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1.0 PURPOSE

To define a procedure for handling of market complaints.

2.0 SCOPE

2.1 This procedure is applicable to all the market complaints of drug products received directly or from any other source at……..

3.0 REFERENCE(S) & ATTACHMENTS

3.1 **References**

3.1.1 In-house

3.2 **Attachments**

3.2.1 Attachment – I : Flow Chart for handling of Market complaints.

3.2.2 Attachment – II : Market Complaint Log at manufacturing location.

3.2.3 Attachment – III : Market Complaint Preliminary Investigation Report (PIR).

3.2.4 Attachment – IV : Examples of market complaints-guideline for investigation.

3.2.5 Attachment – V : Market Complaint Final Investigation Report (FIR).

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Complaint: A market/consumer complaint is notification that a product in commercial distribution (which also includes physician sample):

- May be in violation of the laws or regulations administered by the FDA (Drug Control Authority).
- May have caused an illness, injury or death.
- Is alleged to have caused problems not covered by the above.

4.2 Abbreviations

4.2.1 C & F: Carrying & Forwarding agent

4.2.2 CAPA: Corrective and Preventive Action

4.2.3 CQA: Corporate Quality Assurance

4.2.4 FDA: Food & Drug Administration

4.2.5 FIR: Final Investigation Report

4.2.6 FP: Finished Product

4.2.7 PIR: Preliminary Investigation Report

4.2.8 QA: Quality Assurance

4.2.9 QC: Quality Control

4.2.10 SOP: Standard Operating Procedure

5.0 RESPONSIBILITY:

5.1 Corporate Quality Assurance

5.1.1 To receive & log the market complaint at CQA.

5.1.2 To collect the adequate information required for complaint investigation, if not available.

5.1.3 To send the complaint to the manufacturing location for the investigation.

5.1.4 To receive Preliminary Investigation Report (PIR) or Final Investigation Report (FIR) from the location.

5.1.5 To review both PIR & FIR, as applicable.

5.1.6 To send the final reply to the complainant.

5.2 Quality Assurance:

5.2.1 To log in the complaint in market complaint register.

5.2.2 To prepare PIR in case of quality related complaint where investigation may take time to prepare final report.

5.2.3 To conduct market complaint investigation.

5.2.4 To prepare investigation (PIR & or FIR) report.

5.2.5 To get it reviewed and approved from concern persons.

5.2.6 To send a copy of the investigation report to CQA.

5.2.7 To perform periodic review of the complaints & ensure CAPA implementation, if any.

5.3 Quality Control:

5.3.1 To monitor the analysis of complaint sample, any another sample in relation to the complaint investigation or control sample.

5.3.2 To provide analytical results or any other data with conclusion.

5.4 Production Head:

5.4.1 To cooperate QA in the process of complaint investigation.

5.4.2 To review the complaint investigation report.

5.5 Quality Assurance Head:

5.5.1 To receive complaint from CQA or any other source & handover to QA for investigation.

5.5.2 To provide guidance for the investigation of market complaint.

5.5.3 To approve the complaint investigation report.

5.6 Plant Head:

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5.6.1 To provide guidance for the investigation of market complaint.

5.6.2 To approve the complaint investigation report.

6.0 Distribution:

I. Quality Assurance

II. Quality Control

III. Production

7.0 PROCEDURE:

7.1 Source of Complaint:

A complaint may be received from C & F agent, consumers, field source government agencies, trade sources & healthcare professionals or any other source.

7.2 Types of Complaints:

Complaints are categorized in 3 categories:

7.2.1 **Quality Related:** The complaints which are life threatening or cause serious adverse health consequences or do not match designed specification.

The Quality related problems are again divided into 3 categories as under:

7.2.1.1 **Critical:** They are the complaints which directly affect the health of the consumer or violate the law or regulations by drug regulatory authorities of India, FDA. e.g. Reflecting poor quality, ineffectiveness, product deterioration, product mixing, batch coding problems, sterility problems, contamination like microbial growth & presence of foreign matter, product having low assay, failure of dissolution rate, product causing adverse effect / adverse reactions to the patient or death.

7.2.1.2 **Major:** These are the complaints which do not affect the health of the customer but causes him/her the financial loss and somehow or the other violates the laws or regulations administered by FDA. e.g. Marked change in description, smudged prints, empty pockets.

7.2.1.3 **Minor:** The complaints do not require immediate or prompt actions but may be investigated, referred or closed without further investigation at management's discretion. e.g. Any other complaints not covered in critical and major category.

7.2.2 **Packing Related:** The complaints are not life threatening and related to packing of product and need to be investigated.

7.2.3 **Shortage Related:** The complaints do not require immediate or prompt actions but may be investigated, referred or closed without further investigation at management's discretion.

7.3 Procedure for handling of complaints (Quality related):

7.3.1 **Receipt & Registration:**

7.3.1.1 On the receipt of complaint from any of the source. CQA shall log the complaint, shall allocate the complaint registration number & shall forward it to the manufacturing location. The complaint registration number shall be allotted as under:

Complaint Registration Number: **MC-XX-YYY**: The complaint registration number shall be a 9 digit number wherein:

- The first 2 digit 'MC' stands for Market Complaint
- The third Digit is '–' stands for dash
- The fourth & fifth digit i.e. 'XX' stands for the last two digits of the year of registration of complaint.
- The sixth digit number is '–'stands for dash.
- The last 3 digits i.e. 'YYY' represents the serial number of complaints registered in the year.

e.g.: **MC-22-001**: Herein:

- 'MC' is market complaint
- '–' is dash
- '16' represents year 2022
- '–' represents dash
- '001' is the first complaint registered in the year 2016.

7.3.1.2 On the receipt of the complaint from CQA or any other source necessary entries shall be made at the manufacturing location in the market complaint register (refer attachment –II).

76.3.1.3 If location receives the complaint from any other source than CQA, copy of the complaint shall be sent to CQA immediately after receipt to get CQA registration number.

7.3.2 **Investigation of the complaint:**

7.3.2.1 Any quality related complaint investigation shall be completed within 30 days from the date of complaint receipt, if does not demand for any additional work. If the investigation exceeds 30 days reason for the same shall be documented & prior justification from QA head shall be taken .

7.3.2.2 In case of critical complaint where investigation may take time, location QA shall prepare PIR; refer (Attachment-III) & send to CQA within 2 working days of the receipt of Complaint (PIR may include but

not limited to review of BMR/BPR/Control sample/Product literature/Trends depending on nature of complaints).

7.3.2.3 CQA shall send initial reply to the complainant if required, with or without replacement.

7.3.2.4 Plant QA shall attach the PIR with the complaint, which shall be the part of market complaint investigation report.

7.3.2.5 Following are the examples of critical complaints.

- Ineffectiveness
- Melt back of lyophilized cake
- Foreign matter
- Colour change
- Change in physical form
- Adverse event/ Adverse drug reaction
- Any quality defect that may cause Permanent disability or serious health consequences

7.3.2.6 QA shall conduct the investigation with the help of concern departments.

7.3.2.7 QA shall arrange for the physical inspection of control sample if required & shall prepare report of the same, which shall be part of the investigation report.

7.3.2.8 QA shall provide required quantity of control sample to QC for analysis if required.

7.3.2.9 QA shall provide required batch manufacturing documents to production or QC for Review & data collection.

7.3.2.10 Production & QC shall provide required information to QA for the preparation of investigation report.

7.3.2.11 QA shall prepare FIR as per attachment V & shall get it reviewed and approved by the concerned persons.

7.3.2.12 QA shall send copy of the final investigation report to CQA along with necessary attachments like control sample physical inspection report, trial batch report, quality control analytical data (in process trend, FP trend, stability data, complaint sample analytical results, control sample analytical results, trial batch results), training record or any other data .

7.3.2.13 CQA shall review the investigation report & ask for further investigation details, if required.

7.3.2.14 On receipt of FIR, CQA shall send final reply to the complainant, as required.

7.3.3 **Reply to complainant:**

7.3.3.1 In case of critical complaint, CQA head shall send initial reply to the complainant, if required.

7.3.3.2 Subsequently, CQA shall send copy of initial reply to the concern location for the record.

7.3.3.3 After receipt of FIR, CQA shall send final reply to the complainant.

7.3.3.4 Copy of reply shall be send to Manufacturing location.

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7.4 Procedure for handling of complaint- (Packaging related):

7.4.1 **Receipt & Registration:**

7.4.1.1 On the receipt of complaint from any of the source CQA shall log the complaint, shall allocate the complaint registration number & shall forward it to the concern location. The complaint registration number is allotted as under:

Complaint Registration Number: **MC-XX-YYY**: The complaint registration number shall be a 9 digit number wherein:

- The first 2 digit 'MC' stands for Market Complaint
- The third Digit is '–' stands for dash
- The fourth & fifth digit i.e. 'XX' stands for the last two digits of the year of registration of complaint.
- The sixth digit number is '–'which stands for dash.
- The last 3 digits i.e. 'YYY' represents the serial number of complaints registered in the year.

e.g.: **MC-22-001**: Herein:

- 'MC' is market complaint
- '– ' is dash
- '22' represents year 2022
- '– ' represents dash
- '001' is the first complaint registered in the year 2022.

7.4.1.2 On the receipt of the complaint from CQA or any other source necessary entries shall be made at the location in the market complaint register (refer attachment –II).

7.4.1.3 If location receives the complaint from any other source than CQA, copy of the complaint shall be sent to CQA immediately after receipt to get CQA registration number.

7.4.2 **Investigation of the complaint:**

7.4.2.1 Any packing related complaint investigation shall be completed within 45 days from the date of complaint receipt, if does not demand for any additional work. If the investigation

exceeds 45 days reason for the same shall be documented & prior justification from QA head shall be taken.

7.4.2.2 QA shall conduct the investigation with the help of concern departments.

7.4.2.3 Location QA shall forward the complaint to the production/ packing department.

7.4.2.4 Subsequently production/packing department shall check all the parameters required at the time of packing.

7.4.2.5 The production/ packing head shall discuss the complaint with concern heads, impart the training, document the same and take other action as required based on investigation.

7.4.2.6 Department head shall send a copy of the training record to QA.

7.4.2.7 QA shall provide required batch manufacturing documents to production/ packing department for review & data collection.

7.4.2.8 Production & QC shall provide required information to QA for the preparation of final investigation report.

7.4.2.9 QA shall prepare investigation report as per attachment V & shall get it reviewed and approved by the concerned persons.

7.4.2.10 QA shall send copy of the final investigation report to CQA along with necessary attachments like training record, BPR & BMR or any other supporting documents.

7.4.2.11 CQA shall review the investigation report & ask for further investigation details, if required.

7.4.3 **Reply to complainant:**

7.4.3.1 After receipt of FIR, CQA shall send final reply to the complainant.

7.4.3.2 Subsequently, CQA shall send copy of reply to the concern location for the record.

7.5 Procedure for handling of complaint- (Shortage related):

7.5.1 **Receipt & Registration:**

7.5.1.1 On the receipt of complaint from any of the source, CQA shall log the complaint, shall allocate the complaint registration number & shall forward it to the concern location. The complaint registration number is allotted as under:

Complaint Registration Number: **MCS-XX-YYY**: The complaint registration number shall be a 10 digit number wherein:

- The first 3 digit 'MCS' stands for Market Complaint of Shortages
- The fourth Digit is '–' stands for dash
- The fifth & sixth digit i.e. 'XX' stands for the last two digits of the year of registration of complaint.
- The seventh digit number is '–' which stands for dash.
- The last 3 digits i.e. 'YYY' represents the serial number of complaints registered in the year.

e.g.: **MCS-22-001**: Herein:

- 'MCS' is market complaint of shortages
- '–' is dash
- '22' represents year 2022
- '–' represents dash

- '001' is the first complaint registered in the year 2022.

7.5.1.2 On the receipt of the complaint from CQA or any other source necessary entries shall be made at the location in the market complaint register.

7.5.1.3 If location receives the complaint from any other source than CQA, copy of the complaint shall be sent to CQA immediately after receipt to get CQA registration number.

7.5.2. **Investigation of the complaint:**

7.5.2.1 Any shortages related complaint investigation shall be completed within 60 days from the date of complaint receipt, if does not demand for any additional work. If the investigation exceeds 60 days reason for the same shall be documented & prior justification from QA head shall be taken.

7.5.2.2 QA shall conduct the investigation with the help of concern departments.

7.5.2.3 Location QA shall forward the complaint to the production/ packing department.

7.5.2.4 Production/packing department shall check all the parameters required at the time of packing e.g. use of proper tape, shrink sleeving if done, sealing of shipper with proper BOPP tape.

7.5.2.5 Production/Packing department shall do check weight verification of mono carton, packed shrink sleeve, outer carton & shipper weighing records.

7.5.2.6 The production/packing head shall discuss the complaint with concern heads, impart the training, document the same and take other action as required based on investigation.

7.5.2.7 Department head shall send a copy of the training record to QA.

7.5.2.8 QA shall provide required batch manufacturing documents to production/packing department for review & data collection.

7.5.2.9 Production/Packing shall provide required information to QA for the preparation of final investigation report.

7.5.2.10 QA shall prepare investigation report as per attachment V & shall get it reviewed and approved by the concerned persons.

7.5.2.11 QA shall send copy of the final investigation report to CQA along with necessary attachments like training record & BPR or any other supporting documents.

7.5.2.12 CQA shall review the investigation report & ask for further investigation details, if required.

7.5.3 **Reply to complainant:**

7.5.3.1 After receipt of FIR, CQA shall send final reply to the complainant.

7.5.3.2 Subsequently, CQA shall send copy of reply to the concern location for the record.

7.6. Complaint Investigation Cycle Time:

7.6.1 **Cycle Time (Quality related Complaints):**

7.6.1.1 In the above mentioned case the PIR shall be submitted within 2 days of registration.

7.6.1.2 FIR shall be submitted within 30 days from the date of registration considering following two situations as under:

- **If complaint sample is available:** FIR shall be submitted within 30 days from the receipt of samples at the concerned location.
- **If the complaint sample not available:** FIR shall be submitted within 30 days from the date of confirmation of non-availability of complaint sample.

7.6.2 **Cycle Time (Packing related Complaints):**

7.6.2.1 FIR shall be submitted within 45 days from the date of registration considering following two situations as under:

- **If complaint sample is available:** FIR shall be submitted within 45 days from the receipt of samples at the concerned location.
- **If the complaint sample not available:** FIR shall be submitted within 45 days from the date of confirmation of non-availability of complaint sample.

7.6.3 **Cycle Time (Shortages related Complaints):**

7.6.3.1 FIR shall be submitted within 60 days from the date of registration.

7.6.4 **Six monthly review of complaints:**

Quality review of complaints shall be done after every six months by manufacturing location, conclusion shall be drawn & CAPA shall be implemented by each location. The date of implementation of CAPA & effective B .No. shall be informed to CQA & the record shall be kept by CQA.

NOTE:

Product Recall: In case of confirmation of critical complaints, product(s) shall be recalled as per the product recall SOP of the manufacturing location.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

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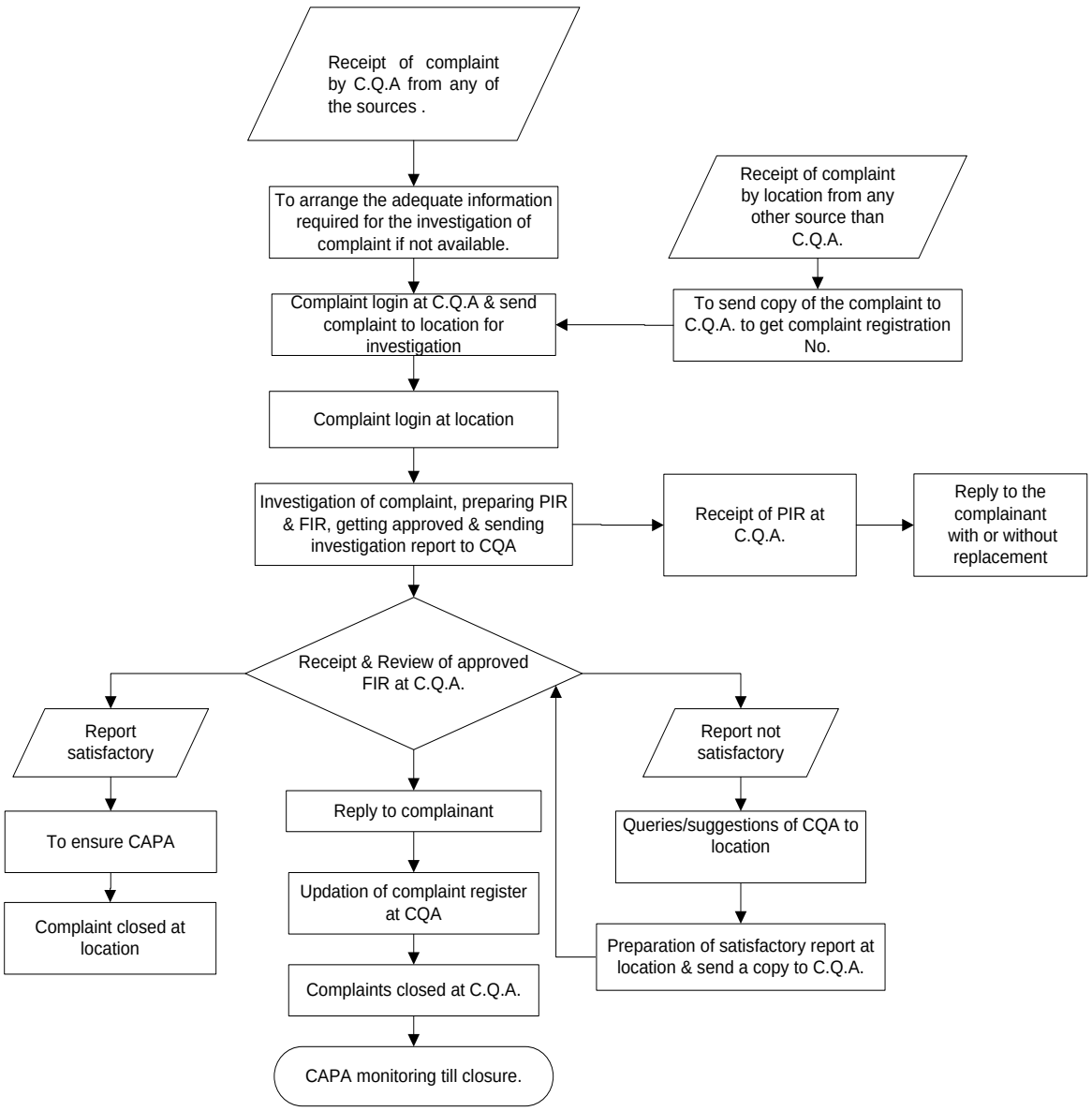
Attachment-I

Flow Chart for handling of Market Complaints



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Attachment – II

MARKET COMPLAINT LOG

S.No.	C.Q.A. Complaint No.	Location Complaint No.	Product Name	Batch Number	Mfg. Date	Exp. Date	Complaint Description	Date of Receiving

Category of Complaint	Received from	Complainant	Investigation Summary	Preventive Action	Date Report Sent to CQA	Status (Open /Closed)	Remarks

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Attachment-III

MARKET COMPLAINT (PRELIMINARY INVESTIGATION REPORT)

CQA Complaint No:		**Mfg. location Complaint No :**	
PRODUCT DETAILS			
Brand Name:		**Packing/Pack Size:**	
Batch No.:		**Date of Receipt:**	
Mfg. Date:		**Exp. Date:**	
Complaint Received on:			
Received from:			
Complaint Description:			
History:			
PRELIMINARY INVESTIGATION OBSERVATION / DETAILS			
PRELIMINARY INVESTIGATION DONE BY			
Department	**Plant Head**	**QA Head**	
Sign/Date			

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Attachment-IV

Examples of market complaints- guideline for investigation.

Note: *This attachment shows only a few examples of market complaint with suggested investigation. This attachment shall be edited based on type of formulation (sterile/non sterile) manufactured at the location & also based on type & trend of the complaint received at the location.*

EXAMPLES OF MARKET COMPLAINT WITH GUIDELINE FOR INVESTIGATION

S.No.	Example of Complaint	Suggested Investigation
1.	Ineffectiveness/ poor quality/ Inadequate response of the drug.	• History of the product. • Physical inspection of complaint & control sample. • Review of batch document for, o Active RM (Raw Material) calculation. o Qty. added of active & inactive RM against bill of material. o Source of material. o Dispensing precautions: e.g. API dispensing & storage in the black/ light resistant bag or container. o Processing precautions: e.g. dissolved oxygen, safe light, nitrogen flushing or any other. o Dose control record. o Processing parameters. o In-process checks by production & QA. o Daily quality observation record. o Any deviation, which has direct or indirect impact on product quality. • In process quality control data. • Review of FP analytical report & trend. • Review of stability data. • Complaint & control sample analysis for (as applicable), o Volume variation. o Content uniformity. o Dissolution. o Assay. o Degradation o Related Substance. o Moisture content. • Biological assay, where required. • Storage condition. • Audit of C & F agent or retailer if required.
2.	Less content in capsules/ tablet/ vial/ ampoule/bottle.	• Physical inspection of complaint & control sample, o For minor crack. o Improper sealing. o Condition of container label &/or show box to eliminate possibility of leakage. • Review of batch mfg. record for, o Active RM calculation. o Qty. added of active & inactive RM against bill of material. o In process checks by production & QA. o Visual inspection record. o Leak test record. o Yield & reconciliation of the batch. • In-process& FP quality control data.

		• Trend of yield. • Sequential log of filling or compression or capsule filing machine for breakdown or any other problem observed during processing . • Daily quality observation record. • Complaint & control sample analysis for as applicable, o Dissolution. o Content uniformity. o Assay. o Degradation. o Related Substance o Volume variation.
3.	Bulging of strip pockets	• History of the product. • Physical inspection of control & complaint sample. • Improper storage condition. • Review of stability data. • Analysis of complaint &/or control sample for as applicable, o Assay. o Degradation. o Related substance. o Moisture content
4.	Presence of foreign matter (Living/non-living).	• History of the product. • Physical inspection of complaint & control sample for, o Minor crack. o Improper sealing. • Daily quality observation record. • pH trend. • Precipitation. • Physical inspection of particular AR No. used for mfg. of the batch. • Review of batch mfg. record for, o Primary Packing Material o Use of pretreated ampoules (e.g. acid treated amps). o Empty primary Pkg. material washing & sterilization in record. o Cleaning record of mfg., filtration & filling equipments& area. o Sterilization record of filtration & filling equipments. o Filter integrity test results (Pre & post filtration). o Leak test record. o Terminal sterilization record. • Sequential log of washing machine. • Environmental monitoring data. • Quality/compatibility of closure and primary packing material. • Analysis of complaint sample/ control sample for, o pH. o Identification of preservative. o Content of preservative. o Assay. o Degradation. o Related substance • Microbiological analysis of complaint sample/control sample. • Training record of visual inspectors.
5	Adverse event /Adverse drug reactions (e.g. vomiting, severe	• History of the product. • Microbiological analysis of complaint sample/control sample.

	cramps/Rashes)	• Pharmacology of the API & related formulations.
6	Discoloration of solution or tab/cap/ liquid.	• History of the product. • Physical inspection of complaint & control sample for, o Minor crack. o Improper sealing. • Review of batch mfg. record for, o Special precautions required during processing e.g. dissolved oxygen, low light, nitrogen flushing or any other. o Cleaning record of mfg., filtration & filling equipments& area. o Leak test record. • Daily quality observation record. • Recovery procedure. • In-process checks by production & QA during mfg. & packing. • Analysis of control &/or complaint sample for as applicable, o pH. o Assay. o Degradation. o Related substance • Stability data. • Storage condition.
7	Damaged/broken/ leaking capsule/ ampoule/vial.	• Physical inspection of complaint & control sample. • Review of batch mfg. record for, o Visual inspection record. o Temp. & humidity conditions. o Filling machine setting parameters. o In process checks during mfg. & packing by QA & production. • Vendor of empty capsule/ampoule/vial. • Sequential log of capsule filling machine for breakdown. • Training of the visual checkers. • Compatibility study of empty hard gelatin cap/ampoule/vial with excipient. • Monitoring of de-foiling & repacking activity.
8	Melt back (of lyophilized cake).	• History of the product. • Physical inspection of control & complaint sample. • Review of batch document for, o Filling in process checks by production & QA o Lyophlization menu. o Visual inspection record. o Hold time at different stages. o Temp. & humidity conditions at different stages. • Review of trend of processing, in-process & FP parameters. • Daily quality observation record. • Review of stability data. • Analysis of complaint &/or control sample for, o Moisture content. o Assay. o Degradation. • Training record of visual inspectors.
9	Broken tab.	• History of the product. • Physical inspection of complaint & control sample. • Review of batch mfg. record for, o In process checks by production & QA during mfg. & packing.

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		o Visual inspection record. o NFD checking of cracking • Review of trend of processing, in process & FP parameters. • Daily quality observation record. • Handling of the bulk product and hold time. • Training record of the visual checkers & strip packing machine operators. • Analysis of control &/or complaint sample for, o Friability. o Hardness • Monitoring of defoiling & repacking activity.
10	Product or batch mixup.	• Physical inspection of control & complaint sample for physical appearance of primary pkg. material of two products under question. • System followed to ensure proper segregation product at different stages. • Sequential log of machine at every stage to know the previous or next product taken on the same machine & to ensure absence of same /similar product in the surrounding area. • Other products packed on the same day on the nearby labeling machine or packing line of product under question. • Review of batch mfg. record for, o Machine & line clearance record at different stages. o Reconciliation of packaging materials. o Reconciliation of bulk & FP. • Analysis of control &/or complaint sample for, o Identification test of two products under question. o Identification test of preservative. • Wrong labeling/ packing. • Daily quality observation record. • Monitoring of defoiling& repacking activity. • Training record of packers. • Repacking if done at any C& F location.
11	Poor quality of cap (Dropper/ Dispenser).	• History of the product. • Physical inspection of control &/or complaint sample. • Vendor of pkg. (cap or dropper) material. • Compatibility study. • Review of stability data.
12	Fake product.	• History of the product. • Comparison of complaint sample with control sample for appearance of strip/ label (font size of letters, printed text matter, size of the pocket, gap between the two pockets, knurling pattern, logo of the company, movement of tab or cap in the pocket etc.). • Comparison of complaint sample with control sample for appearance of tablet or capsule (size or dimensions, color, imprint, embossing, edge type etc.). • Comparison of primary packaging material (Vial/ampoule/strip/blister/bottle) for shape & size, sealing, height, type of seal, logo on the seal, color of the seal, type of rubber stopper etc. • Analysis of complaint &/or control sample.
13	Empty primary container (Vial/ampoule/bottle/ pocket of strip or blister)	• Physical inspection of control &/or complaint sample. • Sequential log of filling or striping or blistering machine for breakdown or any other problem. • Review of batch document for,

		o In process checks by production & QA during filling. o Leak test record. o NFD challenge & working. o Visual inspection record. o In process checks by production & QA during packing (e.g. on line compressed air flow or any other system followed to remove empty plastic container or empty pocket in strip or blister). o Yield & reconciliation of the batch & comparison with trend. • Balance performance & calibration check record. • Weight variation record of packed show boxes &/or shippers. • Proper segregation of packed & empty boxes. • Daily quality observation report. • Training record of the visual inspectors. • Vendor of primary container (as cause of empty container may be hair line cracks due to weak MOC of container).
14	Receipt of product in different show box/ having different label.	• Complaint sample observation. • Physical inspection of control sample. • Previous & next product packed on the same machine. • Appearance of packing material of two products under question. • Review of batch document for, o Line clearance (by packing & QA) record. o Reconciliation of packing material. o Machine & line clearance record. o In process checks by packing & QA. o Product packed on adjacent lines/nearby area. • Daily quality observation record. • Storage of packing material in the store & in pkg. Dept. • Procedure to be followed for the left over pkg. Material after completion of packing. • Monitoring of delabeling & relabeling/repacking activity. • Inspection of reaming stock of PM of the products under question. • PM vendor audit. • Training of packers. • Repacking if done at any C& F location/depot.
15	Strip Short in mono carton / Carton short in shipper	• Physical evaluation of complaint/control sample • Review of batch document for, o In process checks by packing & QA. o Visual Inspection record o Sealing of mono carton & shipper by proper cello tape/BOPP tape. • Balance and check ware system performance & Calibration check records. • Weight variation record of packed show boxes (mono cartons) &/or shippers. • Proper segregation of packed & empty boxes. • In case of loose shippers, sealing of shipper as per SOP.

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Attachment-V

MARKET COMPLAINT (FINAL INVESTIGATION REPORT)

CQA Complaint No:		**Mfg. location Complaint No:**	
PRODUCT DETAILS			
Brand Name:		**Packing/Pack Size:**	
Batch No.:		**Date of Receipt:**	
Mfg. Date:		**Exp. Date:**	
Complaint Description:			
Received from:			
History:			

INVESTIGATION DETAILS

PARAMETERS	OBSERVATIONS
Complaint Sample Available	
Physical Evaluation of Complaint Sample	
Testing/ Analysis performed on complaint sample	
Physical Evaluation of control sample	
Testing/ Analysis performed on control sample	
Raw Material Review	
In process trend review	
Finished Product trend review	
Stability Trend Review	
Batch Record (Manufacturing & Packing) review	
Manufacturing Process Trend Review	
Review of Change control/ Incident/ Deviation	
Any Other Remark	
ROOT CAUSE/ PROBABLE CAUSE	

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

IMPACT ANALYSIS	
CORRECTIVE & PREVENTIVE ACTION (CAPA)	
FINAL CONCLUSION	
STATUS	
ATTACHMENTS/ SUPPORTING DOCUMENTS	

INVESTIGATION DONE BY

Department	Production	Q.A.
Sign/Date		

INVESTIGATION REPORT APPROVED BY

Department	Production Head	Plant Head	QA Head
Sign/Date			