DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Contract Laboratory	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 PURPOSE

To define a procedure for Qualification of contract analytical laboratory utilized for conducting analysis.

2.0 SCOPE

2.1 This procedure applies for qualification of contract analytical laboratory for ……

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 SOP: Preparation of Quality Agreement

3.1.2 SOP: Handling Out of Specification (OOS) results

3.1.3 SOP: Handling of Out of Trend (OOT) results

3.2 Attachments

3.2.1 Attachment- I: Questionnaire for Evaluation of Contract Analytical Laboratory

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Contract Giver:** Pharmascholars Pvt. Ltd.

4.1.2 **Contract Acceptor:** The non-clinical analytical laboratory that will analyze samples from …….. on a contract basis.

4.2 Abbreviations

4.2.1 OOS: Out of Specification

4.2.2 OOT: Out of Trend

4.2.3 GLP: Good Laboratory Practices

5.0 RESPONSIBILITY:

5.1 Quality Control Head and Quality Assurance Head:

5.1.1 Shall make assessment of the contract analytical laboratory as per procedure mentioned in this SOP.

5.1.2 Shall participate in the audit of contract laboratory.

5.2 Plant Head:

5.2.1 To ensure implementation of the defined procedure.

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6.0 Distribution:

I. Quality Assurance

II. Quality Control

7.0 PROCEDURE:

7.1 Head-QA or designee shall initiate qualification of contract acceptor by sending "Questionnaire for Evaluation of Contract Analytical Laboratory" (Attachment-I) to the prospective laboratory.

7.2 The Head-QA, after receiving the filled form from the contract analytical laboratory, shall evaluate and forward it to Head-QC or designee with comments, if any.

7.3 Head-QC or designee shall evaluate the questionnaire and see if the site audit of contract acceptor is required or not.

7.4 The site audit, if planned shall be intimated to contract acceptor through the representatives of contract giver.

7.5 The audit shall cover all Good laboratory Practices (GLP) aspects, facility, capacity, working procedures, documents, personnel's, training and quality systems.

7.6 Based on audit findings, audit report shall be prepared and shared with contract acceptor.

7.7 The compliance report received from contract acceptor shall be reviewed by Head-QC and Head-QA.

7.8 Final approval of contract acceptor shall be from Head-Corporate QA.

7.9 A written contract as per SOP (Preparation of Quality Agreement) shall be signed by the contract analytical laboratory.

7.10 If the contract is approved, the following shall be ensured by contract giver:

7.10.1 Testing method and specification. It shall be the responsibility of Contract Giver to provide current testing methods to the Contract Acceptor. In case, any change or revision in method is observed, contract giver shall provide the latest method to the contract acceptor.

7.10.2 Working standard/Reference standard or Impurity standard, if required by the analytical laboratory.

7.11 In an event of OOS results, results shall be conveyed and informed to Head-QC with supporting data and findings.

7.12 Investigation of OOS/OOT shall be done by authorized designee of both contract acceptor and contract giver as per SOP (Handling Out of Specification (OOS) results) and Handling of Out of Trend (OOT) results.

7.13 Head-QC in consultation with Head-QA shall decide whether the sample is to be accepted or rejected.

7.14 As intimated in the contract, audit of functioning of the facility shall be planned and documented. Audit shall be conducted once in two years or in case of incident or OOS or new method, the audit may be planned based on joint decision of Head, QA and QC.

7.15 Contract laboratory shall provide the analytical raw data to the contract giver.

8.0 REVISION HISTORY

Version No.	00	**Effective Date**	
Details of revision: New SOP Prepared			

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Attachment-I

EVALUATION OF CONTRACT ANALYTICAL LABORATORY

Subject: Evaluation of Contract Analytical Laboratory	**Date:**
Address:	**Name of Contact person:**
	Contact No.:
	E-mail ID:
Remarks (if any): **Head-QA (Sign/Date)**	

Sent On:	**Sent By (Name):**	**Sent By (Sign):**

(Sign/Date)

To be filled by the Contract Analytical Laboratory

A. Basic Information:

Name and Address of the firm / laboratory:

Name of the In-charge of the laboratory:

Phone No.:

Fax No.:

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E-mail:

Contact person (if other than laboratory in charge):

Accreditation by (Name of Agency like ISO, NABL, NIBD, BIS, etc.) and year:

Renewals due on:

Organizational membership (if any):

B. Good Laboratory Practices Checklist :

S.No.	Qualification Aspects	Yes/No/NA	Remarks/Comments (if any)
Chemical and instrumentation (Section-I)			
1.	Is there any general housekeeping schedule?		
2.	Is the environmental condition of laboratory maintained and recorded?		
3.	Does qualified person receive samples?		
4.	Is any documentation or coding used to track a sample received for test?		
5.	Are samples adequately stored before and after testing?		
6.	For how long samples are stored after test results are reported?		
7.	Is the storage facility for samples monitored for temperature and humidity?		
8.	Are equipment's/instruments available for testing (Provide list along with their Make Model and capacity/size)?		
9.	Is there any schedule for performing calibration of equipments/ Instruments? (If yes, please attach key equipment/ Instrument calibration schedule).		
10.	Is calibration performed internally or through external agencies? If, through outside agency, please mention name of agency with the instrument name.		
11.	Are internal standards used for calibration traceable to any National / International Accreditation Agency?		
12.	Are there written procedures for operation and calibration of instruments?		

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S.No.	Qualification Aspects	Yes/No/NA	Remarks/Comments (if any)
13.	Is there any preventive maintenance programme for instruments?		
14.	Is the records and certificates of calibration and preventive maintenance of equipment/ instrument available?		
15.	Please provide brief description of training program followed including evaluation and documentation (attach separate sheet if required)		
16.	Is there any SOP for maintaining the documents/ records of the laboratory?		
17.	What is the proposed lead time for reporting of results/ dispatch of results for: a) Chemical Analysis (Should not be more than 3 days) b) Microbiological Testing (Should not be more than 10 days) c) Sterility Testing (Should not be more than 20 days)		
18.	Are all data (final report and relevant raw data) reported and provided to client?		
19.	Does laboratory retain records of original observation, derived data and test records?		
20.	Are records readily retrievable and have a procedure for back up of records stored electronically?		
21.	What is the retention period or documentation retention policy?		
22.	Is there an SOP on Out-of-Specification test results?		
23.	Is out-of-specification test results investigated and evaluated?		
24.	Is there any SOP of data integrity?		
25.	Does the laboratory have a policy and procedure(s) for tests results that do not comply with its own procedures /specifications or agreed requirements of the client?		
26.	Are the testing reports including graphs and print outs signed and dated by analyst?		
27.	Are the testing records counter checked / signed by QC in charge before dispatch of report?		
28.	Do you have a Quality Manual including quality system policies and objectives?		
29.	Does the laboratory have procedures to control all documents forming part of quality system e.g. regulations, standards, test methods, specific instructions, etc.		

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S.No.	Qualification Aspects	Yes/No/NA	Remarks/Comments (if any)
30.	Are all documents issued to personnel in laboratory, reviewed and approved by authorised personnel before issuing?		
31.	Do you have the latest copies of Pharmacopoeias i.e. I.P., B.P., U.S.P.?		
32.	Are written procedures/ test methods reviewed and updated?		
33.	Are written procedures for testing of samples received from client properly documented?		
34.	Is there a protocol that requires the client to be notified of changes made to test procedures?		
35.	Are the chemicals and media purchased through approved vendors?		
36.	Is ledger maintained for stock of chemicals and media?		
37.	Is First In First Out (FIFO) system followed for use of chemicals / reagents / media?		
38.	Are chemicals examined for proper labels and expiration date, if applicable, at the time of receipt?		
39.	Are chemicals and reagents stored properly with different chemicals differentiation?		
40.	Are working/reference standards stored properly?		
41.	Is secondary or working reference standards calibrated against primary reference standards?		
42.	Are lab reagent bottles properly labelled (like Name of reagent, date of preparation, use before date, prepared by, standardization factor, Code No., storage temperature)?		
43.	Software used in the laboratory, should have unique user ID and password policy.		
44.	Electronic raw data and record, should be human readable and suitable for inspection and review.		
45.	Electronic raw data should have following traceability, Performed by with date and time, Print by with date and time, Reviewed by with date and time.		
46.	Electronic data backup shall be done on regular basis and store in protected drive.		
47.	Electronic raw data shall not be edited or altered or overwrite without authorization.		
48.	Software used in the laboratory should have Audit Trail, to track for all creations, modifications, and deletions performed in the		

S.No.	Qualification Aspects	Yes/No/NA	Remarks/Comments (if any)
	system. All activity should be logged such as login and log out with time and date along with user details.		
49.	Software date and time shall change automatically, it shall be locked and not editable unless performed by authorized user, shall be defined through user rights distribution.		
50.	Is there any Laboratory software and information management system with features that support a modern laboratory's operations such LIMS?		
Microbiology (Section-II) [please proceed if applicable]			
51.	Is entry to microbiology laboratory restricted?		
52.	Is there gowning/de-gowning procedure for entry and exit from the microbiology laboratory?		
53.	Is the area monitored where microbiological testing is performed?		
54.	Are personnel working in microbiology lab examined for personal hygiene?		
55.	Is there an SOP describing (I) Preparation and usage of culture media? (II) Discarding of used cultured media?		
56.	If microbiological media is prepared internally, can these be tracked to respective preparation date, batch number and sterilizing cycles?		
57.	Are the standard bacterial cultures available?		
58.	Is there a SOP for cleaning and operation of LAF?		
59.	Is LAF validated and re-validated as per a written protocol?		
60.	Have sterilization cycles been validated for media preparation?		

Note: Wherever necessary, attach details as annexure.

Please enclose list of following documents:

1. Organogram (with qualification, experience and job responsibilities of key personnel).
2. Copy of certificates of approval by State/ FDA Authorities or any other approval.
3. List of Equipments/Instruments with make/model No. along with the mention of calibration of critical Analytical Instruments like HPLC, UV Spectrophotometer, GC, etc.
4. List of equipments in microbiology section

5. List of Working/Reference/Impurity standards along with their source.
6. List of SOP's.
7. SOP for Handling of Out of Specification.
8. SOP of Data Integrity.
9. List of Clients.

_____

Authorised Signatory (Sign & date)
(Contract Analytical Laboratory)

Evaluation by Head-QC and Head-QA of Contract giver:

1. Pre-audit required		Yes/No
2. Out of Specification evaluated and closed (if applicable)		Yes/No
3. Additional testing required (if applicable)		Yes/No
4. Affected documents closed (if applicable)		Yes/No
5. Evaluation found (Satisfactory/Not Satisfactory)		
Evaluated By	**Head-QC**	**Head-QA**
Sign & Date		