRI saves time and economical resources for laboratories comparing with participation in PT schemes offered by foreign based organization.

Benefits of PT participation:

While some laboratories may view participation in PT program as a necessity only to satisfy the requirements of accreditation bodies, they could be overlooking the more fundamental benefits that can be achieved by taking part in well-designed PT program.

Clearly the laboratories are the major stakeholders in PT program participation, but there may be other stakeholders who also have a major interest in such programs and in the performance of laboratories involved i.e. professional bodies, regulatory authorities, reference materials producers, direct & indirect customers etc.

The following are some of the potential benefits for PT participating laboratories:

- Compliance to the accreditation requirement.
- Determining method precision and accuracy.
- Demonstrate competence.
- Comparing methods and procedures.
- Improve testing performance.
- Training & educating of staff.
- Instilling confidence in staff, management & lab customers / clients.
- Comparing analysts' capabilities.
- The remaining amount of PT sample is considered as best reference material provided it is maintained under stable conditions.

Finally, the successful performance of a laboratory in a proficiency test (or its effective correction of testing problems after an unsuccessful performance) may provide accreditation bodies with confidence in the laboratories for granting and/or maintaining accreditation. The clear benefit for the laboratories is the confidence of their standing as competent organizations.

Repeated PT participation will provide them excellent opportunity to ensure that results of laboratory are consistent over time.

Criteria for Participation in the PT Scheme:

This round is open to all accredited laboratories, as well as other labs who intend to go for accreditation, and also for those labs which are interested to ensure the validity of their results using proficiency testing as a tool.

Salient features of the PT scheme offered by QRI:

Matrix: Pharmaceutical Related Items

Sr. #	Bottle Code	Parameters	Sample Size	Range	Rate Offered (USD) (Including Shipment Charges)
01	Pharma Compliance PHC	D-Time	20 Tablets	NMT 01 Hrs.	204/- per sample (10 parameters)
02		Tablets Hardness	30 Tablets	3 - 7 Kpa	
03		Friability		<1 %	
04		Melting Point	3 Grams	180 - 250 Celsius	
05		Loss on Drying (LOD)	25 Grams	NMT 03 %	
06		pH	120ml	3 – 6	
07		Specific Gravity		1.3500 – 1.3700	
08		Refractive Index (RI)	120ml	1.4600 – 1.4700	
09		Paper Grammage	4 Sheets (A4 Size)	60 – 90 g/m^2	
10		Brimful	03 Bottles (PET)	240-280ml	

Payment: The above-mentioned rates are exclusive of sales tax on services (PRA/KPRA). Payment to be made in favor of "Qarshi Research International Pvt. Ltd". GST @ provincial law will be applicable.

1. Expression of interest (EOI)

Potential participants are requested to participate through E-portal https://www.qri.com.pk/pt. This exercise is needed to gather information about the interest of PT among participants and number of expected participants. QRI anticipates the total number of participants to be higher than 20. This is necessary to increase the reliability of PT, and to improve the data evaluation through appropriate statistical tool.

2. Preparation of samples

Based upon the feedback received through EOI, a bulk amount of sample is prepared, followed by distribution of appropriate amount of sample in carefully selected vessels/containers. Sufficient number of sample vessels are prepared ensuring the stability and homogeneity studies in addition to distribution to the participants.

3. Labelling of vessels and coding of participants

Each vessel is given a unique code number using pre-defined criteria. Each participant is assigned a code in order to maintain the requirement of confidentiality in compliance with the ISO/IEC 17043. This code is only available to a given participant.

4. Homogeneity and stability of PT samples

Samples of the PT are rigorously analyzed in order to monitor the homogeneity with regards to parameters offered: Stability studies are performed at various temperatures in order to assure that each sample is stable throughout the life cycle of given PT scheme. Climatic chambers are used for studying the stability at elevated temperatures.

5. Distribution of samples

Samples are carefully packed and transported to the participants under controlled temperature, where it is necessary. Participants are provided instruction for handling of samples after receipt to ensure their integrity during analysis by the participants.

6. Handling of results submitted by the participants

Each participant is required to submit their results in a pre-defined format. After receipt of results, the data is evaluated to identify any possible outlier using appropriate statistical tool. The results identified as outlier are rejected and are not used for further statistical handling.

7. Evaluation of performance of the participant

On the basis of results received from all participants, a consensus value is derived (after rejecting possible outliers) by using appropriate statistical approach. The consensus value is used to evaluate the performance of each participate. The performance is expressed in terms of Z score.

8. Individual Lab Performance Report:

After preliminary data analysis each participating lab will receive an individual performance report where their performance will be evaluated by using Z – Score model.

9. Final report of the PT

Each participant receives a final report electronically within 3 months after submission of results. This report provides details of the PT including results from homogeneity and stability studies, results submitted by all participants, statistical handling of data and graphic presentation of results. An overall summary of the PT is also presented. In the report, each participant is identified with the code given to them. Each participant receives the code assigned to them in separate letter so that they check their own performance.

10. Complaints and appeals

Each participant is encouraged to submit their suggestions, complaints, appeal and any possible complaints. These are handled in compliance with the requirements of ISO/IEC 17043.

The PT participants can appeal against within one month after receiving the preliminary PT report in written.

11. Certificate of participation

Each participant receives a certificate where their performance is highlighted. The certificate also serves to demonstrate their participation as evidence to appropriate authority such as accreditation body.

12. Confidentiality

All information submitted by the participants will be handled strictly confidential. Each laboratory will be assigned a unique identification in terms of code number. This code number will be made available to only the laboratory concerned authorized representative(s).

13. Purchase of Reference Material

After successful completion of PT, the remaining amount of sample bottles will be made available to the participants at competitive prices. These samples can be used as reference materials. These will be provided with a certificate indicating the reference value along with the associated uncertainties.