



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 by contract laboratory.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department
Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

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

5.2 There shall be consent letter from contract acceptor to contract giver.

5.3 Handling of Analysis by Contract Laboratory

5.3.1 Prepare the requisition of analysis and mention the test to be carried out along with the specifications or monograph of Pharmacopoeia to be followed for testing.

5.3.2 Pack the quantity of sample sufficient for analysis ensuring that the package is safe in transportation and the packing will protect the sample.

5.3.3 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.

5.3.4 If the sample is sent for a specific test for which in house facility is not available, do not approve the material until and unless the test report of passing the test is not received from contract laboratory.



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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- 5.3.5 Check the results on Test report and if the results are not within limit of specifications inform to Quality Control in charge.
- 5.3.6 Investigate the reason of failure of sample.
- 5.3.7 File the copy of Test report along with other test data and acknowledge the receipt.

6.0 ABBREVIATION(S):

QCD - Quality Control Department
SOP - Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure- I: List of approved contract laboratories.

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

