PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of analysis by Contract laboratory	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for handling of analysis by contract laboratory.

2.0 SCOPE:

This SOP is applicable for handling of analysis of raw materials and finished products by contract laboratory, Quality Control Department of other units of ……..

3.0 RESPONSIBILITY:

Officer, Executive – Quality control

Head – Quality Control

4.0 PROCEDURE:

4.1 There shall be written technical agreement between contract giver and contract accepter with agreeable term and condition duly authorized by both the party.

4.2 There shall be consent letter from contract accepter to contract giver.

4.3 The list of approved contract laboratories is as per Annexure-II.

4.4 **Handling of Analysis by Contract Laboratory**

4.4.1 Prepare the requisition of analysis (as per Annexure-I) and mention the test to be carried out along with the specifications/standard testing procedures or monograph of Pharmacopoeia to be followed for testing.

4.4.2 Pack the quantity of sample sufficient for analysis.

4.4.3 Solid samples shall be packed in Polythene bags while liquid samples shall be packed in suitable container.

Ensure that the sample is air tight packed and packing is safe.

4.4.4 Label the sample with complete details like - Item / Material Batch No. /Lot No., Quantity received /Quantity manufactured / supplied by, sample quantity and date of sample etc.

4.4.5 After receiving the report from the contract laboratory, review the results and chromatograms (if any).

4.4.6 The material/ product shall not be approved unless the test report of passing the test is not received from contract laboratory. However in case of existency facsimile results shall be considered.

4.4.7 File the copy of Test report along with other test data and acknowledge the receipt.

4.4.8 If the results are not within the limit of specifications inform to Quality Control head.

4.4.9 Investigate the reason of failure of sample.

4.5 For sample to be analysed from ARD, prepared the test request form as per Annexure – III and follow the procedure mentioned in 4.4.2 to 4.4.9.

5.0 ANNEXURE (S):

Annexure - I : Format for requisition of analysis.

Annexure - II: List of approved contract laboratories.

Annexure - III : Format for test request of analysis to ARD.

6.0 REFERENCE (S):

SOP: Preparation, Approval, Distribution, Control, Revision and Destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

OOS : Out of Specification

ARD : Analytical Research and Development

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	-

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ANNEXURE I

REQUISITION FOR ANALYSIS

Reference SOP No.:

Date:

To,

(Name of laboratory)

Name of material	
Batch No.	
Batch size	
Original Mfg.	
Mfg. date	
Exp. Date	
AR No:	
Sample quantity	
Test Required	

Signature

(QC Department)

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ANNEXURE II
LIST OF APPROVED CONTRACT LABORATORIES

S.No.	Name of laboratory	Address	Fax/ Phone number

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ANNEXURE III
FORMAT FOR TEST REQUISITION OF ANALYSIS TO ARD

Department: Quality Control			**TRF No.:**
To, Analytical Research and Development Lab			**Date: ……**
Project Name and Code:			
Sample Name:			
Batch No. / AR No.:			
Condition (Initial / Stability):			
Mfg. By:		**Quantity of Sample Submitted:**	
Mfg. Date:		**Batch Size:**	

STP No.:	
Specifications with Spec No.:	
Tests to be performed:	

	Sent By	**Approved By**
Name:		
Signature and Date:		

From this point onwards, receiving person will make the entries.

Sample Received On:		**A. R. No. assigned:**	
Name and Signature:			