TITLE: QA RELEASE FOR DISPATCH PRODUCTS

1.0 PURPOSE:

To lay down the procedure for Quality Assurance release of products for dispatch.

2.0 SCOPE:

This procedure is applicable for all products manufactured and dispatches to customer at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of Quality Assurance personnel to follow the procedure to release the product.

3.2 It is the responsibility of Production / packing personnel shall pack the material and raise the label requisition to Quality Assurance.

3.3 It is the responsibility of Quality Control personnel to prepare the COA for Dispatch Batch.

3.4 It is the responsibility of Warehouse personnel to prepare the Invoice and Excise documents etc.

3.5 Head-QA/Designee is responsible for approval of relevant documents for Product release.

4.0 DEFINITIONS:

Nil

5.0 PROCEDURE:

5.1 QA representative shall initiate the batch release upon the receipt of documents like purchase order copy, packing list, material transfer note pertaining to dispatch batch from Production /packing section.

5.2 Batch release involves the review of data pertaining to the respective batch manufacturing and the following steps involved, but not limited to;

5.2.1 Review of batch production and control records.

5.2.2 Review of packing and labeling operations and control records.

5.2.3 Review of finished product analysis records.

5.2.4 Checking the final packed product status and labeling.

5.3 **Batch Production Record Review:**

5.3.1 Production personnel shall verify the completed batch production record as per BPR review checklist current format No. of QA007-FM008. After completion of review the Production Incharge/ HOD shall sign in BPR and its review checklist.

5.3.2 Production personnel shall submit the BPRs along with completed checklist to Quality Assurance.

5.3.3 QA personnel shall verify the BPR as per the review checklist. QA chemist shall verify whether the BPRs contain the complete information about raw materials, operations.

5.3.4 QA shall verify that all raw material inputs, critical process parameters, yields, Quality, signature, dates and second person checks are present and shall ensure all operations are carried out as per pre defined instructions.

5.3.5 QA checks whether necessary analytical reports are attached to the BPRs.

5.3.6 QA shall verify that deviations, if any are documented, investigated.

5.3.7 QA representative shall ensure that deviations pertaining to batch are investigated and appropriate correction, corrective and preventive action proposed/ taken before release the batch.

5.4 **Batch Analytical Data Sheet and Certificate of Analysis Review:**

5.4.1 Quality control Incharge shall verify the complete analytical data after complete the analysis and shall submit certificate of analysis with analytical raw data to Quality assurance.

5.4.2 QA personnel shall review the results against the product specification for product compliance.

5.4.3 QA In charge verify the raw data in analytical work sheet and certificate for correctness.

5.5 **Release Procedure for Dispatch/ Blending (Approved batches only)**

5.5.1 Once the batch production record, analytical documents are received as per requirement, QA shall start the release procedure.

5.5.2 Only QA authorized persons shall release the product. List of authorized personals shall be prepared by QA and whenever required list shall be revised.

5.5.3 QA shall generate the product labels as per the current format No.: QA001-FM171 upon receipt of the Packing List from Production Department.

5.5.4 The printed labels shall be checked by QA personnel according to master labels. The number of labels shall correspond to the number of containers of the dispatch batch and one is additional label of any one containers for attaching to ‘Packing record’.

5.5.5 The printed labels shall be handover to Production Department.

5.5.6 QA shall maintain the reconciliation of product labels and record in product label reconciliation register as per current format No.: QA028-FM080.

5.5.7 QA shall receive the Certificates of Analysis (COA) against the analytical data sheet pertaining to dispatch batch from quality control (QC) and ensure the COA is as per the customer's requirements/ order Processing Document.

5.5.8 QA In charge shall ensure the regulatory requirements are met prior releasing the batch,if any.

5.5.9 QA shall generate the QA Release labels as per the current format No.: QA010-FM009. The number of labels shall correspond to the number of containers of the dispatch batch and one is additional for attaching to 'Packing record'.

5.5.10 QA shall maintain the reconciliation of QA release labels and record in "QA Release" "Labels reconciliation register" as per the current format No.: QA028-FM080.

5.5.11 QA In charge shall ensure the Manufacturing and Expiry/retest date on the product label are correct. In case the dispatch batch is a blend of two or more batches/ lots, and then the date of manufacture shall be the date of manufacture of the oldest batch/ lot blended. Expiry / retest shall be based on stability data.

5.5.12 QA shall ensure that the physical conditions of the containers are good.

5.5.13 QA shall check the product labels are attached to the containers and shall check the gross weights of containers against the product label.

5.5.14 QA person shall fill the "Dispatch Batch Release Check List" as per the current version QA010-FM010.

5.5.15 On satisfactory verification, QA Chemist shall paste the QA release labels on the containers.

5.5.16 The COA of the dispatch batch shall be photocopied and shall be stamped with "Quality Assurance Released"stamp (the stamp shall be in green color as depicted below) and duly signed by the person who is responsible for release of the batch.

5.5.17 The certificate of analysis with stamp of "Quality Assurance Released"shall be photocopied and the same shall be handed over to Ware House department along with photo copy of packing list.

5.5.18 Photo copy of COA and packing list shall be sent to customer along with material. If customer required more copies of COA, the same shall be generated by photocopying the "Quality Assurance Released" stamped certificate of analysis

5.5.19 Upon receipt of QA released certificate of analysis and packing list, commercial documentation shall be completed and material shall be sent to the customer by Warehouse personnel.

5.5.20 After of batch release, QA shall enter the details in "Dispatch Details Log" as per the Current format No.: QA010-FM011.

5.5.21 QA shall keep one product label and one QA release label along with packing list and also Original COA and photocopy with "Quality Assurance Released" COA for each dispatched batch.

6.0 FORMATS / ANNEXURE(S):

6.1 QA Released : QA010-FM009

6.2 Dispatch Batch Release Check List : QA010-FM010

6.3 Dispatch Details Log : QA010-FM011

6.4 Product Label : QA010-FM171

6.5 List of Authorized Personnel for product release : Annexure-1

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.06.2007	New SOP	---
01	01.07.2009	SOP format changed and reviewed for more clarity.	---
02	05.05.2011	To introduce the QA release stamps for implement the SOP.	---
03	15.06.2014	Formats are the part of SOP. So prepared separately and more clarity.	---
04	01.01.2018	1. SOP format changed make to inline with SOP-QA- 001-05. 2. Responsibilities are elaborated. 3. Altogether procedure has been rephrased for better clarity. 4. In QA Released label format Batch No. Column inserted for better clarity. 5. Dispatch details log contents revised for better clarity. 6. Product Label format has been removed from Q.C(Ref. format No.:QC001-FM107) and introduced in this SOP (Ref. Format No.:QA010-FM171).	CCF/GEN/ 17037
05	15.06.2019	1. Instruction for verification of deviations closure before release and preparation and handover of COA to warehouse personnel included. Annexure of List of authorized persons for product release is included	CCF/GEN/ 19010

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality