STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Analyst Qualification in Microbiology Laboratory	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Analyst Qualification in Microbiology Laboratory

2.0 SCOPE:

This SOP is applicable to qualification of newly joined analyst, completing satisfactory training and to the qualified analyst annually, or earlier, if necessary in Quality Control Department.

3.0 RESPONSIBILITY:

Executive / Manager-QC

4.0 ACCOUNTABILITY:

Head-QC

5.0 PROCEDURE:

Analyst Qualification shall be carried out in the following areas.

- Sterility Testing
- BET Analysis
- MLT

5.1 STERILITY TESTING

5.1.1 Following items shall be required before execution of Analyst Qualification for Sterility Testing:

- Stericheck Canisters.
- Stericheck Dilutor.
- Sterile Water for Injection.
- Laminar Air Flow
- Sterile Forceps & Scissor
- Sterile Fluid Thioglycollate Medium.
- Sterile Soyabean casein Digest Medium.
- Microbial Culture Suspension
- Steritest Equinox.
- Membrane Filtration Assembly

5.1.2 Prepare 60 X 10 ml Water for injection vials**.**

5.1.3 Seal the vials with rubber stoppers and aluminum seals in media preparation room.

5.1.4 Sterilize the vials in autoclave using standard cycle.

5.1.5 Segregate the sterilized vials in to group containing 20 vials in each group**.**

5.1.6 Give the identifications to each group as A, B, and C**.**

5.1.7 Contaminate one or two vials in any one or two groups with 10-100 CFU's / ml of any one Known cultures using a syringe in culture handling room**.**

5.1.8 **Note:** Spiking (contamination) shall be done by In charge-Microbiology and shall keep spiking information sheet confidential till completion of the test. So, that the Analyst shall not know the spiking information till completion.

5.1.9 Perform the sterility test for all Three groups of sterile water for injection using membrane filtration method By Closed or open method in which analyst has to be qualify.

5.1.10 Perform these tests on 3 consecutive days to confirm the reproducibility of the analyst performance.

5.1.11 Record the activity as per **Format** for Sterility Test"

5.1.12 **Acceptance criteria**:

- The un-spiked groups (1 or 2groups) of sterile water for injection samples should pass the sterility test in all three trials.
- The spiked group (1or 2 group) of sterile water for injection samples should fail the sterility test in all three trials.
- The organism isolated should be same as inoculated.
- After successful completion of the test, a certificate shall be prepared for the approval of analyst qualification as per format.

5.2 For Bacterial Endotoxin Test:

5.2.1 Following items shall be required before execution of Analyst Qualification for Bacterial Endotoxin Testing:

- LAL Reagent
- CSE with COA
- LRW with COA
- Cyclo Mixer

- Depyrogenated 10 X 75 mm glass test tubes
- 12 X 75 mm /16 X 75mm depyrogenated borosilicate glass tube
- Calibrated heating block
- Calibrated micropipette
- Endotoxin free tips
- Depyrogenated glass pipette
- Test tube stand etc.

5.2.2 Prepare 06 X 10 ml Water for injection vials**.** Seal the vials with rubber stoppers and aluminum seals in media preparation room.

5.2.3 Sterilize the vials in autoclave using standard cycle.

5.2.4 Segregate the sterilized vials in to group containing 02 vials in each group**.** Give the identifications to each group as A, B, and C**.**

5.2.5 Challenge one vials in any one or two groups with 1EU / ml of Endotoxin using a syringe in bet room**.**

5.2.6 Note: Spiking (Challenged) shall be done by In-charge-Microbiology and shall keep spiking information sheet confidential till completion of the test. So, that the Analyst shall not know the spiking information till completion.

5.2.7 Perform the BET test for all Three groups of sterile water for injection using Gel-clot Method in which analyst has to be qualify.

5.2.8 Perform these tests on 3 consecutive days to confirm the reproducibility of the analyst performance.

5.2.9 Record the activity as per **Format** for Bacterial Endotoxin Test"

5.2.10 Acceptance criteria:

- The un-spiked groups (1 or 2groups) of sterile water for injection samples should pass the BET test in all three trials.

- The spiked group (1or 2 group) of sterile water for injection samples should fail the BET test in all three trials.

- After successful completion of the test, a certificate shall be prepared for the approval of analyst qualification as per format.

5.3 MLT Testing.

5.3.1 Following items shall be required before execution of Analyst Qualification for MLT Testing:

- Sterile Water for Injection.
- Laminar Air Flow
- Sterile Forceps & Scissor
- Sterile Soyabean casein Digest Medium.
- Microbial Culture Suspension
- Membrane Filtration Assembly

5.3.2 Prepare 6 X 100 ml Water for injection container**.**

5.3.3 Seal the vials with rubber stoppers and aluminum seals in media preparation room.

5.3.4 Sterilize the vials in autoclave using standard cycle.

5.3.5 Segregate the sterilized vials in to group containing 02 vials in each group**.**

5.3.6 Give the identifications to each group as A, B, and C**.**

5.3.7 Contaminate one vials in any one or two groups with 10-100 CFU's / ml of any one Known cultures using a syringe in culture handling room**.**

5.3.8 Note: Spiking (contamination) shall be done by In charge-Microbiology and shall keep spiking information sheet confidential till completion of the test. So, that the Analyst shall not know the spiking information till completion.

5.3.9 Perform the MLT test for all Three groups of sterile water for injection using MLT Testing Method.

5.3.10 Perform these tests on 3 consecutive days to confirm the reproducibility of the analyst performance.

5.3.11 Record the activity as per **Format** for MLT Test"

5.3.12 Acceptance criteria:

- The spiked groups (1 or 2groups) of sterile water for injection samples should pass the MLT Testing test in all three trials in which recovery of challenge organism should meet Not Less Than 70 %.
- The un spiked group (1or 2 group) of sterile water for injection samples should show no CFU or growth observed.
- After successful completion of the test, a certificate shall be prepared for the approval of analyst qualification as per format.

5.4 After successful completion of the test, a certificate shall be prepared for the approval of analyst qualification as per **Format.**

5.5 The Head QC shall identify the analyst and the activity in which Qualification is required.

5.6 The Head QC shall identify the sample of known Analytical value which may include pass/ fail sample and shall code the same.

5.7 The details of coded sample & Code No. shall be recorded by Head QC as per **Annexure-I**, Title **"Analyst Qualification Sample Log Book"**.

5.8 Sample code number consists of following characters:

AV-XXXX/DDMMYY

Where,

AV **:** Analyst Validation

\- **:** Separator

XXXX **:** Product, first four letters.

/ **:** Separator

DDMMYY **:** Date to sample given for analysis (i.e. for 12 July 2023 it is 100723)

5.9 The Head QC shall brief the analyst regarding the importance of qualification, acceptance / Re-Approval criteria.

5.10 The coded samples shall be hand over to analyst along with the specification & detailed with method of analysis and other necessary information.

5.11 The Analyst shall perform the analysis in triplicate.

5.12 The Analyst shall record his / her results / observation in format as per format shown in **Annexure-II**, Title **"Analyst Qualification Report"**, given to him and handover to Head QC.

5.13 Head QC shall evaluate the result given by analyst as per **Annexure-III**, Title **"Analyst Qualification Acceptance Criteria Guidelines"**.

5.14 The Analyst shall be qualified on the basis of his / her performance and the certificate shall be issued as per **Annexure-IV**, Title **"Analyst Qualification Certificate"**.

5.15 In case of failure to comply with the Acceptance criteria for certification the Analyst shall be Retrained / Revaluated.

5.16 In case, two consecutive failures the Analyst shall be considered Non-Qualified.

5.17 In case an analyst fails to qualify more than three consecutive training, he / she shall not be allowed to perform the critical analysis.

5.18 In case the analyst is not performing the task / test for which he / she is qualified for a period of more than one year then he / she shall under go re-qualification prior to performing the task / test.

6.0 REFERENCES:

Not Applicable

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Analyst Qualification Sample Log Book	
Annexure-II	Analyst Qualification Report	
Annexure-III	Analyst Qualification Acceptance Criteria Guidelines	
Annexure-IV	Analyst Qualification Certificate	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 — Quality Assurance Department
- Controlled Copy No. 02 — Quality Control Department
- Master Copy — Quality Assurance Department

9.0 ABBREVIATIONS:

BET	Bacterial Endotoxin Test
E. Code	Employee Code

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Ltd.	Limited
NMT	Not More Than
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE-I
ANALYST QUALIFICATION SAMPLE LOG BOOK

S.No.	Date	Name of Analyst	E. Code	Name of Sample	Sample Code No.	Batch No.	Manager QC Sign & Date	Remarks

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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ANNEXURE –II
ANALYST QUALIFICATION REPORT

Name of Analyst		**Employee Code No.**	
Name of Sample		**Sample Code No.**	
Number of groups prepared		**No. of vials spiked:**	
Identifications of the Groups		**No. of vials in each group:**	
Name of the Culture selected for Spiking		**Date of Sample Received**	
I.D. of the Group spiked with the culture suspension:		**Date of Report**	
No. of vials spiked:		**Reference Specification No.**	
		Reference STP No.	
Sample Issued By		**Reference SOP No.**	

S.No.	Parameter	Remarks
1.	Adherence to SOP	Yes / No
2.	Adherence to Testing Method	Yes / No
3.	Correctness of Culture Media used/Reagent	Yes / No
4.	Usage of Calibrated Instruments	Yes / No
5.	GLP in Handling of Samples	Yes / No
6.	Correct usage of Membrane Filter, Instruments etc.	Yes / No / NA
7.	GLP in Performing Dilutions	Yes / No / NA
8.	Correctness of Calculations	Yes / No/NA
9.	Correctness in Reporting of Results	Yes / No
10.	Good Documentation Practices	Yes / No

Results of Analyst under Certification Sample							Complies / Does Not Comply
Sample	**Trial-1**		**Trial-2**		**Trial-3**		
	Initial Result	**Test Result**	**Initial Result**	**Test Result**	**Initial Result**	**Test Result**	
Group-A							
Group-B							

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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Group-C							

Remarks (if any):

_____

_____

_____

Conclusion: The analyst is Qualified / Not Qualified for carrying out the above Analysis independently.

Evaluated By:
Sign & Date

Date of Qualification:

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ANNEXURE-III
ANALYST QUALIFICATION ACCEPTANCE CRITERIA GUIDELINES

S.No.	TEST	ACCEPTANCE CRITERIA
MICROBIOLOGICAL TESTING		
1.	BET	The un-spiked groups (1 or 2 groups) of sterile water for injection samples should pass the BET test in all three trials. The spiked group (1or 2 group) of sterile water for injection samples should fail the BET test in all three trials.
2.	MLT	The spiked groups (1 or 2 groups) of sterile water for injection samples should pass the MLT Testing test in all three trials in which recovery of challenge organism should meet Not Less Than 70 %. Of the initial challenge cfu. The un spiked group (1or 2 group) of sterile water for injection samples should show no CFU or No growth observed.
3.	Sterility	The un-spiked groups (1 or 2groups) of sterile water for injection samples should pass the sterility test in all three trials. The spiked group (1or 2 group) of sterile water for injection samples should fail the sterility test in all three trials. The organism isolated should be same as inoculated.

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ANNEXURE –IV

LOGO

ANALYST QUALIFICATION CERTIFICATE

Name of Analyst : _____
Department : _____
Designation : _____
E. Code : _____

This is to Certify that Mr./Ms._____dated_____has been Qualified to

Carryout ----------Analysis.

Head Quality Control _____

(Date & Sign)