TITLE: HANDLING OF CONTRACT MANUFACTURING ACTIVITIES/JOB WORK

1.0 PURPOSE:

To provide a procedure for the handling of contract manufacturing activities/ Job work.

2.0 SCOPE:

This procedure is applicable for all the products manufactured contract manufacturing activities/ Job work in Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of all concerned departments to follow the procedure as described in this SOP.

3.2 It is the responsibility of Quality assurance department to implement the procedure across all the manufacturing units of the products.

4.0 DEFINITIONS:

Nil

5.0 PROCEDURE:

5.1 Before starting of any contract manufacturing, contract giver shall invite the technical team.

5.2 Technical team consists of QC, QA, R&D, Production and Management for technical discussion.

5.3 A written agreement shall be made between contract giver and Technical team as per the contract giver procedure.

5.4 Contract giver shall provide Technology transfer package containing the following documents to technical team.

5.5 Specification and method of analysis (Spec & MOA) for

5.5.1 Raw material used in the manufacturing process.

5.5.2 In-process controls.

5.5.3 Intermediate analysis

5.5.4 Finished product analysis (Dispatch material).

5.6 Material safety data sheets (MSDS) for all Raw materials, Intermediates and finished product.

5.7 Route of Synthesis.

5.8 Process flow chart.

5.9 List of Critical process parameters (stage wise)

5.10 Approved vendors list of the contract giver for the raw materials used in the manufacturing process.

5.11 Working standards for intermediates/ finished products.

5.12 Technical team will prepare the BPR as per the process provided by the contract giver and sent to the contract giver for approval.

Note: BPR shall be prepared in technical team format/Customer format / Customer recommendations in technical team format.

5.13 After receiving the required raw material from contract giver, Warehouse personnel shall handle the raw material as per the raw material receipt and handling procedure.

5.14 All the raw material received from the contract giver shall be approved based on the contract giver certificate of analysis and will not be analyzed. Analysis shall be performed in case of the material is directly received from vendor and any damage is happened to the container during the transit from contract giver.

5.15 All the vendors of the material received from the contract giver/ contract giver recommended Vendors (Direct source) shall be considered as approved vendors.

5.16 After receiving the indent from production Warehouse shall dispense the respective indented materials to production as per the FIFO system.

5.17 Technical team shall follow the rules and regulations mentioned in the agreement of the contract giver.

5.18 QA shall provide the technical support to the concerned departments during manufacturing of the contract manufacturing products, if required.

5.19 Technical team shall inform all the changes to contract giver and take the prior approval for the implementation.

5.20 Technical team shall inform all the deviations/ Observations/ non conformities to contract giver and obtain necessary approvals from contract giver prior to the dispatch.

5.21 Technical team shall provide all the documentation support as per the contract giver requirements.

5.22 Discovery shall inform all the changes to contract giver and take the prior approval for the implementation.

5.23 Discovery shall inform all the Deviations /Observations /non conformities to contract giver and obtain necessary approval from contract giver prior to the dispatch.

5.24 Discovery shall provide all the documentation support as per the contract giver requirements.

6.0 FORMATS / ANNEXURE(S):

Nil

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	12.05.2015	New SOP is introduced	--
01	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/ 17037

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