PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procedure for Subcontracting of Work	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for Subcontracting of Work to evaluated subcontractor.

2.0 SCOPE:

This SOP is applicable to Quality Control Deprtment.

3.0 RESPONSIBILITY – Execution - QC Executive.
Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 EVOLUTION OF SUBCONTRACTOR:

Before subcontracting any work to subcontractor, the said contractor should be evaluated as per following procedure

5.1.1 Manager QC or Manager QA shall audit the contract laboratories for checking the compliance of the laboratory as per requirement.

5.1.2 Audit shall be carried out in accordance with the check list, GLP guidelines and to the scope of agreement (Annexure - I).

5.1.3 After completion of audit , Auditor shall submit the audit report to the CQA Head with the comments.

5.1.4 CQA shall review the audit reports and make a remark for the approval of subcontractor.

5.1.5 After approval Manager QC ask the consent letter from the subcontractor and file the same and assure for the compliance.

5.2 GENERAL PROCEDURE:

5.2.1 If facility is not available for the testing, instrument under maintance or in case of other unavoidable circumstances , material shall be sent to the contract laboratory by coordinator for the respective test.

5.2.2 Coordinator shall prepare “Sample analysis request slip-(Annexure-II)”, in duplicate and fill the details for “Slip No.”, “Date”, “Product / Material” , “Batch No. / AR No.” , “Sample quantity and size” , “S. No.”, “Test”, “Reference”, “Name of contract lab” and “Remarks(if any)” , “Attachment(if any)” , and take the approval of head QC or designee . One copy of the “Sample analysis request slip’ shall remain with Coordinator.

5.2.3 .Coordinator shall make entry in the “Outside testing register” (Annexure-III) for “Slip

No." , "Date" , "Product / Material" , "Batch No. / AR No." "Test", "Name of contract lab".

5.2.4 Pack the required quantity of sample in the double self lock poly bag or in the other suitable pack with proper identification and send along with the "Sample analysis request slip' to the contract laboratory.

5.2.5 In case of analysis required as per In- house procedure than Coordinator shall provide the reference test procedure along with the sample. Reference test procedure shall be sent only once or as on when required. Coordinator shall ensure that current version of reference test procedure available with the contract laboratory and analysis is performed as per the current version.

5.2.6 In case of working standard / reference standard / impurity standard is not available with contract laboratory then Coordinator shall provide the working standard / reference standard / impurity standard to the contract laboratory.

5.2.7 After receiving of the COA, coordinator shall fill the result in analytical report , shall write the reference certificate No. of COA in "Remark" column. COA shall attach with the analytical report and submit for the review to the designated person.

5.2.8 The COA submitted by the contract laboratory shall contain :

a) Name and identification No. (e.g. Slip # or lot #).

b) Test results and methods of analysis followed

c) Required standards and Limits

d) Statement of compliance or noncompliance (As per the reference specification given)

e) Date and signature of designated qualified professional of contract laboratory.

5.2.9 After reviewing , checker shall put stamp of reviewed by and put initial / date In case of any discrepancy shall be coordinated by coordinator with the contract laboratory and shall be resolved.

5.2.10 The slip which states "Complies" of test from contract laboratory can be acceptable for releasing the material other than finished product . The same is to be reviewed when detailed COA is received as per procedure.

5.2.11 Coordinator shall make entry in the "Outside testing register" for the "Status" (Approved / Rejection) , "Received by" , "Date" , and make remarks in the "Remarks" column if any .

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

CQA : Corporate Quality Assurance

COA : Certificate of Analysis

Annexure – I : Check List For Audit

Annexure –II : Format For Sample Analysis Request Slip

Annexure – III : Format For Outside Testing Register

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ANNEXURE – I

CHECK LIST FOR AUDIT

S.No.	Name of Inspect Document / Record/ System	Remarks of Auditor	Corrective Action	Remarks of QC Head
1.	FDA Registration			
2.	Medical report of Employees			
3.	Facility			
4.	Qualification of Analyst			
5.	Training of employee			
6.	Volumetric solution system			
7.	Preparation and usage of working standards			
8.	Sample inventory system for testing			
9.	Sample allocating system for testing			
10.	SOP’s			
11.	Glassware washing			
12.	Control samples			
13.	Qualification of instruments			
14.	Instruments Calibration			
15.	Raw data handling system			
16.	Deviation			
17.	Storage chemicals			
18.	Upkeep of current version of company’s specification			
19.	Microbiological culture / all culture upkeep and system (if in scope of			

	Audit)			
20.	Performance and control of animal testing for the suitability and reliability (if in scope of Audit)			

Head QC :_____ **Head QA _____**

Final Conclusion : Satisfactory / Unsatisfactory

Sign / Date of CQA Head_____

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ANNEXURE –II

SAMPLE ANALYSIS REQUEST SLIP

Slip No.: ----------

Date: ----------

Product / Material :

Batch No. / AR No. :

Sample quantity x size :

Test:

S.No.	TEST	REFERENCE

Name of Contract Laboratory:
Remarks (if any)
Attachment (if any)

Send by: ----------

Authorized by ----------

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ANNEXURE – III

OUTSIDE TESTING REGISTER

Slip no.	Date	Product/ Material	B.No. / AR No.	Test

Name of Contract Laboratory	Received by / Date	Remarks