SHILPA PHARMA LIFESCIENCES LIMITED	
STANDARD OPERATING PROCEDURE	
Document No.: SOP/QA/GEN/008/22	Issue date : 14/08/23 Effective date : 26/08/23
Supersedes : SOP/QA/GEN/008/21	Next Review : JUL-2025 Page 1 of 16
TITLE: HANDLING OF CUSTOMER COMPLAINTS	

1.0 **Purpose:**

To describe the procedure for handling customer complaints and take appropriate corrective actions to prevent recurrence as well as redress of the complaint.

2.0 **Scope:**

This procedure applies to complaints received from customers on quality of the product and packaging. This procedure does not apply to complaints related to pricing, over / under shipments, error in shipment, back order items, sales return due to commercial reasons or ambiguity in customer specification/requirement, sales return based on customer request, bad handling and damage of containers during the transit.

3.0 **Definitions / Abbreviation:**

3.1 **Complaint**: A written or oral expression of dissatisfaction report originating from a customer 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, Services received and non-conformance with customer requirements should be treated as complaint.

3.2 **Critical complaint**: A complaint which has a definite impact on product quality and creates any health hazard needs to be investigated with topmost priority is categorized as critical complaint.

3.3 **Major complaint**: A complaint which may impact the product quality is categorized as major complaint.

3.4 **Minor complaint**: Any complaints, other than product quality related complaints, are categorized as minor complaint.

3.5 **Substantiated:** Complaints where investigations fail to provide any corroboration of the complaint.

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Sign & Date	05/08/23	10/08/23	12/08/23

3.6 **Non-Substantiated:** Complaints where investigations provide corroboration of the complaint.

4.0 **Responsibility:**

4.1 Marketing department shall send complaints with appropriate details to Head-Quality Assurance (QA) through mail or oral (Telephone) as the way received from customer.

4.2 Any person/department in the organization, apart from Marketing, who receives a complaint, shall also forward the complaint with appropriate details to Head-QA.

4.3 The designated person in Quality Assurance shall allot the complaint number and enter the details in register.

4.4 Head – Quality Assurance or designated deputy is responsible for carrying out the investigation and taking necessary corrective actions.

4.5 Head-QA or his authorized deputy is responsible to make communication with customer on complaints received under copy to marketing department to resolve any technical matters if required.

4.6 Head – Quality Control (QC) or designated deputy is responsible for carrying out the analysis of samples as per requirement if applicable.

4.7 Head of concerned department is responsible to support the investigation of complaint, wherever required.

4.8 Head – R&D and ARD (or) designated deputy is responsible to provided necessary investigation and testing support as and when required.

4.9 Head – RA (or) designated deputy is responsible to provided necessary regulatory support as and when required.

5.0 **Accountability:**

Person/Persons directly associated with the systems.

6.0 **Procedure**:

6.1 **Receipt of complaints :**

6.1.1 All complaints received by Marketing department shall be forwarded through mail or oral (Telephone) as the way received from customer to Head-QA or designee with in 24hours with details of the complaint, name and address of the customer, details of the product name, batch no. manufacturing and expiry/retest date.

6.1.2 Head – QA is responsible for arranging investigation, after assigning the category (critical / major / minor) to the complaint.

6.1.3 In some instances, complaints related to product quality may be received directly by any other person in the organization through e-mail or any other way of communication. Such complaints shall be forwarded to Head – QA or designee within 24 hours for necessary initiation of investigation.

6.1.4 The complaint number allotted by QA personnel is a specific unique number as follows

CC/NNN/YY/U-A

Where,

CC indicates customer complaint,

NNN indicates sequential number i.e. 001, 002 which starts from calendar year

YY indicates last two digits of the year (10 for 2010 etc.) and

U-A indicates Operating unit number (Eg. U-1 for Unit-1 and U-2 for Unit-2 etc.).

6.2 **Investigation of complaints:**

6.2.1 A responsible person in Quality Assurance who is responsible / designated for complaint handling shall register and carry out the detailed investigation of the customer complaint under the supervision of Head–QA. In his / her absence, Head–QA shall nominate other person to carry out any activities in this regard.

6.2.2 The investigator shall record complete details of the complaint in a log (FM-QA-060) which shall include the details of complaint number, product name, batch/ lot number, manufacturing date, expiry/retest date, name and address of the customer, nature of complaint, description, category, date of receipt and date of response, justification, Closed on and signatures where applicable shall be incorporated for better tracking.

6.2.3 The acknowledgement of compliant receipt shall be sent to marketing department or directly to customer by QA on the same day and marketing department shall in-turn forward the same to customer subsequently upon receipt from QA on the same day.

6.2.4 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, seal, etc in comparison with the details of the control sample of the same batch and record the observation.

6.2.5 If no complaint sample is received along with the complaint, the investigator shall record the relevant details disclosed in the complaint.

6.2.6 Upon receipt of complaint, Quality Assurance shall share the information of complaint through Inter Office Communication (IOC) to the concern departments to hold the batch/ lot until completion of investigation.

6.2.7 Upon receipt of the information of the complained batch/ lot, warehouse personnel shall fill the details in the following label and paste to the material containers,

SHILPA PHARMA LIFESCIENCES LIMITED	
MATERIAL ON HOLD	
Name of the Material:	
Batch/ Lot No.:	
Quantity:	No. of Containers:
Mfg. date:	Retest date:
Performed by sign & date:	Verified by sign & date:

FM-QA-132-02

6.2.8 The status of the complained batch / lot shall be changed based on outcome of the investigation.

6.2.9 The investigator in consultation with Head – QA shall arrange to carry out chemical and/or microbiological analysis of the control sample (along with the complaint sample, if available) to establish the genuineness of the complaint. The investigator must also check and compare the analytical results of the original analysis.

6.2.10 If any OOS found during the analysis of the control samples, the investigation shall extended thorough OOS procedure (refer to SOP/QA/GEN/003).

6.2.11 The results of analysis shall be discussed with Head – Production and initiate investigation at production end, if necessary. Head – Production along with respective departmental personnel shall investigate the complaint in details.

6.2.12 The investigation shall include the

6.2.12.1 Scrutiny of batch process records by production and investigator for the batch under reference for any manufacturing and / or packing problems encountered during the production of the batch.

6.2.12.2 Any equipment breakdowns recorded during production of the batch and any packaging materials quality problems faced during packing of the batch must also be studied.

6.2.12.3 The investigation shall include source batch distribution details to identify entire output batch distribution details.

6.2.12.4 The investigation shall include verification of analytical data details.

6.2.12.5 The investigation shall include receipt and verification of the data logger data, if any, from the customer.

6.2.13 In-case of quality related complaint such as (but not limited to)

6.2.13.1 Failure to meet the approved specifications

6.2.13.2 Presence of foreign matter

6.2.13.3 Presence of black / brown / rust particles

6.2.13.4 Damage of containers where the inner packing configuration was compromised.

The investigation should be extended to get the sample of the complaint batch from the customer for confirmation of the complaint results and also need to get the communication about the investigation findings at the customer end.

6.2.14 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, other customers also shall be notified to whom the material is dispatched from the same batch number.

6.2.15 Depending upon the criticality of the complaint if found necessary, a recall shall be initiated as per the respective recall procedure.

6.2.16 Investigation of such complaints shall also include similar complaints reported in the past three years and investigations carried out at the time of reporting of those complaints and review of the stability data shall be done. At the end of investigation, the investigators shall send a written report to Head–QA highlighting the findings of the investigation.

6.2.17 All the decisions and measures taken as a result of the complaint shall be recorded and addressed in all the corresponding documents.

6.2.18 Based on the severity & outcome of the investigation, if material is to be recalled shall be executed by Head-Quality.

6.2.19 The recall of the material shall be followed as per SOP, Procedure for Product Recall (SOP/QA/GEN/007).

6.2.20 In such complaints where no investigation was carried out, the record shall include the reason that an investigation was not found to be necessary.

6.2.21 The completed Customer Complaint Investigation copy with corrective actions and preventive actions, if any, shall be forwarded to Marketing –head.

6.2.22 In case additional information of the complaint such as, sample from the complaint batch or addition investigation data, etc., is received from the customer after closing the complaint, the complaint investigation shall be re-opened and proceed with expanded investigation to get the satisfactory feedback from the customer.

6.3 **Reporting of complaints :**

6.3.1 The investigation of the complaint shall be reported through Customer Complaint Investigation Form (FM-QA-015).

6.3.2 The complaint investigation report must be exhaustive, reveal complete facts of investigation, identify the causes for complaint, may contain recommendations by Head – QA for preventing recurrence of such complaints and also indicate actions already taken, if any, to prevent recurrence. The report shall conclude whether the complaint is substantiated or non-substantiated. The report shall be forwarded to Marketing–Head.

6.3.3 The complaint register must be completed with the details of the complaint.

6.3.4 All records of complaints, reports, corrective and preventive actions taken to resolve the quality problems, responses to complaints, complaint register etc. shall be maintained by Head – QA.

6.3.5 The proposed CAPA (Corrective action and preventive action) should be implemented with the time limits as mentioned below.

6.3.5.1 Critical complaints : Maximum 30 days

6.3.5.2 Major complaints : Maximum - 45 days

6.3.5.3 Minor complaints : Maximum - 45 days

6.3.6 Any delays in above time lines of implementation shall be justified scientifically. The justification for delay shall be initiated by responsible person in the format (FM-QA-080) from the CAPA initiating department and is accepted by the HOD/Designee of initiating department. The justification for delay shall be finally approved by HOD/Designee of QA department. Extension justification is not acceptable if more than two times.

6.3.7 CAPA effectiveness verification shall be performed as per Corrective and Preventive action (CAPA) SOP (Doc. No: SOP/QA/GEN/006).

6.4 **Response to customer :**

6.4.1 For complaints received from customers, the respective site Head–QA shall draft a suitable reply based on the Customer Complaint Investigation Form and forward the report directly to the customer from whom the complaint is received under copy to Marketing department.

6.4.2 The communication sent to the customer/Marketing–Head shall be documented and archieved along with the Customer complaint investigation Form.

6.5 **Response time frame**:

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

6.5.2 Any critical complaint must be investigated within 24-48 hours of receipt by QA and a response with well defined action plan to be forwarded to customer within 48 hours. A detailed investigation report indicating the implementation of action plan and proposed corrective and preventive actions shall be forwarded to Marketing department / customer within 7 working days.

6.5.3 Based on the outcome of the investigation risk assessment shall be performed if complaint is categorized as critical.

6.5.4 A major complaint shall be investigated within 10 days of receipt by QA and the response with investigation details, actions taken and proposed action plan, if any, to be forwarded to Marketing department / customer within 10 working days.

6.5.5 A minor complaint shall be investigated within 15 days of receipt by QA and the response to be given to Marketing department / customer within 15 working days.

6.5.6 Any delay in the time frame of response needs to be justified scientifically. The justification for delay shall be initiated by responsible person in the format (FM-QA-123) from the initiating department and is approved by HOD/Designee of QA department.

6.5.7 If extension of investigations, through justifications, exceeds more than 2 times then the same shall be intimated to and acknowledged by the customer.

6.5.8 Details of the complaint like initiation, initial investigation, extension (if any), Final investigation, CAPA etc., shall be tracked through the Format for "Tracking sheet for activities related to complaints" shall be filled to track the proceedings of the customer complaint process as per format (FM-QA-147).

6.5.9 Customer complaint shall be re-categorized based on the outcome of the investigation.

6.6 **Complaint Redress**:

Head–Marketing department shall appraise the customer on the corrective actions taken and the redressal actions, where applicable.

6.7 **Review of complaints** :

Customer complaints records shall be reviewed for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products and shall be summarized and reviewed in annual product review, management review and quality meeting.

6.8 **Closing time frame :**

6.8.1 After receiving of customer's comments complaint shall be considered as closed.

6.8.2 If the customer did not respond for the reason specified for the genuine of complaint within 45 days, the complaint shall be closed.

6.8.3 The complaint also shall be considered as closed in view of the repeated order for the same product from the same customer.

6.9 **Complaints Trending:**

6.9.1 Compliant reports are trended by QA based on the nature of compliant. The trends are generated on a quarterly on rolling basis and evaluated by QA to ensure that corrective and preventive actions taken are effective. The quarterly trends shall be archived at QA documentation area till final trend approved for the particular year.

6.9.2 Trends of all the compliant reports made during the year and incorporate into annual product review (APR). Customer complaint trend report shall be prepared as per the Annexure-II.

6.10 **Complaint Re-open:**

6.10.1 Complaint shall be reopened if required / Communication received from the customer after closeout of the complaint. Investigation shall be performed as per the format No. FM-QA-207

6.10.2 The re-open complaint number allotted by QA personnel is a specific unique number as follows

CC/NNNR/YY/U-A

Where,

CC indicates customer complaint,

NNN indicates sequential number of sourced complaint

R indicates re-open

YY indicates last two digits of the year of sourced complaint

U-A indicates Operating unit number (Eg. U-1 for Unit-1 and U-2 for Unit-2 etc.).

6.10.3 The investigator shall record complete details of the re-opened complaint in Re-opened Customer complaint log (FM-QA-225).

7.0 Related Documents:

7.1	Customer Complaint Investigation Form	:FM-QA-015
7.2	Customer Complaint log	:FM-QA-060
7.3	Justification for Delay in complaint investigation	:FM-QA-123
7.4	Material on Hold	:FM-QA-132
7.5	Extended investigation form for Customer complaint	:FM-QA-146
7.6	Tracking Sheet For Activities Related To Complaint	: FM-QA-147
7.7	Flow chart for Handling of Customer complaints	:Annexure-I
7.8	Trending of the customer complaints	: Annexure-II
7.9	Procedure for product recall	: SOP/QA/GEN/007
7.10	Customer complaint reopen form	: FM-QA-207
7.11	Justification for delay in closure of CAPA	: FM-QA-080
7.12	Personnel Interview/Interactions For Complaint	: FM-QA-223
7.13	Re-opened Customer complaint log	: FM-QA-225

8.0 Distribution Record:

S.No.	Department/Block	No. of Copies	Remarks
01.	Quality Assurance (Unit-1)	01	-
02.	Quality Assurance (Unit-2)	01	-
03.	Quality Control (Unit-1)	01	-
04.	Quality Control (Unit-2)	01	-
05.	Production (Unit-1)	01	-
06.	Production (Unit-2)	01	-
07.	Microbiology (Unit-2)	01	-
08.	Warehouse (Unit-1)	01	-
09.	Warehouse (Unit-2)	01	-

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S.No.	Department/Block	No. of Copies	Remarks
10.	Maintenance (Unit-1)	01	-
11.	Maintenance/ Engineering (Unit-2)	01	-
12.	Marketing	01	-

9.0 **Revision Record**:

S.No.	Revision Status	Details of Revision	Effective date	Remarks
1.	17	1. Substantiated and Non-Substantiated Definitions incorporated in section 3.0. 2. FM-QA-132-00 Number Incorporated for Material on Hold.	28/01/2019	--
2.	18	1. Annexure-I "Flow chart for handling of customer complaints" updated with incorporation of Extension of investigation and Final investigation report for better clarity. 2. Customer complaint investigation form (FM-QA-015) updated for better clarity. 3. Format for "Extended investigation form for Customer complaint" (FM-QA-146) incorporated. 4. Section 6.5.6 incorporated if extension of investigations, through justifications, exceeds more than 2 times then the same shall be intimated to and acknowledged by the customer. 5. Section 6.5.7 incorporated for tracking of complaint details as per format for "Tracking sheet for activities related to complaint" (FM-QA-147).	25/07/2019	--

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S.No.	Revision Status	Details of Revision	Effective date	Remarks
3.	19	1. Revision as part of Periodical Review. 2. Responsibilities of R&D and RA departments included in responsibility section. 3. Company Name incorporated in Header section for Material on Hold Label (FM-QA-132). 4. Flow chart for handling of customer complaints Annexure-I updated. 5. CAPA effectiveness verification as per CAPA SOP incorporated in section 6.3.6. 6. In response time frame section, critical complaint investigation updated from 15 to 7 days and major complaint investigation updated from 15 to 10 days. 7. Customer Complaint Investigation Form (FM-QA-015) revised with incorporation of complaint batch numbers. 8. Justification for delay in complaint Investigation / CAPA (FM-QA-123) revised with incorporation of Approval of QA HOD/ Designee. 9. Extended investigation form for customer complaint (FM-QA-146) revised with incorporation of Category of the Complaint. 10. Tracking sheet for activities related to complaint (FM-QA-147) revised with incorporation of Category of the Complaint and nature of complaint. Ref. Change Control No.: CRAF/QA/151/21/U-1.	18/08/2021	---

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Sign & Date	05/08/23	10/08/23	12/08/23

S.No.	Revision Status	Details of Revision	Effective date	Remarks
4.	20	1. The company name was changed from "Shilpa Medicare Limited" to "Shilpa Pharma Lifesciences Limited," in the header section of the SOP, in the forms and as well as in the annexure-I. 2. The Company logo was removed from the header section of the SOP, in the forms and as well as in the annexure-I. Refer change control No.: CRAF/QA/061/22/U-1. 3. For critical complaints Risk assessment is introduce at section 6.5.3 accordingly annexure-I modified. 4. Section 7.0 updated Product recall SOP. 5. Extension justification is not acceptable if more than two times is incorporated at 6.3.6 section. 6. Customer complaint re-categorized procedure incorporated at section 6.5.9 accordingly annexure-I and form # FM-QA-147 modified. 7. Compliant trending frequency changed from yearly to quarterly in section 6.9.1. 8. New template Annexure-II is introduced for complaint trend preparation and accordingly related documents section 7.0 updated. 9. Compliant Re-open procedure is introduced at section 6.10 and new form # FM-QA-207 is prepared to track the Re-opened complaints accordingly the form details updated in related documents section 7.0.	02/09/2022	---

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S.No.	Revision Status	Details of Revision	Effective date	Remarks
		10. Form # FM-QA-123 title changed from Justification for Delay in complaint investigation / CAPA to Justification for Delay in complaint investigation accordingly form details were modified. 11. justification for delay in closure of CAPA form # FM-QA-080 number updated in section 6.3.6 and in related documents section 7.0 12. In related documents section 7.0 Product recall SOP number # SOP/QA/GEN/007 is added. 13. Customer complaint investigation form # FM-QA-015 was elaborated as per the procedure. Refer change control No.: CRAF/QA/069/22/U-1. 14. Revision histories from 00 to 14 details were removed from revision record (Section 9.0) to in line with the SOP # SOP/QA/GEN/001. 15. Distribution record (Section 8.0) was updated to in line with the SOP # SOP/QA/GEN/001.		
5.	21	1. At section 6.2.12 the investigation procedure is extended to source batches distribution details and verification of analytical data. 2. In section 6.2.16 complaint investigation extended to past three years for any similar complaints. 3. FM-QA-015 format was updated to in line with the procedure.	30.01.2023	---

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S.No.	Revision Status	Details of Revision	Effective date	Remarks
		4. Format # FM-QA-223 for personnel interview/interactions incorporated. 5. Revision history 15 details were removed from revision record (Section 9.0) to in line with the SOP # SOP/QA/GEN/001. Refer change control No.: CRAF/QA/221/22/U-1.		
6.	22	1. Re-open complaint number system procedure incorporated in section 6.10.2 and 6.10.3 2. Re-open customer complaint log "FM-QA-225" incorporated. 3. Receipt and verification of the data logger data during investigation incorporated in section 6.2.12.5 4. FM-QA-060, FM-QA-015 and FM-QA-146 are updated for better clarity. 5. Section 6.9.1 updated as the quarterly tends are prepared on rolling basis and the quarterly trends shall be archived at QA documentation area till final trend approved for the particular year. 6. Revision history 16 details were removed from revision record (Section 9.0) to in line with the SOP # SOP/QA/GEN/001. Refer change control No.: CRAF/QA/058/23/U-1	26/08/23	---

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SHILPA PHARMA LIFESCIENCES LIMITED	
STANDARD OPERATING PROCEDURE	
ANNEXURE –I	
FLOW CHART FOR HANDLING OF CUSTOMER COMPLAINTS	
Document Reference No. SOP/QA/GEN/008	Effective Date: 26/08/23
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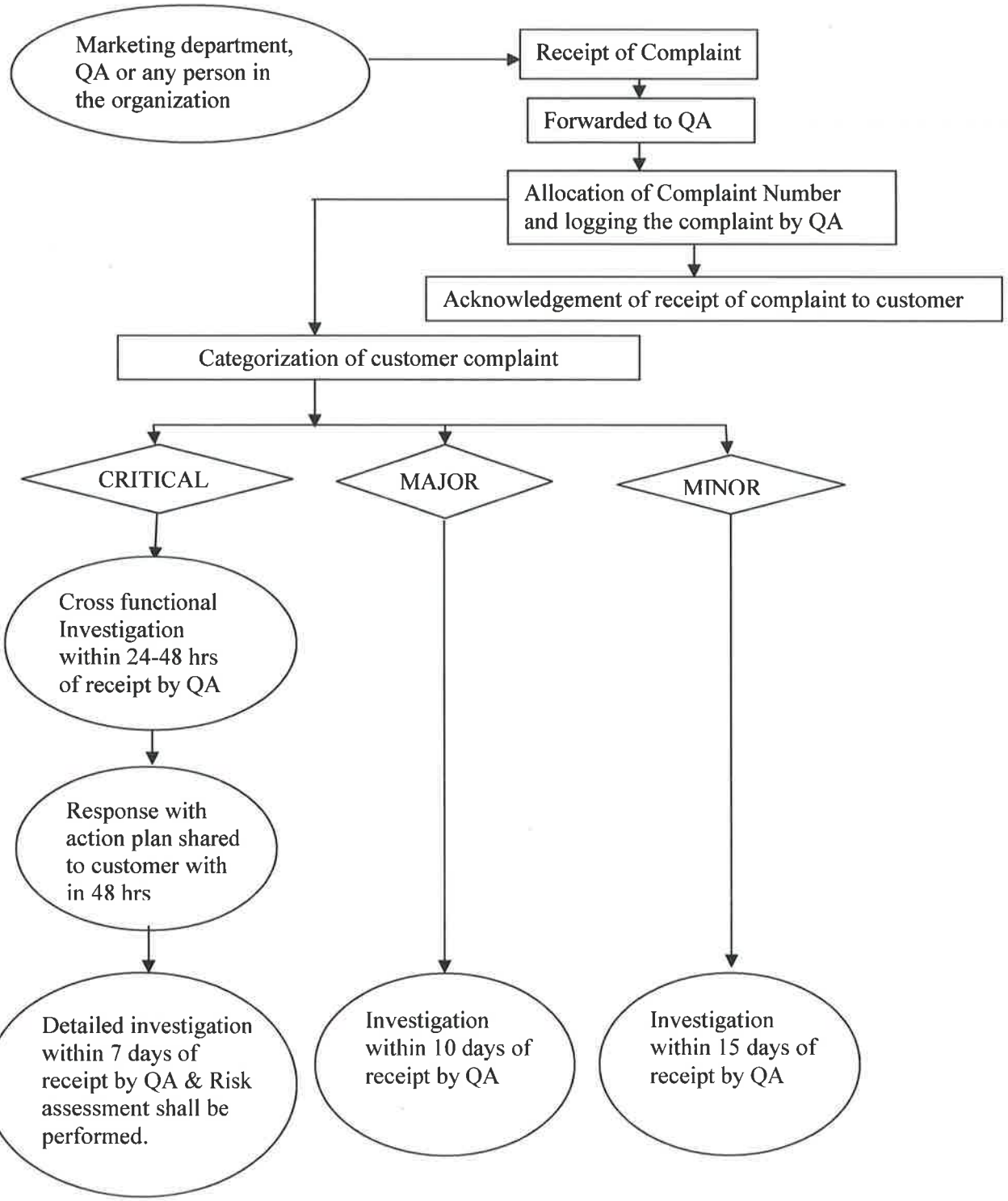

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SHILPA PHARMA LIFESCIENCES LIMITED	
STANDARD OPERATING PROCEDURE	
ANNEXURE –I	
FLOW CHART FOR HANDLING OF CUSTOMER COMPLAINTS	
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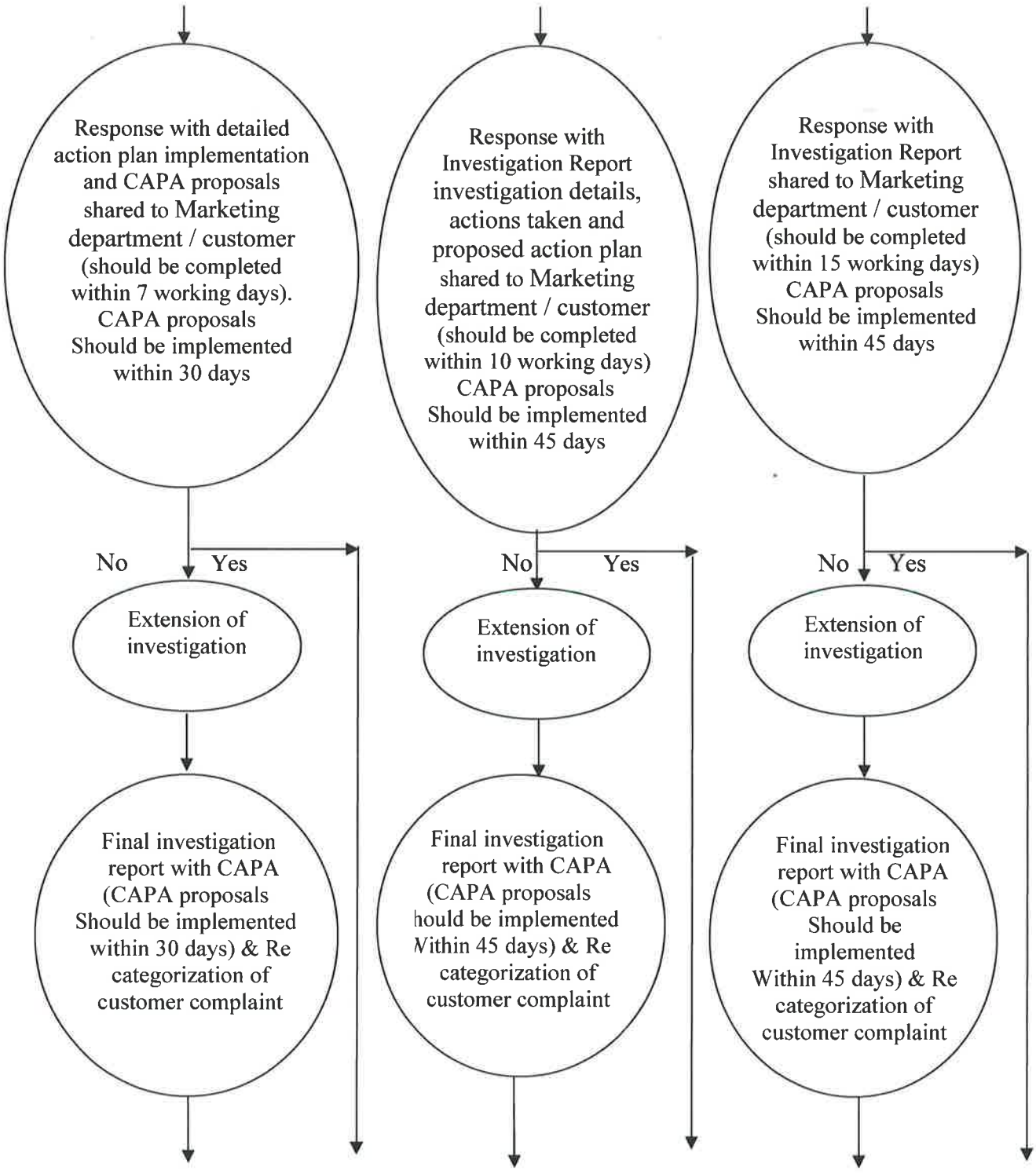

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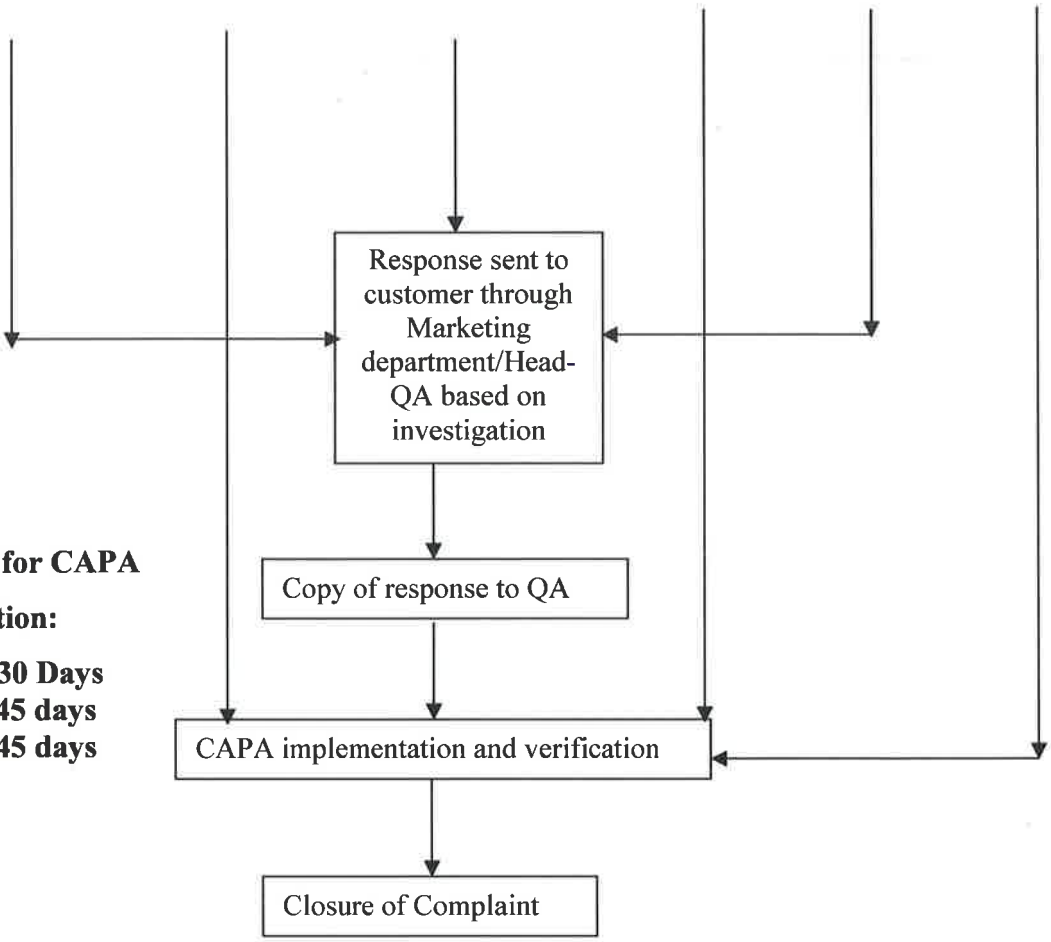

Time frame for CAPA implementation:

Critical : 30 Days
Major : 45 days
Minor : 45 days

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SHILPA PHARMA LIFESCIENCES LIMITED	
STANDARD OPERATING PROCEDURE	
ANNEXURE-II	
TEMPLATE FOR CUSTOMER COMPLAINT TRENDING	
Ref .Doc No: SOP/QA/GEN/008	Effective Date: 26/08/23
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SHILPA PHARMA LIFESCIENCES LIMITED	
TREND ANALYSIS REPORT FOR CUSTOMER COMPLAINT	
Ref .Doc No.: SOP/QA/GEN/008	**Year:** XXXX
Department: Quality Assurance	Page X of Y

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Approval Page

	Department	Name	Designation	Sign & Date
Prepared By	Quality Assurance			
Reviewed By	Production			
	Quality Control			
	Warehouse			
	Maintenance			
	Quality Assurance			
Approved By	Head Quality			

1.0 Objective:

2.0 Scope:

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5.0 GRAPHICAL TRENDS:

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5.6 Status of CAPA:

5.7 Review of customer complaints results in MRM:

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9.0 CAPA:

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SHILPA PHARMA LIFESCIENCES LIMITED

CUSTOMER COMPLAINT INVESTIGATION FORM

Complaint Number: _____ **Date:** _____

Receipt of Complaint : Marketing Dept/ Direct from Customer/Others

If Others (Specify Details) : _____

Way of Communication : Mail/ oral (Telephone)/ Fax

Name and Address of the Customer :

Customer representative name,
Designation & Contact details (if available) :

Description of the complaint :

Date of receipt of complaint :

Name of the product :

Complaint Batch number(s)	Complaint batches Source batch number(s)	Complaint Source batches batch quantity(s)	Total dispatch quantity	Number of containers dispatched

Nature of the Complaint (Tick the relevant item):

Quality / Quantity / Packaging / Method of analysis / Transportation/Suspected counterfeit

If others specify _____

Complaint registered by (Name):

QA Representative (Sign & date):

Attach separate sheet, if required.

SHILPA PHARMA LIFESCIENCES LIMITED

CUSTOMER COMPLAINT INVESTIGATION FORM

Doc. Ref. No. SOP/QA/GEN/008
Form No: FM-QA-015-10

Complaint Number: _____

Acknowledgement sent to : CUSTOMER / MARKETING

Acknowledgement sent on :

Acknowledgement sent by :

QA Representative (Sign & date):

(Attach a separate copy of Acknowledgement)

Customer Sample: Received/Not Received

If Received Batch details:

Sample	Batch Number	Mfg. Date	Retest Date	Sample qty.	Sample Verification		Remarks
					Physical Appearance	Seal Intactness	
Customer Sample							

Control sample verification details:

Sample	Batch Number	Mfg. Date	Retest Date	Sample qty.	Physical appearance	Remarks
Control Sample						

Attach separate sheet, if required.

Complaint Number: _____

Category of the Complaint: **Critical / Major / Minor**

Holding of Left over material: Required / Not required / Not applicable

Complaint batches Source batch number(s)	Available stock in warehouse	Material Hold on	QA Representative (Sign & date)

Cross functional team Action plan:

Action plan	Department	Target date	Responsibility	Sign. & date

Attach separate sheet, if required.

Complaint Number: _____

Initial Investigation:

Initial Investigation completed within specified timeline: Yes / No

If No, Justification for delay copy attached: Yes / No

Initial Investigation completed on:

Initial Investigation details:

Head – QA/Designee
Sign & Date:

Details of Initial investigation sent to customer:

Initial investigation sent on:

Initial investigation sent by:

(Attach a copy of mail communication):

QA Representative (Sign & date):

Extension of Investigation required: Yes/No

If Yes, attach a copy of extended investigation form: Yes/No

Extension Investigation Details (*attach as an annexure*):

Final Investigation:

Complaint Final Investigation Details, (If any):

Head – QA/Designee
Sign & Date:

Details of final Investigation sent to customer:

Final Investigation sent on:

Final Investigation sent by:

QA Representative (Sign. & date)

(Attach a copy of mail communication):

Attach separate sheet, if required.

Complaint Number: _____

Re-categorization of complaint: **Critical / Major / Minor / NA**

Nature of compliant: Substantiated/ Non-Substantiated

QA Representative (Sign. & date)

Ref. CAPA. No:
Corrective Action (if any):

Corrective Action	Department	Target date	Responsibility	Sign. & date

Preventive Action (if any):

Preventive Action	Department	Target date	Responsibility	Sign. & date

CAPA implemented within specified timeline: Yes / No

If No, Justification for delay copy attached: Yes / No

QA Representative (Sign & date):

Attach separate sheet, if required.

Complaint Number: _____

Final decision on (fate of) Batch(s):

Sign of Head - QA/Designee
Date:

Complaint closeout:

Sign of Head - QA/Designee
Date:

Attach separate sheet, if required.

SHILPA PHARMA LIFESCIENCES LIMITED	
STANDARD OPERATING PROCEDURE	
TEMPLATE FOR CUSTOMER COMPLAINT LOG	
Doc. Ref. No. SOP/QA/GEN/008	Effective Date: 26/08/23
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SHILPA PHARMA LIFESCIENCES LIMITED

CUSTOMER COMPLAINT LOG

Doc. Ref. No. SOP/QA/GEN/008

Form No: FM–QA–060–04

Compliant No.	Product Name	Batch/ Lot Number	Mfg. date	Expiry/ Retest date	Name & address of the customer	Nature of Complaint	Description	Category	Date of receipt	Sign	Date of response		Re-categorization	Closed on	Sign
											Initial	Final			

	Prepared by	Reviewed by	Approved by
Name	Mr. N. Damodar Reddy	Mr. M. Panduranga Naidu	Dr. U. Seshachalam
Designation	Sr. Manager - QA	GM - QA	VP - Quality & RA
Sign & Date	05/08/23	10/08/23	12/08/23

SHILPA PHARMA LIFESCIENCES LIMITED

JUSTIFICATION FOR DELAY IN COMPLAINT INVESTIGATION

Doc. Ref. No. SOP/QA/GEN/008 Effective Date: 26/08/23

Form No: FM-QA-123-02 Page 1 of 1

Complaint Number :

Complaint logging Date :

Complaint Description : _____

_____

_____

_____

Reason for Delay in investigation : _____

_____

_____

_____

Tentative target date: _____

Name:
(Initiating department HOD/Designee)
Sign & Date:

Approved by QA HOD/ Designee : Accepted/ Not Accepted

Name :
Sign and Date :

Follow up by QA : _____

_____

_____

_____

Name:
Sign & Date:

Note: Attach separate sheets as Annexure if required that should be authorized respective personnel.

SHILPA PHARMA LIFESCIENCES LIMITED

EXTENDED INVESTIGATION FORM FOR CUSTOMER COMPLAINT

Doc. Ref. No. SOP/QA/GEN/008
Form No: FM-QA-146-03

Effective date: 26/08/23
Page 1 of 1

Complaint Number: _____ **Date:** _____

Category of the Complaint: **Critical / Major / Minor**

Investigation Extension for _____ time

Reason for Extension of investigation:

Approved by QA HOD/ Designee : Accepted/ Not Accepted

Name :
Sign and Date :

Action plan	Department	Target date	Responsibility	Sign & date

Complaint Extended Investigation Details, (If any):

Details of Extension response sent to customer:

Extension Investigation response sent on:

Extension Investigation response sent by:

Customer Acknowledgement required: Yes/No

Customer Acknowledgement received on:

(Attach a copy of mail communication, where applicable):

QA Representative
(Sign & date):

CAPA (if any):

CAPA Proposed	Department	Target date	Responsibility	Sign. & date

Attach separate sheet, if required.

SHILPA PHARMA LIFESCIENCES LIMITED	
TRACKING SHEET FOR ACTIVITIES RELATED TO COMPLAINT	
Doc. Ref. No. SOP/QA/GEN/008	Effective date: 26/08/23
Form No: FM-QA-147-02	Page 1 of 4

Complaint Number: _____

Category of the Complaint: **Critical / Major / Minor**

Description of activities	Details	Remarks, If any	Entered by (Sign & Date)
Complaint Received on			
Complaint logged on			
Acknowledgement for receipt sent on			
Category of the Complaint: **Critical / Major / Minor**			
Complaint classification done on			
Action plan finalized on			
Cross functional investigation done on			
Is initial Investigation report completed within time line	**Yes / No**		
If No, mention the date of approval of justification			
Investigation report completed on			
Initial response sent on			

	Prepared by	Reviewed by	Approved by
Name	Mr. N. Damodar Reddy	Mr. M. Panduranga Naidu	Dr. U. Seshachalam
Designation	Sr. Manager - QA	GM - QA	VP - Quality & RA
Sign & Date	05/08/23	10/08/23	12/08/23

SHILPA PHARMA LIFESCIENCES LIMITED	
TRACKING SHEET FOR ACTIVITIES RELATED TO COMPLAINT	
Doc. Ref. No. SOP/QA/GEN/008	
Form No: FM-QA-147-02	Page 2 of 4

Complaint Number: _____

Description of activities	Details	Remarks, If any	Entered by (Sign & Date)
Investigation extended (Extension – 1)	**Yes / No / NA**	**Extended on** _____ **Extended up to** _____	
Is Extended Investigation report completed within specified extension period	**Yes / No / NA**		
If yes, mention date of extended investigation submission to customer			
If No, mention the date of approval of justification			
Investigation extended (Extension – 2)	**Yes / No / NA**	**Extended on** _____ **Extended up to** _____	
Is extended Investigation report completed within specified extension period	**Yes / No / NA**		

	Prepared by	Reviewed by	Approved by
Name	Mr. N. Damodar Reddy	Mr. M. Panduranga Naidu	Dr. U. Seshachalam
Designation	Sr. Manager - QA	GM - QA	VP - Quality & RA
Sign & Date	05/08/23	10/08/23	12/08/23

SHILPA PHARMA LIFESCIENCES LIMITED	
TRACKING SHEET FOR ACTIVITIES RELATED TO COMPLAINT	
Doc. Ref. No. SOP/QA/GEN/008	
Form No: FM-QA-147-02	Page 3 of 4

Complaint Number: _____

Description of activities	Details	Remarks, If any	Entered by (Sign & Date)
If yes, mention date of extended investigation submission to customer			
If No, mention the date of approval of justification			
Communication sent to customer for 3rd extension approval on			
Customer Approval received on			
Investigation extended (Extension – 3)	Yes / No / NA	**Extended on** _____ **Extended up to** _____	
Is Extended Investigation report completed within specified extension period	**Yes / No / NA**		
If yes, mention date of extended investigation submission to customer			
If No, mention the date of approval of justification			
Re-categorization of the complaint: **Critical / Major / Minor**			

	Prepared by	Reviewed by	Approved by
Name	Mr. N. Damodar Reddy	Mr. M. Panduranga Naidu	Dr. U. Seshachalam
Designation	Sr. Manager - QA	GM - QA	VP - Quality & RA
Sign & Date	05/08/23	10/08/23	12/08/23

SHILPA PHARMA LIFESCIENCES LIMITED	
TRACKING SHEET FOR ACTIVITIES RELATED TO COMPLAINT	
Doc. Ref. No. SOP/QA/GEN/008	
Form No: FM-QA-147-02	Page 4 of 4

Complaint Number: _____

Description of activities	Details	Remarks, If any	Entered by (Sign & Date)
Nature of compliant: Substantiated/ Non-Substantiated			
Final Investigation report sent to customer on			
Feedback received from customer on			
CAPA completed on			
Complaint closed on			

**Attach separate sheet, if required.*

	Prepared by	Reviewed by	Approved by
Name	Mr. N. Damodar Reddy	Mr. M. Panduranga Naidu	Dr. U. Seshachalam
Designation	Sr. Manager - QA	GM - QA	VP - Quality & RA
Sign & Date	05/08/23	10/08/23	12/08/23

SHILPA PHARMA LIFESCIENCES LIMITED

CUSTOMER COMPLAINT REOPEN FORM

Doc. Ref. No. SOP/QA/GEN/008 Effective date: 26/08/23

Form No: FM-QA-207-00

Ref. Customer complaint Number: _____ **Date:** _____

Receipt of Complaint : Marketing Dept/ Direct from Customer/Others

If Others (Specify Details) : _____

Way of Communication : Mail/ oral (Telephone)/ Fax

Name and Address of the Customer :

Customer representative name,

Designation & Contact details (if available) :

Description of the complaint :

Date of receipt of complaint :

Nature of the Complaint (Tick the relevant item):

Quality / Quantity / Packaging / Method of analysis / Transportation/Suspected counterfeit

If others specify _____

Name of the product :

Batch number(s) :

Complaint batches Source batch number(s) :

Reason for reopening of the complaint:

QA Representative (Sign & date):

Attach separate sheet, if required.

Complaint Number: _____

Action plan if any:

Immediate action taken (CAPA)	Department	Target date	Responsibility	Sign. & date

Details of the investigation:

Head – QA/Designee
Sign & Date:

Response sent to customer:

Response sent on:

Response sent by:

(Attach a copy of mail communication):

QA Representative (Sign & date):

Attach separate sheet, if required.

Complaint Number: _____

CAPA (if any):

Corrective Action Proposed	Department	Target date	Responsibility	Sign. & date

CAPA (if any):

Preventive Action Proposed	Department	Target date	Responsibility	Sign. & date

Attach separate sheet, if required.

SHILPA PHARMA LIFESCIENCES LIMITED

CUSTOMER COMPLAINT REOPEN FORM

Doc. Ref. No. SOP/QA/GEN/008
Form No: FM-QA-207-00

Complaint Number: _____

Final decision on (fate of) Intermediate or Batch or Lot:

Sign of Head - QA/Designee
Date:

Complaint closeout:

Sign of Head - QA/Designee
Date:

Attach separate sheet, if required.

SHILPA PHARMA LIFESCIENCES LIMITED

PERSONNEL INTERVIEW/INTERACTIONS FOR COMPLAINT

Doc. Ref. No. SOP/QA/GEN/008

Effective Date: 26/08/23

Form No: FM-QA-223-00

Complaint Number :

Product name :

Complaint Source Batch Number:

Complaint Batch Number :

Name of the Supervisor/In-charge:

Name of the Interview/Interactions of personnel:

Comments on Interview/Interactions of personnel for Supervisor/In-charge:

Name of personnel:

Name of Supervisor/In-charge:

Sign & Date:

Sign & Date:

Note: Attach separate sheets as Annexure if required that should be authorized respective personnel.

SHILPA PHARMA LIFESCIENCES LIMITED	
STANDARD OPERATING PROCEDURE	
TEMPLATE FOR RE-OPENED CUSTOMER COMPLAINT LOG	
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SHILPA PHARMA LIFESCIENCES LIMITED

RE-OPENED CUSTOMER COMPLAINT LOG

Doc. Ref. No. SOP/QA/GEN/008

Form No: FM–QA–225–00

S. No	Date of reopen	complaint number	Source complaint number	Name of the product	Batch/ Lot Number	Name & address of the customer	Complaint Description	Reason for reopen	Sign	Date of response	Closed on	Sign & date

	Prepared by	Reviewed by	Approved by
Name	Mr. N. Damodar Reddy	Mr. M. Panduranga Naidu	Dr. U. Seshachalam
Designation	Sr. Manager - QA	GM - QA	VP - Quality & RA
Sign & Date	05/08/23	10/08/23	21/08/23