 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-006-05	Effective Date:	30.06.2019
	Supersedes :	SOP-QA-006-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	1 of 6
TITLE: HANDLING OF COMPLAINTS				

1.0 PURPOSE:

To lay down the procedure for Handling of Complaints.

2.0 SCOPE:

This procedure is applicable to complaints received from customers on quality of the product and packing at Discovery Laboratories Pvt. Ltd.


3.0 RESPONSIBILITY:

- 3.1 Designated Personnel in QA shall log the Complaint and Categorize with Complaint Number.
- 3.2 Head – QA /Designee is responsible for carrying out the investigation and taking necessary CAPA, providing technical response to customer.
- 3.3 Head – QC / Designee is responsible for carrying out the analysis of samples as per requirement.
- 3.4 Head of concerned department is responsible to support the investigation of Complaint and implementation of proposed CAPA, wherever required.

4.0 DEFINITIONS:

- 4.1 **Complaint:** A written or oral report originating from a consumer which relates to the inadequacy of the quality, i.e. non-compliance with standards or customer requirements and includes any packaging and labeling requirements, any query regarding specifications, analytical procedures, incomplete text, non-conformance with customer requirements should be treated as complaint.
- 4.2 **Critical Complaint:** A complaint which has a definite impact on product quality and creates health hazard, which needs to be investigated with topmost priority is categorized as critical complaint.
- 4.3 **Major Complaint:** A complaint which may impact the product quality is categorized as major complaint.
- 4.4 **Minor Complaint:** Any complaints, other than product quality related complaints, are categorized as minor complaint.

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 Discovery Labs	STANDARD OPERATING PROCEDURE			
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	Supersedes :	SOP-QA-006-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	2 of 6
TITLE: HANDLING OF COMPLAINTS				

5.0 PROCEDURE:

5.1 Receipt of Complaints:

5.1.1 A compliant received from marketing/ Customer/ Regulatory authority or any other source through mail notification / oral communication. Based on that, designated person from QA shall enter the details in Complaint acknowledgement Form (QA006-FM105) with Name and Address of Customer, Name of the Product, Batch No.(s), Mfg. Date, Expiry/ Re-test Date, Details of Compliant.

5.1.2 An acknowledgement shall be sent to the Customer / Regulatory authority or any other source by QA. The original copy shall be retained at QA. The activities shall be completed preferably within 2 working days.

5.1.3 The Complaint Number shall be assigned by QA as follows : CC/PPP/YYXXX

Where,

CC	-	Stands for Customer Complaint
PPP	-	Stands for Product code
YY	-	Stands for the last two digits of the Year
XXX	-	Stands for the Sequential No.001, 002...

e.g.: CC/DAH-II/19001 indicates First Customer Complaint received in the Year 2019.


5.2 Investigation of Complaints:

5.2.1 The QA representative shall record complete details of the complaint in a Complaint Log Register (QA006-FM104) along with complaint number.

5.2.2 QA representative shall contact the Customer for fact findings and shall collect the information as possible/ applicable. Based on the nature of the complaint, Head-QA in consultation with concerned department head shall form the investigation team.


5.2.3 Based on primary data, the designated person from QA shall assign the category (Critical/Major/Minor) and complaint number.

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	Supersedes :	SOP-QA-006-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	3 of 6
TITLE: HANDLING OF COMPLAINTS				

- 5.2.4 If the complaint sample is received along with the complaint, the investigator shall record the quantity of the sample received. The investigator must check and record the physical appearance of the sample, label, etc.,.
- 5.2.5 The available stock (partial quantity) of subject complaint batch shall not be released further till completion of investigation and conclusion.
- 5.2.6 The partial quantity of subject complaint batch which has been distributed to other Customer(s) or is in transit shall be reviewed based on nature of complaint.
- 5.2.7 QC shall check the control sample to verify the complaint.
- 5.2.8 if needed, the sample shall analyze by customer's method, if it is available and different from the current method.
- 5.2.9 The results of analysis shall compare with the original analysis and initiate investigation at production end, if necessary.
- 5.2.10 The investigation shall include the inspection of batch release document, Batch Production Records, logs, equipment breakdowns records, critical parameters, testing procedure, trainings, Raw material / packaging materials quality, analytical documents and its testing instruments performance shall be reviewed.
- 5.2.11 Related documentation such as complaint reports shall be verified for previous complaints of the same nature and batch no. and batch manufacturing records for non-conformances that can explain or confirm quality problem
- 5.2.12 In case of Quality related complaints, Head-QA shall extend the investigation to pre and post complaint batches. Depending upon the criticality of the Complaint (if found necessary), a recall shall be initiated as per "Recall Procedure"
- 5.2.13 All the decisions and measures taken as a result of the complaint shall be recorded.
- 5.2.14 Training shall be given wherever any specific deficiency is identified during the investigation of customer complaints.

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	Supersedes :	SOP-QA-006-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	4 of 6
TITLE: HANDLING OF COMPLAINTS				

5.2.15 Head-QA/Designee shall enter the investigation details in Complaint Investigation Form (QA006-FM106) with proposed CAPA.

5.3 Reporting of Complaints:

5.3.1 The investigation of the complaint shall be reported in the Complaint Investigation Form (QA006-FM106).

5.3.2 The complaint report must be exhaustive, reveal complete facts of investigation, identify the root cause for Complaint, the recommendations for preventing reoccurrence. The report shall conclude whether the complaint is substantiated or non-substantiated.

5.3.2.1 **Substantiated complaint:** A complaint where the investigation has shown the complaint to be valid and that it occurred under company control.

5.3.2.2 **Non-Substantiated complaint:** A complaint where the investigation has shown no valid reason for the complaint.

5.3.3 The Complaint Log Register must be completed with the details of the Complaint.

5.3.4 All records of Complaints, Reports, CAPA taken to resolve the Quality Problems, responses to complaints, Complaint Log Register, etc., shall be maintained by QA.


5.3.5 The completed investigation report with proposed CAPA shall be forwarded to customer by QA, if necessary. Otherwise conclusion shall be communicated to customer.

5.4 Time Frame:

5.4.1 The reply time frame shall be defined depending upon the categorization of the complaint.

5.4.1.1 Any Critical complaint must be investigated within 2 days of receipt by QA and a response with action plan to be forwarded to customer within 2 days. In case it is not completed within 2 days, necessary feedback must be given to customer.

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	Supersedes :	SOP-QA-006-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	5 of 6
TITLE: HANDLING OF COMPLAINTS				

5.4.1.2 A detailed Investigation report indicating the implementation of action plan and status of proposed CAPA shall be forwarded to customer by QA within 15 days.

5.4.1.3 Major and minor complaint shall be investigated and the response with Investigation details, actions taken and proposed action plan, if any, to be completed within 30 days and shall communicate to customer.

5.4.1.4 Any delay in the time frame of response needs to be justified.

5.4.1.5 If satisfactory feedback received or if no feedback received from the Customer within 15 days from the date of communication to customer, then the complaint seems to be closed.

5.4.1.6 If any data / recommendation is requested by customer, the same shall be accessed and customer shall be updated with data.

5.4.1.7 The Head- QA / Designee shall intimate the status on closure of the Complaint to Customer / Regulatory authority.

5.5 Review and trend analysis of Customer Complaints:

5.5.1 The review of complaints (product wise) shall be carried out as per the procedure described in APQR SOP.

5.6 Trend analysis:

5.6.1 Trend analysis of all the complaints shall be done annually.


5.6.2 This analysis shall include, but not limited to, the following:

5.6.2.1 No. of complaints received in various categories (quality- physical & chemical/ logistics/ packaging/ dispatches/ others).

5.6.2.2 No. of complaints are substantiated or non- substantiated complaints.

5.6.2.3 Details of investigation, corrective action & preventive action and closure of complaint.

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	Department:	Quality Assurance	Page:	6 of 6
TITLE: HANDLING OF COMPLAINTS				

6.0 FORMATS / ANNEXURE(S):

- 6.1 Complaint Log Register : QA006-FM104
6.2 Complaint Intimation Form : QA006-FM105
6.3 Complaint Investigation Form : QA006-FM106
6.4 Flow chart for Handling of Complaints : Annexure-1

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.06.2007	New SOP is introduced.	---
01	01.07.2009	SOP format changed and reviewed for more clarity.	---
02	16.06.2014	Revised as per current SOP & more clear and clarity.	---
03	10.03.2017	1. SOP format changed make to inline with SOP-QA-001-04. 2. Definitions are included. 3. Investigation procedure elaborated. 4. Complaint numbering system modified. 5. Reporting of complaint procedure elaborated. 6. Time frame procedure elaborated. 7. Complaint intimation form included. 8. Complaint log and investigation form contents were modified. 9. Altogether procedure has been rephrased for better clarity.	QA-CRF-014/16
04	06.11.2017	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/17028
05	30.06.2019	1. Procedure for trend analysis of complaints is included. 2. Timelines for investigation and closure is redefined. 3. Business development department is removed as per current organogram. 4. Complaint Log register, Complaint investigation form formats and Flow chart was revised to inline with the procedure. 5. Complaint intimation form name has been changed to Complaint acknowledgment form.	CCF/GEN/19025

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