DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for receiving, recording, investigating, reviewing and responding to the market complaint.

2.0 SCOPE:

This procedure is applicable for handling of market complaints at ……. received from contract giver, Regulatory Agencies/National Health Agencies, Wholesaler, Distributor, Retailer, Customer, Medical Practitioner, Patients, field staff.

3.0 RESPONSIBILITY:

Concerned affected department/Quality Assurance department: To initiate, investigate the Quality/system related issues.

3.1 Quality Assurance

3.1.1 To receive and Log the complaint.

3.1.2 To handle complaint samples.

3.1.3 To investigate, review, document and respond to complainant/Head regulatory/Country Manager.

3.1.4 To prioritize complaint investigations for the product complaints indicating high potential risk to product quality.

3.1.5 To inform and involve other departments for investigating the complaint.

3.1.6 To intimate through preliminary investigation about the Field Alert Report and Notification to …….. Management if applicable.

3.1.7 To prepare trend of complaints& product recall.

3.1.8 To ensure the verification and implementation of CAPA.

3.1.9 To inform External Partners about the complaint as per Technical Agreement.

3.1.10 To coordinate for training as and when required.

3.1.11 Head QA is responsible to handle all the market complaints.

3.2 Quality Control

3.2.1 To participate in investigation of complaints with respect to any analytical testing requirement.

3.3 Production Department

3.3.1 To participate in the investigation of complaints.

3.3.2 To initiate and execute corrective and preventive actions in response to complaints.

3.3.3 To participate and support continuous improvement activities to prevent the recurrence of the complaints.

3.3.4 To conduct training to personnel whenever required.

3.4 Head Regulatory/Country Head/Qualified Person (QP)

3.4.1 To coordinate with complainant for getting additional information/samples and facilitating product/batch recall (if required).

3.4.2 To coordinate with regulatory authority for Field Alert Report / Rapid Alert/Recall and other associated activities (If required).

4.0 ACCOUNTABILITY:

4.1 Head Quality: To facilitate decision about product recall (if required) and appraising Management.

4.2 Head QA: To ensure timely investigation of complaint, response to the complainant/Head Regulatory/Country Manager and effectiveness of CAPA.

5.0 DEFINITIONS:

5.1 Complaint: An expression of dissatisfaction related to quality, therapeutic action and (or) packaging of a drug product.

5.2 Field Action: Required action to address non-conformity of a product released to distribution or that may become available to the public. The definition of a field action is driven by the regulatory requirements of the country of distribution (e.g. US distribution the action may involve a Field correction, market withdrawal or a recall, for Europe it is driven through Defective Medicines Report

center, DMRC and as per regulatory requirement for specific country where the particular product is distributed).

5.3 **Field Alert/Field Alert Report**: A formal notification to the FDA as required by the code of Federal Regulation (CFR314) for marketed drug products manufactured or distributed in U.S. Field Alerts are used to notify the FDA of potential issues related to on –market product using from FDA3331.

5.4 **Field Correction**: Repair, modification, adjustment, relabeling, or notification to the user without physical removal of the product from the site to which it was distributed.

5.5 **Regulatory Notifications**: Notification to regulatory agency based on the regulatory requirements for the country (ies) of distribution, of product issues.

5.6 **Site Awareness Date:** The date when complaint is notified to the site by complainant (customer, consumer, pharmacy, external partner/regulatory head/country manager etc.). If a complaint is moved to site after working hours at the manufacturing site, the next working day is considered the Site Awareness Date.

5.7 **Intact Sample**: An “intact” sample is defined as an integral primary container with no evidence of use or tampering.

5.8 **Critical Complaints**: A complaint related to quality, safety, identity, strength, efficacy, and /or purity of drug product, which may cause irreversible medical situation, potential risk to the patient, or noncompliance with regulatory authorization or critical failure of systems For example, not limited to.

5.8.1 Product Mix-Up (Incorrect label, incorrect lot number/expiration date, unreadable critical date, counterfeit etc.)

5.8.2 Microbiological Contamination (Microbial count)

5.8.3 Failure to meet the registered specification for distributed product

5.8.4 Metal embedded on drug product.

5.8.5 Adverse Drug Events, if considered a typical with respect to the reaction itself (Serious/Unexpected ADE)

5.8.6 Any significant deterioration of the product/Component performance issue.

5.9 Major Complaints: A complaint that represents a departure from cGMP, SOPs, manufacturing instructions, test plan or instructions or standards that do not necessarily affect the identity, strength, efficacy, quality, safety, potency or purity of material or product.

5.10 Minor Complaints: A complaint, which does not indicate any detectable impact on the quality of product or less serious observations; isolated incident not indicating system failure.

5.11 Non Substantiated Complaints: (To be classified during course of investigation): Complaint which does not arise due to any problem in manufacturing, analysis, packing or stability and may be due to mishandling at customer's end, incorrect storage/usage not following the instructions given in the literature of the product by the customer and not necessarily require corrective/preventive action at the manufacturing site.

6.0 PROCEDURE:

6.1 RECEIPT AND DOCUMENTATION

6.1.1 Complaints may originate from consumers, regulatory agencies, trade sources, healthcare professionals, distribution chain personnel or internal ……..

6.1.2 Complaints may be received in any form of communication like verbal, post, fax, Email, telephone or In-person.

6.1.3 If complaint is received by any other site the recipient shall forward the complaint to site QA Head/Designee within one working day.

6.1.4 QA Manager /Designee shall record the complaint details in the complaint log within one working day from the receipt of complaint, regardless of the nature of complaint. (Annexure-V).

6.2 CATEGORIZATION OF COMPLAINTS

6.2.1 Complaint categorization is done by QA Head/ Designee in consultation with Production Head. If required other functional department shall be involved for categorization based on the nature of complaint.

6.2.2 Based on the risk involved, nature and evaluation of complaint, complaint shall be categorized as follows;

6.2.2.1 Critical Complaints

6.2.2.2 Major Complaints

6.2.2.3 Minor Complaints

6.2.2.4 Non Substantiated complaint

6.2.3 The complaint categorization may change to higher or lower category in case of repeated complaints.

Note: Special attention shall be given to establishing whether a complaint is due to counterfeiting. The competent regulatory authorities shall be informed in case of detection of counterfeiting.

6.3 FOLLOW UPS FOR ADDITIONAL INFORMATION/COMPLAINT SAMPLES

6.3.1 QA-Head/Designee shall evaluate the adequacy of information received along with the complaint. If additional information is needed, QA Head shall attempt to collect the information.

6.3.2 QA Head/Designee shall make attempts to collect complaint samples, if not received to date. If additional information/feedback is not received from the complainant, send a reminder to the complainant to provide additional information.

6.3.3 QA Head may seek assistance from ……., representative based at the location. All such communications, photo attempts shall be documented.

6.4 HANDLING OF COMPLAINT SAMPLE

6.4.1 On receipt of complaint sample at manufacturing site, document the quantity of sample, batch information, physical condition of pack and product, integrity of pack and take the photograph of the sample including the information being displayed on the sample/ sample pack. Complaint samples shall be stored as per the specified storage conditions.

6.4.2 Information regarding the complaint sample shall be retained in the complaint file.

6.4.3 Complaint samples related to microbiological failures shall be sealed and handed over to microbiological laboratory for analysis.

6.5 INITIAL ASSESSMENT OF COMPLAINT

6.5.1 After recording the details in the Market complaint log, complaint details shall be forwarded to respective department in-charges for investigation. Initial assessment shall continue without waiting for the additional information/sample being requested.

6.5.2 QA person shall intimate the complaint investigation as per Annexure II.

6.5.3 **Verification of Accuracy of Complaints**

6.5.3.1 Verify the accuracy of the information being provided along with the complaint. This includes verification of Batch number/lot number, Drug product name (as appropriate) and whether it belongs to …….manufacturing site.

6.5.4 **Historical Review of Complaints**

6.5.4.1 The historical review shall aid in the determination of the extent of the complaint investigation to be performed.

6.5.4.2 The historical review includes (but not limited to), whether similar complaint or complaint from same batch/product was received in the past one year.

6.5.4.3 Verify if complaint history is indicative of any specific manufacturing /packing issue for the lot or product.

6.5.4.4 Corrective and Preventive action(s) for similar complaints received in past shall be evaluated.

6.5.4.5 Document the historical review in the market complaint investigation form.

Note: The initial assessment is to establish the criticality of the complaint and to determine potential impact on the quality, efficacy and safety of the product in the field and to submit field alert notification within three working days from receiving the complaint at ……., to concerned regulatory authorities irrespective of complaint sample availability.

6.6 TIME LINES FOR INVESTIGATION

6.6.1 Table below (Table No.1) shall be followed for time lines for investigation.

6.7 FIELD ALERT/COMPLAINT NOTIFICATION TO AGENCY

6.7.1 If the complaint is genuine and may directly affect the identity, strength, efficacy, quality, safety, potency or purity of the drug product; field alert notification should be submitted to concerned regulatory authorities. These complaints include but not limited to following:

6.7.1.1 Any incident that causes the drug product or its labeling to be mistaken for, product mix-up, or applied to another article and/or Microbial contamination, Significant chemical, physical, or

other change or deterioration, or Failure of one or more distributed batches of the drug product to meet the specification established for it in the application.

6.7.1.2 If complaint is received from a particular market, and the complaint product/batch is marketed in different countries, similar action shall be initiated voluntarily.

Table No.1

Events	Category of Complaint		
	Critical	**Major**	**Minor/Non Substantiated**
	Time lines in Hours and Working/Calendar days (From Site awareness date)		
Intimation to QA and categorization of complaint	One working day	One working day	One working day
Intimation of Investigation	Immediate	Two working days	Two working days
Preliminary response	24 hours	2-3 working days	2-3 working days
Completion of Investigation	03working days	15 working days	20 working days

6.8 PRODUCT RECALL

6.8.1 Management shall be notified immediately of any complaint resulting to drug product recall or market withdrawal of the batch. Recall of the product/batch shall be authorized by Quality Head.

6.8.2 On the risk to the patient or non-compliance with marketing authorization product recall shall be initiated (Refer SOP for Product Recall)

6.9 INVESTIGATION

6.9.1 Complaint details along with requisite data/samples shall be forwarded to respective production/packing department and QA in charges for investigation.

6.9.2 QA and concerned production Head/Designee shall investigate the complaint and shall forward the investigation report to QA Head. If required Formulation & Development / Engineering or any other department shall be involved in the investigation.

6.9.3 On need basis QA Head shall constitute cross functional team for conducting the investigation.

6.9.4 Investigation may include (but not limited to) the review of following:

6.9.4.1 Material /component used in the batch

6.9.4.2 Batch record review, Review of analytical/Stability report

6.9.4.3 Retain sample examination / microbial evaluation

6.9.4.4 Microscopic examination of complaint sample (for complaints of extraneous matter and other complaints requiring such examination)

6.9.4.5 Equipment used/Maintenance/calibration record

6.9.4.6 Environment control data (As applicable) Qualification and Validation data

6.9.4.7 Other suspected batches (Prior and / or after the complaint batches)

6.9.4.8 Customer complaint sample examination / chemical / microbiological analysis (As applicable)

6.9.5 During the course of investigation, as needed, additional parameters may also be identified for assigning probable cause.

6.9.6 Root cause analysis shall be performed as per SOP and RCA No. shall be mentioned in the market complaint investigation form.

6.9.7 If the investigation of market complaint received shall going to exceed stipulated time period of 30 calendar days then Extension Request for Market Complaint Investigation to be raised by QA and shall be approved by Head QA giving justification for delay in investigation (Refer Annexure-III).

Note: If the complaint samples are not received, initial investigation shall be performed based on historical review of complaints, review of records and retain sample evaluation.

6.10 COMPLAINT INVESTIGATION REPORT

6.10.1 Complaint investigation report shall include the findings and CAPA recommended upon conclusion of complaint investigations and reviews, which may cover the following but not limited to :

6.10.1.1 Description/Background of complaint

6.10.1.2 Details of retain/complaint sample examination/and/or analysis

6.10.1.3 List out of all evaluated documents at the time of investigation

6.10.1.4 Investigation details/findings

6.10.1.5 Root /Probable cause (Refer SOP for Root Cause Analysis)

6.10.1.6 Risk assessment of complaint, if applicable

6.10.1.7 Identification of CAPA (Refer SOP for CAPA)

6.10.1.8 Conclusion

6.10.1.9 Date of report preparation.

6.10.2 The necessary corrective and preventive actions shall be initiated to avoid recurrence to the complaint. SOP shall be followed for documentation and evaluation of CAPA and reference CAPA No. shall be recorded in the market complaint investigation form.

6.11 IMPACT ASSESSMENT

6.11.1 QA Head/Designee shall assess the risk of the complaint with respect to impact of complaint on other batches or markets or products and record the same in the market complaint investigation form.

6.11.2 QA Head/Designee shall forward the response/feedback to the complainant within 3 days after completion of investigation.

6.12 COMPLAINT CLOSURE

6.12.1 The complaint shall be closed based on following criteria

6.12.1.1 The required corrective and preventive action(s) are implemented (QA shall verify the implementation of recommended corrective and preventive actions and record the implementation details in the form).

6.12.1.2 Complainant/External partner agency has no further comments within 30 days from the date of response even after follow up.

6.12.1.3 The investigation is concluded to its logical end.

6.12.1.4 If any additional information/complaint sample is received from the complainant after closure of complaint, complaint shall be reopened and additional investigation shall be carried out (as applicable).

6.12.2 Complaint investigation and closure shall follow the same process as mentioned above.

6.13 TREND ANALYSIS AND EFFECTIVENESS CHECKS

6.13.1 Trend analysis of complaints & product recall shall be carried out on half yearly basis to study whether any specific trend is emerging from the complaints received (Refer Annexure-V)

6.13.2 Trend shall be compared with the earlier trend and will include effectiveness check of CAPA taken during last one year.

6.13.3 Based on the review of trend data if complaints received are found to be repetitive in nature and at higher frequency post implementation of corrective and preventive action(s), gap analysis in existing CAPA to detect inefficiencies in actions taken or need for reinvestigation to find probable or root cause and subsequent CAPA shall be analyzed and recommended.

6.14 RECORD RETENTION

6.14.1 Market complaint records shall be maintained up to ten years from the date of receipt of complaint.

6.14.2 A photocopy of Market complaint and investigation report shall be filled in Batch production record of affected batch (s).

Note: Where an investigation is not performed, the written record shall include the reason that an investigation was found not to be necessary and should have name and signature of QA Head/designee making such decision.

6.15 QA shall assign a unique, sequential number for each market complaint received.

Numbering System:

MC/XX/YYY

Where,

MC- Market Complaint

XX- Last Two Digit of the Calendar Year (example- 21 represents year 2021, 22 represents year 2022, etc.)

YYY- The Serial Number of the complaint during the calendar year (001, 002, 003…)

7.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
QP	:	Qualified Person
NA	:	Not Applicable
CAPA	:	Corrective Action & Preventive Actions
SME	:	Subject Matter Expert
RA	:	Regulatory Affairs

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure I	Market complaint form	
Annexure II	Market complaint Log Book	
Annexure III	Extension Request for Market Complaint Investigation	
Annexure IV	Flow chart - Market complaint	
Annexure V	Trend Analysis of Market Complaint	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01Quality Assurance Department.

10.0 REFERENCES:

In House

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE- I

MARKET COMPLANT LOG BOOK

Date	Market Complaint No.	Product Name	Batch No.	Mfg./Exp. Date	Name, address of the complainant	Details of the complaint	Nature of Complaint (Minor/Major/ Critical)	Reference CAPA No.	Complaint Closed on	Sign QA Head	Remark

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-II

MARKET COMPLAINT INVESTIGATION FORM

Market complaint No.:		**Date of Complaint received:**
Name: **Sign/Date:**		**Date of log in of Complaint:**
Product Name: **Generic Name:**	**Batch No.:** **B. Size:** **Mfg. Date:** **Expiry Date:**	**Quantity involved:** **Mode of complaint received:** **Complaint sample (s)** Received ☐ Not Received ☐
Nature of Complaint: --- --- --- --- --- --- --- --- --- ---		**Name and Address of Complainant:**
Categorization of Complaint: Minor ☐ Major ☐ Critical ☐		

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Information on Complaint Sample

- Integrity of original manufacturer's pack: Intact/Not Intact
- Lot / Batch No. available on container Yes/No. (If Yes specify) Lot No./ Batch No.:_____
- Photograph of complaint sample captured at site: Yes/No (If, No specify the reason)

Any additional remarks for complaint sample (If any) :

Preliminary Investigation &Details of earlier complaint of similar nature if any:

Following guideline may be followed:

1) Evaluation of Control / Retain Sample
2) Evaluation of Complaint Sample
3) Review of Batch manufacturing and batch packing record
4) Review of other related documents
5) Review of inputs(Raw Materials / Packing Materials)
6) Machine related / Operator related
7) Microscopic examination of complaint sample (For complaints of extraneous matter and other
8) complaints requiring such examination)
9) Environmental control data
10) Qualification and Validation Data
11) Review of Analytical documents
12) Additional parameter (If any)

Verification of Accuracy of complaint

- Drug Product Name : Adequate / Inadequate
- Lot No./ Batch No. : Adequate / Inadequate

(Inadequate: if Lot No. / Batch No. does not match with product name / strength or does not belong to ……..)

- Complaints belongs to ……site : Yes / No
- If No, complaint forwarded to respective site or informed to complainant. Yes / No
- Follow up for additional information (If Any): Yes / No (If yes specify)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Physical Description of the Complaint Sample:

QA (Sign/Date):

Investigation & Root Cause Analysis:
(Perform RCA as per SOP, reference RCA No.:)

Production Head (Sign/Date): QA (Sign/Date):

Corrective and Preventive Actions (CAPA): Reference CAPA No.:

Head Quality Assurance
Sign/Date:

Impact of complaint on other batches/Markets:

Head Quality Assurance
Sign/Date:

Head QA/Designee review and remarks:

Sign/Date:

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Response to the Complainant:

Head QA/Designee
(Sign/Date):

Implementation of CAPA:

Concerned Department
Sign/Date:

Review & Closure Comments:

Head Quality Assurance
Sign/Date:

Closure of Complaint by QA

Date of Closure:

QA (Sign/Date):

ANNEXURE- III

EXTENSION REQUEST FOR MARKET COMPLANT INVESTIGATION

Date: / /

Subject: _____days extension request for investigation report of market complaint No.

Product Name:

Batch No.:

- **Nature of Complaint:**
- **Justification for delay in investigation:**

_____ _____

Prepared by
(Departmental QA)

Approved by
(Head-QA)

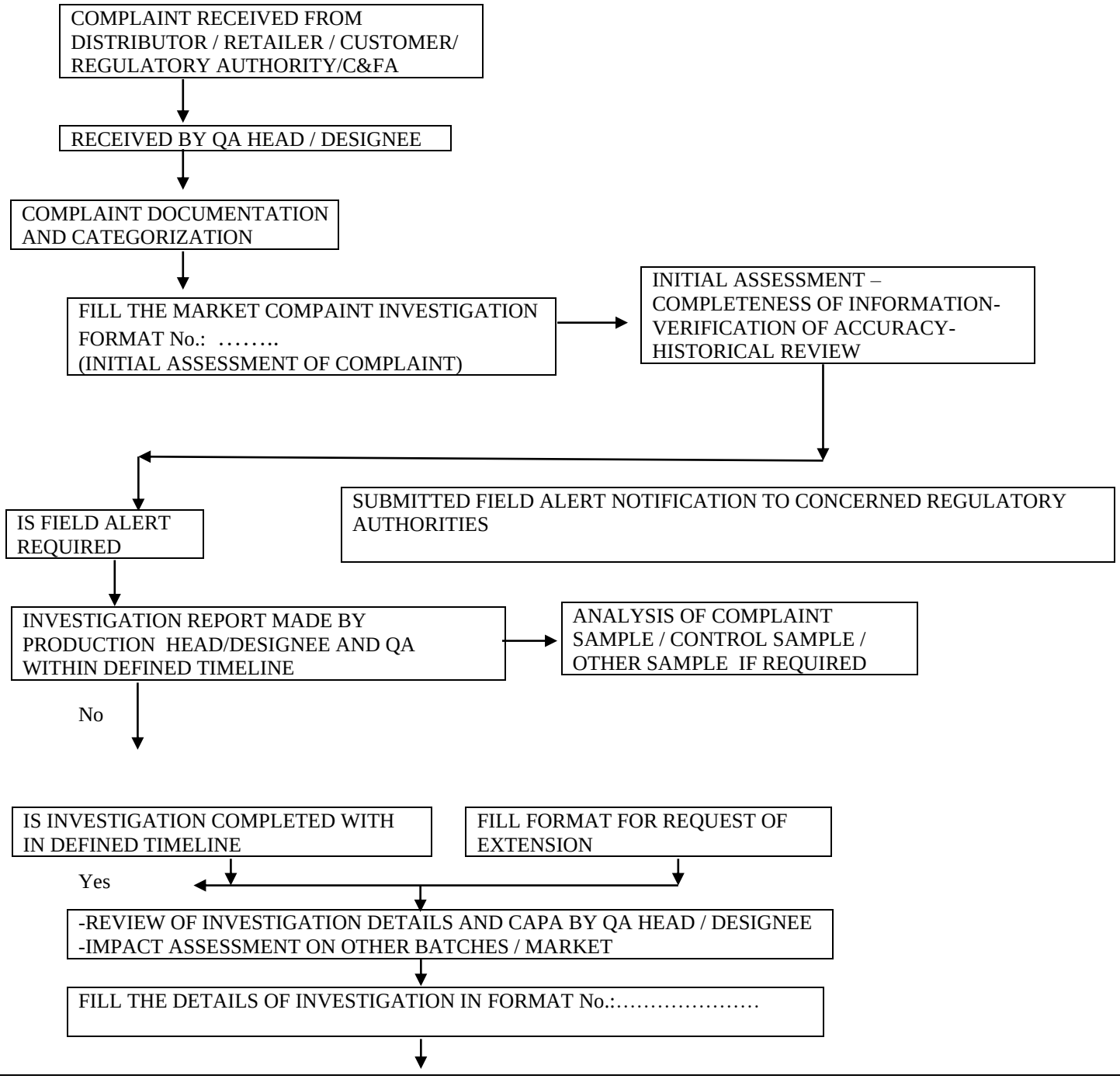
DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE- IV

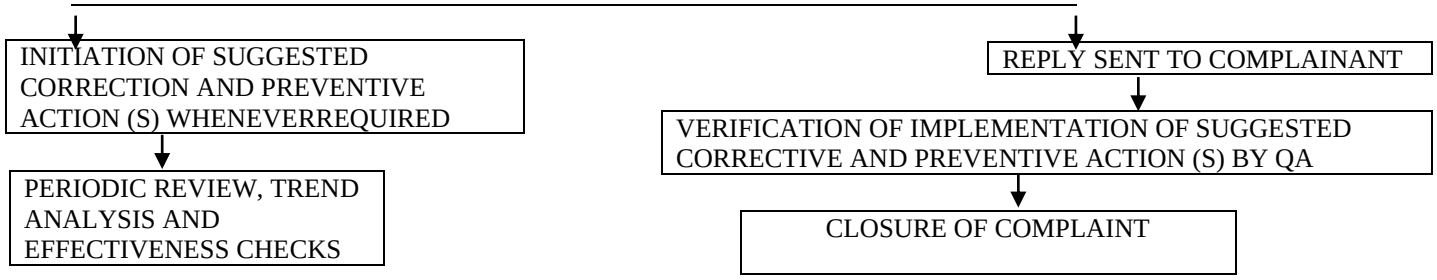
MARKET COMPLANT FLOW CHART



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**



STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Market Complaint	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE- V

TREND ANALYSIS OF MARKET COMPLAINT

YEAR: **Frequency:** Half Yearly

S.No.	Description of Complaint received	Market Complaint Number	Category	Reference CAPA No.	Product Recall triggered (If Yes Doc. No.)

Total number complaint received:

Number of Critical complaints:

Number of Major complaints:

Number of Minor complaints:

Effectiveness of CAPA:

Gap Analysis to be conducted: (Yes/No)

Prepared by QA:
Sign & Date

Checked by Head QA:
Sign & Date