Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-028-02	Effective Date:	01.01.2018
	Supersedes :	QA-028-01	Next Review Date:	31.12.2020
	Department:	Quality Assurance	Page:	1 of 2
TITLE: HANDLING OF LABELS				

1.0 PURPOSE:

To lay down the Procedure for Handling of Labels at Discovery Laboratories Pvt. Ltd.

2.0 SCOPE:

This procedure is applicable for all type of labels which are maintained as part of Quality system at M/s. Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of all departments to follow the SOP.

3.2 It is the responsibility of Quality Assurance department to make master copies of labels and issue a similar copy of the same to user department.

4.0 DEFINITIONS:

Nil

5.0 PROCEDURE:

5.1 **Label Preparation:**

5.1.1 User department prepares a draft label, as per the requirements.

5.1.2 User department shall send draft label to QA, along with CCF (Change Control Form) current version QA005-FM001.

5.1.3 QA verifies the suitability and Approve/Reject the label.

5.1.4 User/ QA department identifies a printer with help of purchase.

5.1.5 Proofs prepared by the printer should be sent to QA department for authorization.

5.1.6 QA verifies and approved/ reject the label.

5.1.7 QA shall prepare a master file contains all original labels which will be used across the plant as per the current version Format No.: QA028-FM054.

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5.1.8 Whenever new/ revised format of the label received QA shall verify the same, if approved append the same in master label file.

5.1.9 Obsolete version of master label shall be achieved separately byQAdepartment.

5.1.10 Each label shall be affixed on A4 size white paper and place it in a plastic foil.

5.1.11 Reconciliation shall be recorded for below specified labels.

5.1.11.1 Approved Labels

5.1.11.2 Rejected Labels

5.1.11.3 Product Labels

5.1.11.4 QA Release Labels

6.0 FORMATS / ANNEXURE(S):

6.1 Master Specimen Label : QA028-FM054

6.2 Label Reconciliation Record : QA028-FM080

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	24.01.2011	New SOP is introduced	--
01	01.01.2014	1. Reconciliation for labels is included. 2. Clearly explained the procedure. 3. SOP title changed.	--
02	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/ 17037

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