PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

1. **Purpose:** The purpose of this SOP is to define the procedure for handling of market complaints.

2. **Scope:** This procedure is applicable to handling of market complaints of drug products manufactured at ……..

3. **References, Attachments & Annexures:**

3.1 **References:**

3.1.1 21 CFR, Part 314.80 and part 211.198
3.1.2 WHO TRS 961.
3.1.3 SOP: Product Recall
3.1.4 SOP: Corrective/Preventive Action Recommendation
3.1.5 SOP: Global Handling of Adverse event/Adverse drug reaction
3.1.6 Rules and guidance for Pharmaceutical Manufacturing & Distribution-Medicine & Health care Regulatory Agency.
3.1.7 EU-GMP Part I, Chapter II, Section 08 – Complaint and Product Recall.

3.2 **Attachments:**

3.2.1 Attachment – 1 : Market Complaint Register
3.2.2 Attachment – 2 : Time lines associated with Handling of Market Complaints
3.2.3 Attachment – 3 : Preliminary Investigation Report
3.2.4 Attachment – 4 : Initial Market complaint Investigation Report
3.2.5 Attachment – 5 : Interim Market complaint Investigation Report
3.2.6 Attachment – 6 : Final Market complaint Investigation Report
3.2.7 Attachment–7 : Addendum to Market complaint Investigation Report
3.2.8 Attachment – 8 : Register for Extension Note
3.2.9 Attachment – 9 : Extension Note for investigation of Complaint
3.2.10 Attachment – 10 : History of complaints
3.2.11 Attachment –11 : Flow chart for Handling of Quality complaints
3.2.12 Attachment–12 : Flow chart for Handling of Commercial Market Complaints

3.3 **Annexures:**

3.3.1.Annexure –1: Assignment of Unique Complaint No. at each Complaint coordinator
3.3.2.Annexure –2: Market complaint code classification
3.3.3.Annexure –3: Examples of Market Complaint with Guideline for investigation

4. **Responsibilities:**

4.1 **Global Pharmacovigilance Cell:**

4.1.1. To receive the complaint.
4.1.2. To evaluate the complaint and classify it as ADE, ADE + Manufacturing or Non ADE.
4.1.3. To forward the complaint classification to CQ for further actions.
4.1.4. To log & prepare response in case of ADE and ADE + Manufacturing complaints within 3 working days.

4.2 **Corporate Quality (CQ):**

4.2.1. To receive and login the market complaint in market complaint register.

4.2.2. To forward the complaint to GPV (if received directly) for classification of Complaints.
4.2.3. To forward the classified complaint from GPV to the concerned location for investigation.
4.2.4. To co-ordinate with complainant to get additional information and complaint samples if available.
4.2.5. To receive investigation report.
4.2.6. To review, if required, investigation report received from Location.
4.2.7. To send the investigation details/ to respond to complainant.

4.3 **Quality Assurance:**
4.3.1. To log in the complaint in market complaint register.
4.3.2. To prepare PIR in case of adverse drug reaction and/or where investigation may take time to prepare final report.
4.3.3. To conduct market complaint investigation.
4.3.4. To prepare investigation report.
4.3.5. To get it reviewed and approved from concern persons.
4.3.6. To send a copy of the investigation report to Corporate QA & Corporate Regulatory Affairs (if applicable).
4.3.7. To follow up for implementation of corrective/preventive action as recommended in investigation report.

4.4 **Quality Control:**
4.4.1. To monitor the analysis of complaint sample &/or control sample if required for investigation and provide analytical results or any other data with conclusion.

4.5 **Head-Production:**
4.5.1. To guide & cooperate with investigation team in the process of investigation.
4.5.2. To review the investigation report.
4.5.3. To implement CAPA as defined in the investigation report.

4.6 **Head-Quality Assurance:**
4.6.1. To verify and review the investigation report.
4.6.2. To ensure that complaint investigation are reported in timely manner.

4.7 **Head-Quality:**
4.7.1. To review and approve the investigation report.
4.7.2. Inform QP in case of EU or other countries wherever applicable.

4.8 **Plant Head:**
4.8.1. To provide guidance for the investigation of market complaint.
4.8.2. To review and approve the investigation report with special reference to CAPA.
4.8.3. To facilitate resources for CAPA implementation.

5. **Distribution:**

5.1 Quality Assurance
5.2 Packing
5.3 Production
5.4 Quality Control

6. **Abbreviations and Definition of Terms:**

6.1 **Abbreviations :**

6.1.1	ADE	: Adverse Drug Event.
6.1.2	C and F Agent	: Carrying and Forwarding Agent.
6.1.3	CAPA	: Corrective Action & Preventive Action
6.1.4	CQ	: Corporate Quality
6.1.5	CRA	: Corporate Regulatory Affairs
6.1.6	FAR	: Field Alert Report
6.1.7	FDD	: Formulation Development Department
6.1.8	NDA	: New Drug Application
6.1.9	ANDA	: Abbreviated New Drug Application
6.1.10	OOS	: Out of Specification
6.1.11	OOT	: Out of Trend
6.1.12	PIR	: Preliminary Investigation Report
6.1.13	QA	: Quality Assurance
6.1.14	QC	: Quality Control
6.1.15	RA	: Regulatory Affairs
6.1.16	SME	: Subject Matter Experts
6.1.17	GPV	: Global Pharmacovigilance
6.1.18	US	: United States
6.1.19	QP	: Qualified Person
6.1.20	CFT	: Cross Functional Team
6.1.21	BMR	: Batch Manufacturing Record

6.2 **Definition of Terms:**

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

6.2.1.1 May be in violation of the laws or regulations administered by the FDA.
6.2.1.2 May have caused an illness, injury or death.
6.2.1.3 Is alleged to have caused problems not covered by the above.

6.2.2 **Complainant:** A person from whom a complaint is received.

6.2.3 **Quality Complaints:** Any complaint which is directly or indirectly associated with manufacturing or packing of the drug product shall be termed as Quality Complaints.

6.2.4 **Commercial Complaints:** Any complaint which is associated with shortage or excess in secondary or tertiary packing of the drug product (except shortage in mono-carton or combi-packs) shall be termed as Commercial complaints.

Note:1 strip missing from the show-box having 10 strips shall be termed as Commercial complaints whereas, 1 strip missing from the mono carton (i.e. show box containing 1 strip only) shall be termed as Quality complaint.

6.2.5 **Critical Complaints:** Any complaints which are life threatening or can cause serious adverse health consequences to the patient or do not match the designed specification shall be termed as Critical Complaints.

6.2.6 **Major Complaints:** Any complaints which are not life threatening or can cause serious adverse health consequences but do not match the designed specification and can significantly impact the quality of the product shall be termed as Major Complaints.

6.2.7 **Minor Complaints:** Any complaints which is not life threatening and does not require immediate or prompt actions but indicates flaw in the quality of the product shall be termed as Minor Complaints.

6.2.8 **Complaint sample:** Sample returned by the Complainant (User, doctor, Pharmacy etc.).

6.2.9 **Market Sample:** Sample procured from the retailer, stockist, CNF agent or distribution department for further investigation.

6.2.10 **Subject Matter Experts:** Individual or a group of individuals who has better understanding of the matter either through qualification or training or experience or combination of above.

6.2.11 **Repetitive ADE Complaints:** Complaints of same nature received from same batch shall be termed as Repetitive Complaints.

6.2.12 **Complaint Coordinator:** Person responsible for coordinating the complaint & working as an inter-phase between complainant & investigation team at manufacturing location. The same are tabulated below.

S.No.	Complaint received from market	Product Manufactured by	Complaint Coordinator
1.	Rest of World	-	-
2.	India	-	-

7. Procedure:

7.1 Source of complaint:

7.1.1 A complaint may be received from consumers, healthcare professionals, government/ regulatory agencies, trade sources, C and F agent or from any other source, in any form (written or verbal, post, fax, email or through website).

7.1.2 Complaint can be received by marketing personnel, head office, CQ, manufacturing location, distribution partners, business or regulatory offices of business associates.

7.2 Receipt, Registration & Classification:

7.2.1 Whom so ever is receiving any complaint, shall forward it to .....
Note: All the commercial complaints can be directly forwarded to CQ.

7.2.2 GPV shall evaluate the complaints and shall categorize these complaints into ADE, ADE + Manufacturing and Non-ADE Complaints within 1 working day & shall communicate the same to CQ.

7.2.3 In case of ADE and ADE + Manufacturing complaint, GPV shall register the complaint in Argus database & communicate the Argus login no. to CQ along with complaint communication.
Note: Any Quality Complaints if received directly at site or CQ shall be forwarded to GPV for evaluation purpose at mail ID .....

7.2.4 CQ shall forward all ADE + Manufacturing and Manufacturing and Commercial Complaints to respective Quality Head or Designee at the respective manufacturing location for investigation.

7.2.5 All ADE Complaints shall be processed by GPV.

7.2.6 All ADE + Manufacturing complaints shall be processed by GPV. Manufacturing location shall also carry out investigation of such complaints.

7.2.7 For trending purpose, all manufacturing and packing complaints shall be further sub classified into different categories as per Annexure-2.

7.2.8 In order to understand the nature of complaint, efforts shall be made by location QA/ complaint coordinator/CQ by contacting complainant &/or doctors or nursing staff directly or through field staff in marketing department.

7.2.9 Efforts to procure the complaint samples shall be made by complaint co-ordinator for all manufacturing and packing related complaints.

7.2.10 Count related complaints for missing tablet/capsule in blister/strip, empty show box, shall be treated as quality complaints and not as commercial complaints.

7.2.11 Location QA shall log these complaints into Location Market complaint Register (Attachment –1) within 1 working day and shall allot a unique location complaint number.

7.2.12 All complaints shall be logged in a common register.

7.2.13 Complaints shall be investigated by a team of cross functional team formed by QA/Quality head. This team may have one or more members.

7.2.13.1 On the receipt of the complaint from CQ, QA shall verify and make necessary entries in the market complaint register. (Refer Attachment – 1)

7.2.13.2 Location market complaint number is given as …….. In which '…' stand for Location code, '…' stands for market complaint. Numeric code '001' means 1st complaint of the year and YY indicates the calendar year (Jan to Dec)

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

7.3 Investigation of the complaint: Adverse/Unexpected Drug Event/Quality complaint

7.3.1 Preliminary Investigation:

7.3.1.1 In case of critical or quality complaint where there is a risk to patient health, adverse drug reaction and/or where investigation may take time, preliminary investigation shall be over within three working days from the date of receipt of the complaint & preliminary investigation report (Attachment-3) shall be sent to CQ within three working days.

7.3.1.2 Numbering of preliminary investigation report is given as BS/PIR/YY/001. In which 'BS' stand for Location code, 'PIR' stands for preliminary investigation report. Numeric code beginning from 'YY' and '001' means 1st preliminary investigation report and for the year last two digits of calendar year Example for 2020 mentioned 20.

7.3.1.2.1 The following shall be reviewed in preliminary investigation, but not limited to

- Batch Records
- Inspection and/or analysis of control sample
- Inspection and/or analysis of complaint sample
- Complaint History
- Patient History
- Package Insert regarding contraindications, dosing, route of administration, use of suspected drug product in combination with other drug products etc.

If the complaint is confirmed, further actions shall be taken as per the SOP of Product Recall.

7.3.1.3 QA shall forward the PIR to complaint coordinator for forwarding to complainant, if complaint coordinator has any queries or suggestions for improvement, PIR shall be returned back to location for up-dation.

7.3.1.4 QA shall file the PIR. On completion of investigation, the PIR shall be attached with complaint Investigation Report.

7.3.2 **Detailed investigation:**

7.3.2.1 Cross functional team shall investigate the complaint in details to identify the root cause of the complaint.

7.3.2.2 QA shall co-ordinate with complaint coordinator and try to get as much information as possible from the complainant and/or healthcare professional. Such efforts should be documented and enclosed with final Investigation Report.

7.3.2.3 All efforts shall be made to procure the complaint sample for effective investigation.

7.3.2.4 If the lot number is not available, complaint sample (if available) will be obtained and tested. If the test results are within specification, no further detailed investigation is required. If the test results are not within specifications, then detailed investigation is required that may require reviewing all the manufacturing and stability data for all lots that have not passed the expiration date. If complaint sample is not available then detailed investigation is not feasible.

7.3.2.5 Depending on the nature of complaint, QC analytical data shall also be reviewed. If required stability data and trend data shall also be reviewed.

7.3.2.6 Control samples and complaint samples, if available, shall be inspected.

7.3.2.7 Control samples and complaint samples (if available) shall be analysed for relevant parameters to establish acceptability of product.

7.3.2.8 If required, hypothesis shall be proved by experimentation.

7.3.2.9 Based on the root cause identified during the investigation, impact assessment on the complaint batch & other batches of same product or different product manufactured on same line shall be evaluated.

7.3.2.10 If the root cause is identified & CAPA is initiated, risk assessment & impact analysis shall be performed & decision on marketed batch shall be taken accordingly.

7.3.2.11 Market complaint investigation shall be completed within 30 calendar days from the receipt of complaint. If complaint samples are expected but not received or received but not analysed within 30 days, complaint investigation except for analysis of complaint samples shall be concluded and reported through initial/interim investigation report as per Attachment- 4 & 5.

7.3.2.12 Investigation details may include, but not limited to, following information for Adverse/Quality related complaints in document review:

- Check the history of product for similar type of complaint.
- Check the complaint sample.
- Review of incident if any taken place while batch manufacturing which could lead to such complaint.
- Check the retained control samples of the particular batch.
- Check the BMR for processing parameter and analytical results.
- Any major machine breakdown, which may lead to such complaint.
- Any abnormal in-process observation, which may induce such complaint.

7.3.2.13 Final report including analytical results and additional investigation if carried out based on the analytical results of complaint/control samples, shall be prepared within 15 days from the receipt of complaint samples except for tests where test period is more than 3 days, such as antimicrobial efficacy test, microbial limit test or biological assays, shall be completed within 7 days from the date of receipt of analysis results.

7.3.2.14 Implementation status of CAPA shall be updated periodically through CAPA progress report until CAPA is implemented.

7.3.2.15 Upon receipt of any comments (Complaint co-ordinator, RA or Regulatory authority) or additional information received after final report, it shall be addressed in the Addendum report within 7 working days, unless justified.

7.3.2.16 Comments on initial/interim investigation report shall be addressed through subsequent interim/final report unless an addendum report is requested by the reviewer.

7.3.2.17 Final investigation report shall be compiled as per the format (Refer Attachment – 6).

7.3.2.18 Remaining quantities of complaint samples after completion of investigation, shall be retained in control sample room till one year after expiry of the product. Complaint samples received without specific batch number, shall be retained for 1 year from the date of receipt of complaint sample.

7.3.2.19 If the complaint sample cannot be retained because of nature of the product or any other reason, justification for not retaining complaint samples, shall be documented in investigation report and a photograph of complaint samples shall be kept in record.

7.3.2.20 During investigation, if investigation findings reveals any findings which can have larger impact on the batch or batches, QA in consultation with RA & complaint coordinator shall evaluate the need of submissions of FAR or similar regulatory filings within 3 working days from the date of noticing the defect, without waiting for investigation to conclude.

7.3.2.21 Complaint sample can be retained for longer period if required by law.

7.3.2.22 In case non availability of complaint sample investigation report shall be prepared on the basis of available information, later upon receipt of complaint sample final report shall be reopened and addendum report shall be prepared and sent to CQ.

7.3.2.23 QA shall send copy of the investigation report to complaint coordinator along with necessary attachments.

7.3.2.24 All decisions made and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records. refer Attachment – 11

7.3.2.25 Complaint coordinator may review the investigation report and ask for further investigation details if required.

7.3.2.26 Complaint coordinator shall send summarized investigation details to the complainant.

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7.3.3 **Extension to the investigation:**

7.3.4 Extensions to time lines can be given by quality head or his designee subjected to appropriate justification for extension (Refer Attachment – 9).

7.3.5 Each extension shall be maximum for 15 days however, for those cases wherein investigation is pending from vendor or supplier, it can be extended for more than 15 days with justification.

7.3.6 There can be more than one extension for a complaint, if justified.

7.3.7 Extension notes shall bear unique number & shall be assigned as....., wherein,
.....stands for Market Complaint Extension
.....stands for Manufacturing Location code
.....stands for last 2 digit of current year (eg. 20 for 2020)
NNN stands for Serial no. starting from 001 for each calendar year.

7.3.8 A log shall be maintained in register as per Attachment – 8.

7.3.9 Extension request note shall be filed with Investigation Report.

7.4 **CAPA:**

7.4.1 After completion of the investigation, if required, location QA shall initiate CAPA as per location SOP on CAPA.

7.4.2 If required, Formulation Development Department or Packing Development Department shall be involved for adequate CAPA.

7.4.3 Risk based decision shall be taken for the batches, which are impacted.

7.4.4 Periodic status report of such open CAPA shall be prepared.

7.5 **Handling of ADE complaints:**

7.5.1 All ADE Complaints shall be processed by GPV cell.

7.5.2 If the ADE are not listed in product literature then current product literature of reference (Innovator) drug shall be reviewed to ensure that there are no update in innovator's literature.

7.5.3 Matter shall be discussed with Medical department and CRA department to evaluate any need of revision in product literature.

7.5.4 GPV shall submit safety update as per the regulatory requirement (Refer Global Pharmacovigilance SOP.

7.5.5 GPV shall provide a response letter to be sent to complainant through complaint coordinator.

7.5.6 Copy of such letter shall be forwarded to manufacturing location if complaint is classified as ADE & Manufacturing.

7.6 **Handling of Repetitive ADE complaints:**

7.6.1 If ADE complaint of similar nature & from the same batch are reported by more than one complainant at a time, complaint coordinator shall instruct location to investigate the manufacturing and analytical aspects of the complaint.

7.7 **Reply to complainant:**

7.7.1 If required, complaint coordinator shall send initial response to the complainant and send a copy to CQ.

7.7.2 Subsequently, CQ shall send copy of the initial response to the concern location for record purpose.

7.7.3 After receipt of the investigation Report, CQ shall send either investigation details or reply for complaint to complainant or concern department with copy to concerned location for record purpose.

7.7.4 Location shall file these response along with an investigation report.

7.8 **Closure of Quality Complaints**

7.8.1 Complaint shall be closed upon completion of investigation. CAPA monitoring shall be done as per respective location SOP.

7.9 **Handling of Commercial Complaints (Secondary or Tertiary Packing Related complaints, Shortage/Excess Receipt or Improper packing):**

NOTE: Complaints related to primary packing (such as Count variation in bottle, empty pocket, missing component, missing label or batch details on the unit pack, missing applicator, leakage in bottle, Damaged primary packing such as bottles, sachets shall be classified as Quality complaints. Refer Annexure-2.

7.9.1 These are the complaints related to shortages or excess quantities of product in secondary packing (less or excess bottles/strips/blisters etc. in show box or shipper boxes, less or excess number of show boxes in a shipper box, damaged outer or inner shippers, missing labels on outer or inner shipper (but proper labelling on unit pack) missing leaflet/product literature (where applicable), difference in weight mentioned on shipper and actual weight of the shipper on receipt).

7.9.2 Location QA shall forward the complaints related to Shortage/excess to Packing Department Head. Department Head in consultation with quality Head shall identify the cross functional team for investigation.

7.9.3 Cross functional team shall investigate the complaint to identify the root cause of the complaint.

7.9.4 Based on the root cause identified during the investigation, impact assessment on the complaint batch and other batches of same product or different product manufactured on same line shall be evaluated.

7.9.5 Market complaint investigation shall be completed as per the time lines mentioned in Attachment-2.

7.9.6 During investigation, if investigation findings reveals any findings which can have larger impact on the batch or batches, QA in consultation with RA & complaint coordinator shall evaluate the need of submissions of FAR or similar regulatory filings within 3 working days from the date of noticing the defect, without waiting for investigation to conclude.

7.9.7 If market complaint investigation is not completed within 30 days an extension through extension request note (refer Attachment – 11), justifying the delay in investigation shall be submitted to Quality Head.

7.9.8 Extension request note shall be filed with investigation report.

7.9.9 Final investigation report shall be compiled as per the format. (refer Attachment – 6).

7.9.10 QA shall send copy of the investigation report to complaint coordinator along with necessary attachments.

7.9.11 Complaint coordinator may review the investigation report and ask for further investigation detail, if required

7.9.12 Complaint coordinator shall send investigation report to the appropriate Department/ Complainant/Distributing location.

7.9.13 Product complaint information shall be recorded in Annual product review.

7.10 **Closure of Commercial Complaints**

7.10.1 Complaint shall be closed upon completion of investigation. CAPA monitoring shall be done as per respective location SOP.

7.10.2 Periodic status report of such open CAPA shall be prepared.

7.11 **Trending of Complaints:**

7.11.1 Trends for manufacturing and packing related market complaints with reference to product, nature of complaints, open and closed complaint, time required for closure of complaint, CAPA status and its effectiveness shall be prepared on half yearly basis by location QA.

7.11.2 Trends for commercial complaints with reference to product, nature of complaints, Zone, CNF agent, open and closed complaint, time required for closure of complaint, CAPA status and its effectiveness shall be prepared on Half yearly basis by location QA.

7.11.3 Based on trending, if required, Umbrella investigation report shall be prepared. Decision for Umbrella investigation shall be taken by QA Head in consultation with Quality Head.

7.11.4 Emerging trend and some appropriate recommendation to be given and action shall be initiated.

7.11.5 Previous year trend shall be compared & CAPA effectiveness shall be checked and addressed in the current year trend.

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Attachment – 1
Market Complaint Register

Date of complaint received	Reference complaint no.	CQ Complaint No.	Complaint No.	Product	Batch No.	Dosage form	Complaint details	Nature of complaint	Complaint received from	Type	Category	Market	Zone	Date of investigation completion	CAPA required/Not required	Date on which Investigation Report sent to CQ	Recommended CAPA	CAPA closing (by/date)	Remarks

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Attachment – 2

Time lines associated with Handling of Market Complaints

S.No.	Series of Activities		Time lines
1.	Complaint Classification by GPV		1 Working day
2.	Logging by CQ		1 Working day
3.	Complaint forwarded to Manufacturing location by CQ		1 Working day
4.	Logging of complaint at Manufacturing location		1 Working day
5.	Initial Investigation*	Critical	3 Working days
		Others	30 Calendar days
6.	Final Investigation	Where samples not available	30 Calendar days from Logging of complaint
		Where samples are available	30 Calendar days from Logging of complaint or 15 Calendar days from receipt of sample whichever is later
		Where samples are available & analysis time is more than 3 days	30 Calendar days from Logging of complaint or 7 days from the receipt of sample results whichever is later
7.	Addendum report		7 days from the receipt of any comments or additional information.

* Initial report can be skipped if final report can be prepared within 30 days.

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Attachment – 3
Preliminary Investigation Report

To:

From:

Date:

Subject: (Mention Reference location, Complainant, complaint numbers, if available).

Product:

Batch No.:

Manufacturing Date:

Expiry Date:

Pack style and NDC no. (if applicable):

Complaint reference and date:

Complaint Details:

Complainant:

Complaint History:

Preliminary Investigation details:

Regards,

(Quality Head)

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Attachment – 4
Initial Market Complaint Investigation Report

S.No.	Parameters
•	Location complaint No:
•	CQ Complaint No :
•	Reference Complaint no. and date
•	Product :
•	Batch No:
•	Mfg. date
•	Exp. Date
•	Pack style and NDC No. If any
•	Complaint details
•	Complainant
•	Reference & Date
•	History
•	Other details
•	Qty. of complaint sample:
•	Physical inspection of complaint sample
•	Physical inspection of control sample
•	Tests to be performed on complaint sample
•	Analytical results of complaint sample
•	Tests to be preformed on control sample
•	Evaluation of processing parameter trend
•	Evaluation of in process analytical trend
•	Evaluation of FP analytical trend
•	Review of stability data
•	Review of batch document
•	Review of other related documents (like sequential log of m/c)
•	Analytical results of control sample
•	Review of trial batch results
•	Interpretation/Probable cause
•	Impact on current batch / Other batches of same product / Other products.
•	Conclusion
•	Immediate Action taken
•	CAPA

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- Attachment

Prepared by

Reviewed by Production/Packing Head

Reviewed by QA

Approved by QA Head

Approved by (Quality Head)

Approved by (Location Head)

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Attachment – 5
Interim Market Complaint Investigation Report

S.No. Parameters

1. Location complaint No:
2. CQ Complaint No :
3. Reference Complaint no. and date
4. Product :
5. Batch No:
6. Mfg. date
7. Exp. Date
8. Pack style and NDC No. If any
9. Complaint details
10. Complainant
11. Reference & Date
12. History
13. Other details
14. Preamble:
15. Qty. of complaint sample:
16. Physical inspection of complaint sample
17. Physical inspection of control sample
18. Tests to be performed on complaint sample
19. Analytical results of complaint sample
20. Tests to be preformed on control sample
21. Analytical results of control sample
22. Evaluation of processing parameter trend
23. Evaluation of in process analytical trend
24. Evaluation of FP analytical trend
25. Review of stability data
26. Review of batch document
27. Review of other related documents (like sequential log of m/c)

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28.Review of trial batch results
29.Interpretation / Probable cause
30. Impact on current batch/Other batches of same product/Other products.
31. Conclusion
32. Immediate Action taken
33. CAPA
34. Attachment

Prepared by

Reviewed by Production / Packing Head

Reviewed by QA

Approved by QA Head

Approved by (Quality Head)

Approved by (Location Head)

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Attachment – 6
Final Market Complaint Investigation Report

S.No.	Parameters
1.	Location complaint No:
2.	CQ Complaint No :
3.	Reference Complaint no. and date
4.	Product :
5.	Batch No:
6.	Mfg. date
7.	Exp. Date
8.	Pack style and NDC No. If any
9.	Complaint details
10.	Complainant
11.	Reference & Date
12.	History
13.	Other details
14.	Preamble:
15.	Qty. of complaint sample:
16.	Physical inspection of complaint sample
17.	Physical inspection of control sample
18.	Tests to be performed on complaint sample
19.	Analytical results of complaint sample
20.	Tests to be preformed on control sample
21.	Analytical results of control sample
22.	Evaluation of processing parameter trend
23.	Evaluation of in process analytical trend
24.	Evaluation of FP analytical trend
25.	Review of stability data
26.	Review of batch document
27.	Review of other related documents (like sequential log of m/c etc)
28.	Review of trial batch results
30.	Impact on current batch/Other batches of same product / Other products.
31.	Conclusion
32.	Immediate Action taken
33.	CAPA
34.	Attachment

Prepared by

Reviewed by Production / Packing Head Reviewed by QA

Approved by QA Head

Approved by (Quality Head) Approved by (Location Head)

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Attachment – 7
Addendum to Market Complaint Investigation Report

S.No.	Parameters
1	Location complaint No:
2	CQ Complaint No :
3	Reference Complaint no. and date
4	Product :
5	Batch No:
6	Mfg. date
7	Exp. Date
8	Complaint details
9	Complainant
10	Preamble:
11	Investigation findings
12	Probable Cause/ Root Cause
13	Impact Analysis
14	Conclusion
15	CAPA

Prepared by Approved by QA / Quality Head

$ (Additional rows as required may be added. Points which are not applicable may be Omitted).

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Attachment -8
Register for Extension Note

S.No.	Date	Reference complaint number.	Initial Target date for completion	Proposed Date for completion	Extension Note Number	Approved on	Sign / Date	Remarks

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Attachment – 9

Extension Note for investigation of Complaint

Extension Note No. _____ Date : _____

Ref. Location Complaint No. _____ Ref. CQ Complaint No. : _____

Ref. third party Complaint No. : _____

Initial Target Completion date : _____

Current status of Investigation :

Pending activities for Investigation (as per action plan) :

Reason for delay :

Justification for Delay :

Revised target Date :

Prepared by : Reviewed by: Department Head
Reviewed by : QA

Approved by: Quality Head

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Attachment – 10
History of complaints

S.No.	Parameters	Details
1.	Product	
2.	Batch No.	
3.	Location complaint No:	
4.	CQ. Complaint No.	
5.	Complaint Details	
6.	Complainant	
7.	Nature of Complaint	
8.	Category of Complaint (Genuine / non genuine)	
9.	Total Similar Nature of Complainant	
10.	Time taken for complaint closing (with in time line or exceed)	

Checked By	Reviewed By

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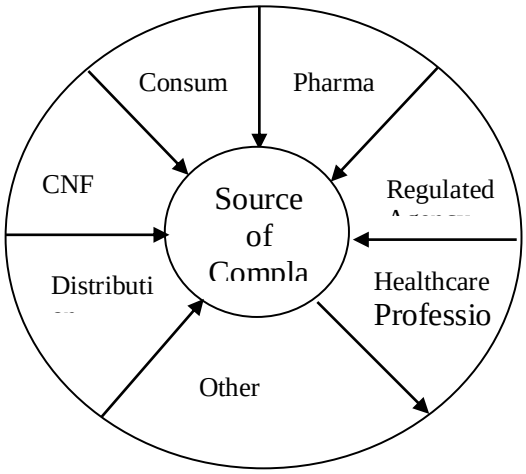
Attachment – 11
Flow Chart for handling of Quality Complaints



Communication received

employee through

-E-mail
-Letter
-Telephone
-Web query
-Any other media

Forwarded to GPV

Receipt & Evaluation of Complaint by GPV

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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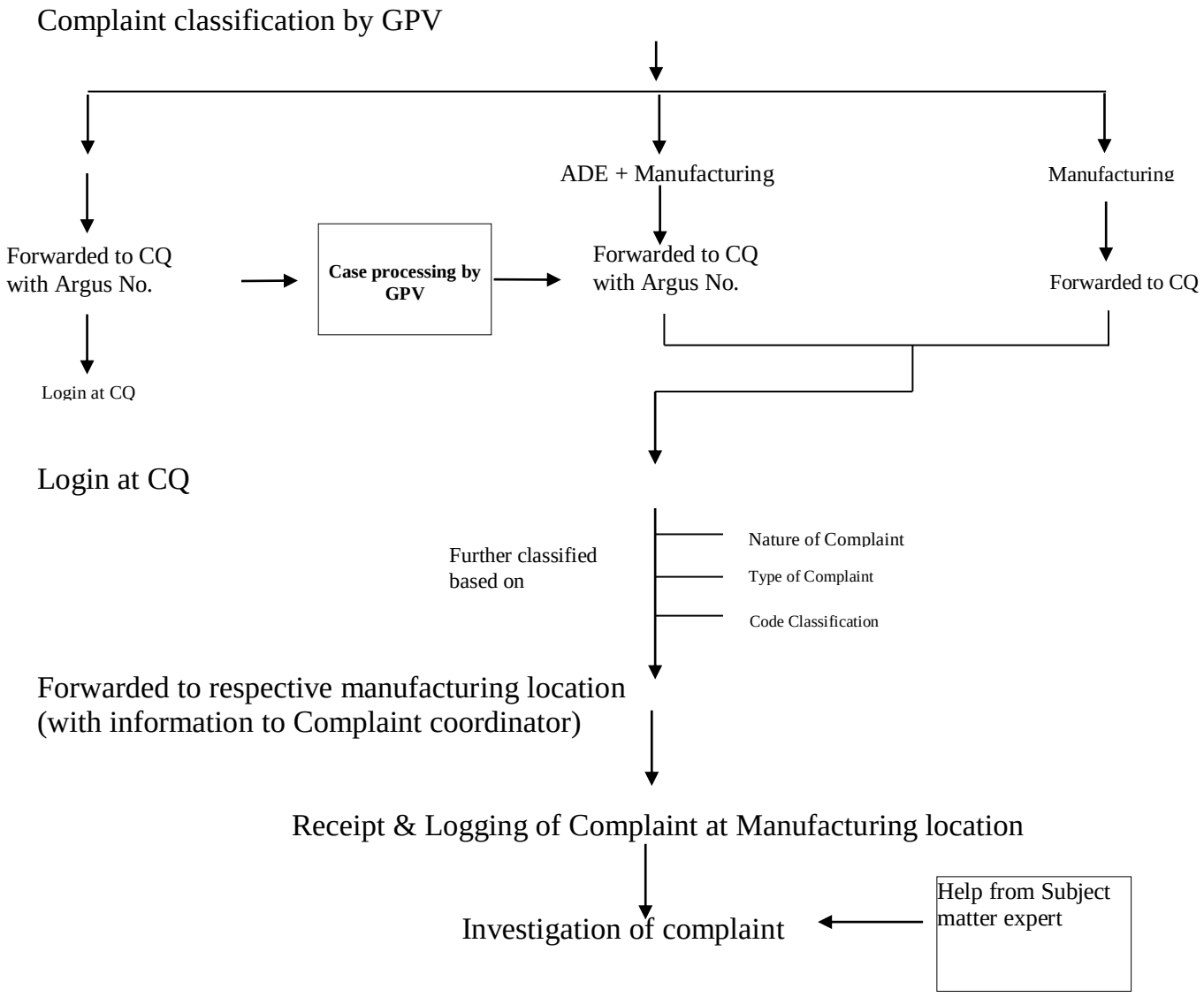

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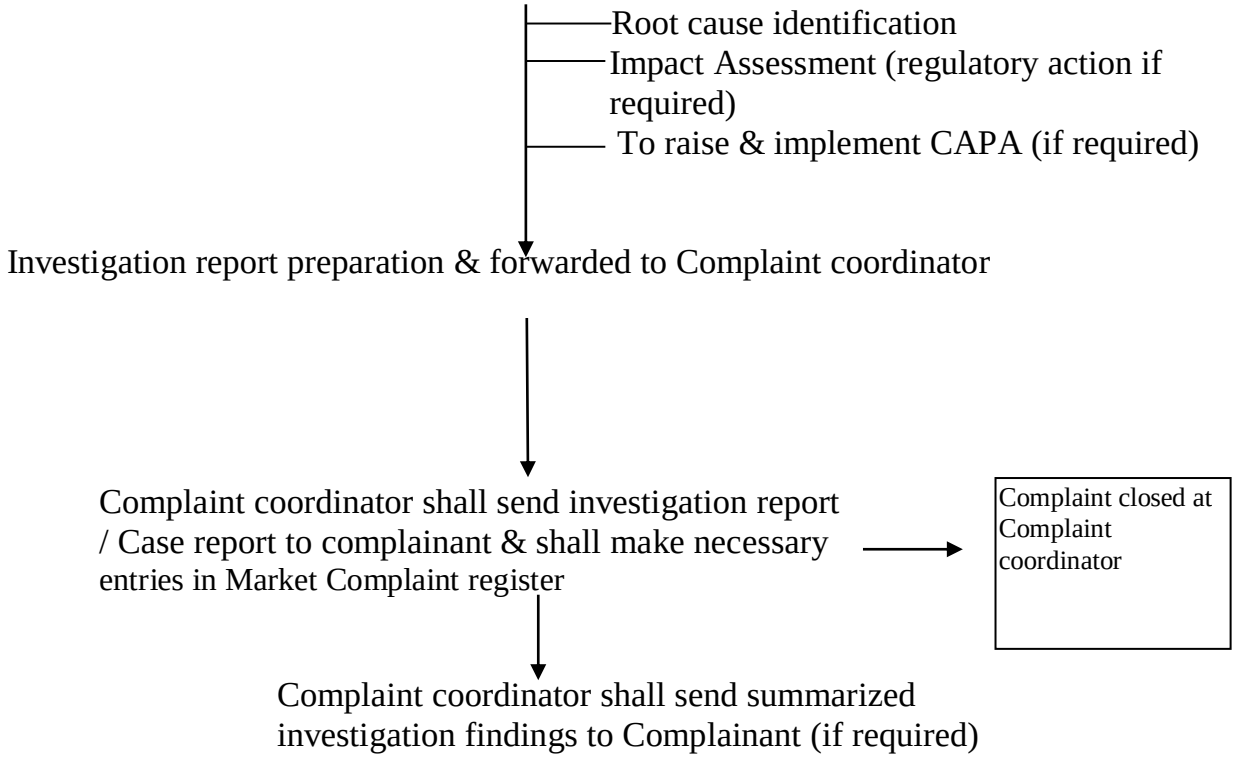

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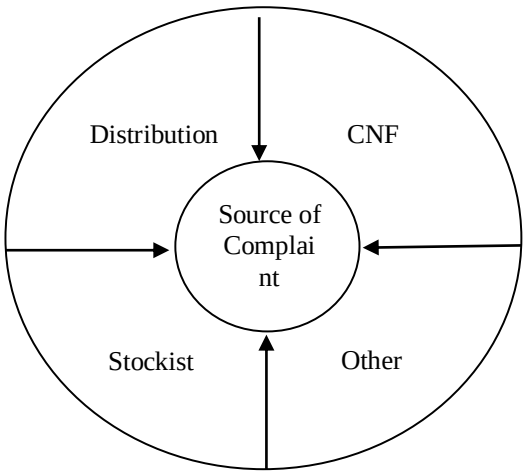
Attachment – 12
Flow Chart for handling of Commercial Market Complaints



Communicated to CO

Receipt & logging of Complaint by CQ

Complaint forwarded to Manufacturing location

Receipt & Logging of Complaint at Manufacturing location

Investigation of complaint

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Attachment – 12
Flow Chart for handling of Commercial Market Complaints

Root cause identification
To raise & implement CAPA (if required)

Investigation report preparation & forwarded to CQ

CQ shall send investigation report to complainant &
shall make necessary entries in Market Complaint register

Complaint closed at CQ

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Annexure – 1

Assignment of Unique Complaint No. at each Complaint Coordinator

S.No.	Complaint Coordinator	Complaint No. format		Logic of Assigning complaint no.
1.	CQ	Quality Complaints	MC-YY-NNN	MC-Market Complaint
				MCS- Shortage related Market Complaint
		Commercial Complaints	MCS-YY-NNN	YY-Last 2 digit of current year
				NNN-Serial no. starting from 001 for each calendar year.

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Annexure – 2

Market Complaint Code Classification

A	**Manufacturing**
M1	Failing specification / Adulterated
M2	Unexpected results, Reactions, Adverse event, Ineffectiveness, Poor Quality, Poor efficacy
M3	Organoleptic – Change in physical form, Appearance, change in colour, odour, taste, Phase separation, Size of tablets / capsule, Precipitation, Turbidity
M4	Broken Tablets / Open Capsules, Dented Capsules, Melted, Rough surface, chipping, splitting, Sticking, damaged coating, Hard / Soft tablets
M5	Suspended matter, Foreign Matter, Microbial Contamination, Specks or stains on surface of Tablets / Capsules, Particulate matter, stopper fragments
M6	Improper / Wrong / Missing Imprint
M7	Filled weight, Filled volume, Less / excess volume, Empty bottle / Vial / Ampoules / Syringe, oozing from tube
M8	Reconstitution
M9	Prefilled Syringe – Broken, Needle missing or Bend, leakage, empty, bubbles, Hard to soft in operation
M10	Foreign Tablets / Mix of products
M11	Others

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Annexure – 3

Examples of Market Complaint with Guideline for Investigation

Note: This annexure 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 and also based on type and trend of the complaint received at the location.

1. Ineffectiveness/poor quality/Inadequate response of the drug.

1. History of the product.
2. Physical inspection of complaint and control sample.
3. Review of batch document for,
   - ◆ Active RM calculation.
   - ◆ Qty. added of active and inactive RM (MRO and Coupons) against bill of material. Source of material.
   - ◆ Dispensing precautions: e.g. API dispensing and storage in the black/ light resistant bag or container.
   - ◆ Processing precautions: e.g. dissolved oxygen, low light, nitrogen flushing or any other.
   - ◆ Processing parameters.
   - ◆ In process checks by production and QA.
   - ◆ Daily quality observation record.
   - ◆ Any deviation, which has direct or indirect impact on product quality.
4. In process quality control data.
5. Review of FP analytical report and trend.
6. Review of stability data.
7. Complaint and control sample analysis for,
   - Volume variation,
   - Content uniformity.
   - Dissolution.
   - Assay.
   - Degradation.
   - Moisture content.
   - Storage condition.

2 **Less content in capsules /Pouch / bottle.**

1. Physical inspection of complaint and control sample,
   - For minor crack.
   - Improper sealing.
   - Condition of container label and / or show box to eliminate possibility of leakage.
2. Review of batch manufacturing record for,
   - Active RM calculation
   - Qty. added of active and inactive RM (MRO and Coupons) against bill of material.
3. In process checks by production and QA

- Visual inspection record.
- Leak test record.
- Yield and reconciliation of the batch.

4. In process and FP quality control data.
5. Trend of yield.
6. Sequential log of filling or compression or capsule filing machine for breakdown.
7. Daily quality observation record.
8. Complaint and control sample analysis for, breakdown for

- Dissolution.
- Content uniformity.
- Assay.
- Degradation.
- Volume variation.

3 Bulging of strip pockets.

1. History of the product.
2. Physical inspection of control and complaint sample.
3. Improper storage condition.
4. Review of stability data.
5. Review of Packing material Quality.
6. Analysis of complaint sample for,

- Assay.
- Degradation.

4 **Presence of foreign matter (Living / non living)**.

7. History of the product.
8. Physical inspection of complaint and control sample for,

- Minor crack
- Improper sealing.

9. Daily quality observation record.

- pH trend (to correlate with leaching from container).

10. Precipitation.
11. Physical inspection of RM / PM of particular AR No. used for manufacturing of the batch.
12. Review of batch manufacturing record for,

- Use of pretreated ampoules (e.g. acid treated amps).
- Empty primary Pkg. material washing and sterilization in record.
- Cleaning record of manufacturing, filtration and filling equipments and area.
- Sterilization record of filtration and filling equipments.
- Filter integrity test results (Pre and post filtration)
- Leak test record.

- Terminal sterilization record.

13. Sequential log of washing machine.
14. Environmental monitoring data.
15. Quality/compatibility of closure.
16. Microbiological analysis of complaint sample.
17. Training record of visual inspectors.

5 **Adverse reactions**

18. Review of complaint history
19. Review history of the patient.
20. Review of package insert.
21. Microbiological analysis of complaint sample.
22. Pharmacology of the API and related formulations.
23. Analysis of complaint / control samples for :

- Assay / Dissolution
- Related Substances.

6 **Discoloration of solution or tablet / Capsule**

24. History of the product.
25. Physical inspection of complaint and control sample for,

- Minor crack.
- Improper sealing.

26. Review of batch manufacturing record for,

- Special precautions required during processing e.g. dissolved oxygen, low light, nitrogen flushing or any other.
- Cleaning record of manufacturing, filtration and filling equipments and area.
- Leak test record.
- Terminal sterilization record.

27. Daily quality observation record.
28. Recovery procedure.
29. In process checks by production and QA during manufacturing and packing.
30. Analysis of control and / or complaint sample for,

- pH.
- Assay.
- Degradation.

31. Stability data.
32. Storage condition.

7 **Damaged / broken / leaking capsule**

33. Physical inspection of complaint and control sample.
34. Review of batch manufacturing record for,

- Visual inspection record.
- Temp. and humidity conditions.

- Cap filling machine setting parameters.
- In process checks during manufacturing and packing by QA and production.

35. Vendor of empty capsule.
36. Sequential log of capsule filling machine for breakdown.
37. Training of the visual checkers.
38. Compatibility study of empty hard gelatin cap with excipients.
39. Monitoring of defoiling and repacking activity.

8 **Broken tablet**

40. History of the product.
41. Physical inspection of complaint and control sample.
42. Review of batch manufacturing record for,
    - In process checks by production and QA during manufacturing and packing.
    - Visual inspection record.
43. Review of trend of processing, in process and FP parameters.
44. Daily quality observation record.
45. Handling of the bulk product.
46. Training record of the visual checkers and strip packing machine operators.
47. Analysis of control and / or complaint sample for Friability.
48. Monitoring of de-foiling and repacking activity.

9 **Melt back (of lyophilized cake)**.

49. History of the product.
50. Physical inspection of control and complaint sample.
51. Review of batch document for,
    - Filling in process checks by production and QA
    - Lyophylization menu.
    - Visual inspection record.
    - Hold time at different stages.
    - Temp. and humidity conditions at different stages.
52. Review of trend of processing, in-process and FP parameters.
53. Daily quality observation record.
54. Review of stability data.
55. Analysis of complaint and/or control sample for,
    - Moisture content
    - Assay.
    - Degradation
56. Training record of visual inspectors.

10 **Product or batch Mix up**

1. Physical inspection of control and complaint sample for physical appearance of primary pkg. material of two products under question.
2. System followed to ensure proper segregation product at different stages.

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3. Sequential log of machine at every stage to know the previous or next product taken on the same machine and to ensure absence of same /similar product in the surrounding area.
4. Other products packed on the same day on the nearby labeling machine or packing line of product under question.
5. Review of batch manufacturing record for,

- Machine and line clearance record at different stages.
- Reconciliation of packaging materials.
- Reconciliation of bulk and FP.

6. Analysis of control and complaint sample (if available) for,

- Identification test of two products under question.

7. Wrong labeling / packing.

- Daily quality observation record.
- Monitoring of de-foiling and repacking activity.
- Training record of packers.
- Repacking if done at any C and F location.

11 **Poor quality of cap (dropper), Applicator**

57. History of the product.
58. Physical inspection of control and/or complaint sample.
59. Vendor of pkg. (cap or dropper) material.
60. Compatibility study.
61. Review of stability data.

12 **Fake product:**

1. 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).
2. Comparison of complaint sample with control sample for appearance of tablet or capsule (size or dimensions, color, imprint, embossing, edge type etc).
3. Comparison of primary packaging material (Vial / ampoule) for shape and size amp. sealing height, type of seal, logo on the seal, color of the seal, type of rubber stopper etc.
4. Analysis of control and complaint sample (if available).

13 **Empty primary container (bottle / pocket of strip or blister)**

62. Physical Inspection of control and complaint sample (if available).
63. Sequential log of filling or striping or blistering machine for breakdown.
64. Review of batch document for,

- In process checks by production and QA during filling
- Leak test record.
- Visual inspection record.
- In process checks by production and 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).

- Yield and reconciliation of the batch and comparison with trend.

65. Balance performance and calibration check record.
66. Weight variation record of packed show boxes and / or shippers.
67. Proper segregation of packed and empty boxes.
68. Daily quality observation report.
69. Training record of the visual inspectors.
70. 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

71. Complaint sample observation.
72. Physical inspection of control sample.
73. Previous and next product packed on the same machine.
74. Appearance of packing material of two products under question.
75. Review of batch document for,

- Line clearance (by packing and QA) record.
- Reconciliation of packing material.
- Machine and line clearance record.
- In process checks by packing and QA.

76. Daily quality observation record.
77. Storage of packing material in the store and in pkg. Dept.
78. Procedure to be followed for the left over pkg. Material after completion of packing.
79. Monitoring of de-labeling and relabeling/ repacking activity.
80. Inspection of remaining stock of PM of the products under question.
81. PM vendor audit.
82. Training of packers.
83. Repacking if done at any C and F location.

15. Count variation of tablets and capsules in bottles

84. Physical Inspection of control and complaint sample (if available).
85. Sequential log of filling machine for breakdown.
86. Review of batch document for,

- Start up clearance.
- In process checks by production and QA during filling
- Leak test record.
- Visual inspection record.
- Challenge tests / performance check for the sensors on line.
- In process checks by production and QA during packing (e.g. on line compressed air flow or any other system followed to remove such container).
- Yield and reconciliation of the batch and comparison with trend.

87. Balance performance and calibration check record.
88. Weight variation record of packed show boxes and / or shippers.
89. Proper segregation of packed and empty boxes.
90. Daily quality observation report.
91. Training record of the visual inspectors.

16. Non working Devices (Auto injector pens, Prefilled syringes or devices for inhalation)

92. Physical Inspection of control and complaint sample (if available).
93. Sequential log of filling / assembling machine for breakdown.
94. Review of batch document for,

- Start up clearance.
- In process checks by production and QA during filling
- Leak test record.
- Visual inspection record.
- Challenge tests / performance check for the sensors on line.

95. In process checks by production and QA.
96. Yield and reconciliation of the batch and comparison with trend.
97. Performance check record during assembling / filling.
98. Daily quality observation report.
99. Training record of the visual inspectors.

17. Missing Label / Missing batch details

100. Complaint sample observation.
101. Physical inspection of control sample.
102. Review of packing materials used for packing of the batch.
103. Review of batch document for,

- Line clearance (by packing and QA) record.
- Reconciliation of packing material.
- Machine and line clearance record.

104. In process checks by packing and QA.
105. Performance check for sensors on line.
106. Daily quality observation record.
107. Storage of packing material in the store and in pkg. Dept.
108. Procedure to be followed for the left over pkg. Material after completion of packing.
109. Monitoring of de-labeling and relabeling/ repacking activity.
110. Inspection of remaining stock of PM of the products under question.
111. PM vendor audit.
112. Training of packers. Repacking if done at any C and F location.

Note: Processing parameters include:

- Quality of input material.
- Source of input material (vendor).

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- Quality of purified water and water for injection.
- Nitrogen flushing.
- Mesh size of sifter, direction of knife.
- Mixing speed and time.
- Speed of mill and screen size used during milling.
- Type (MOC) of the filter used.
- Drying inlet and out let temp. time, end point (LOD).
- Lubrication time, rpm of blender.
- Speed of compression machine.
- Temp. and Humidity conditions at different stages.
- Ampoule sealing height.
- Sterilization cycle of empty primary containers.
- Porosity of filter used.
- Granulation time and qty. of binder consumed.
- Terminal sterilization cycle.
- Pre and post integrity test results of filter.
- Leak test cycle.
- Strip packing machine speed.
- Temp. of sealing roller.
- Hold time at different stages.
- Lyophylization cycle.
- Any special precautions to be taken like manufacturing under low light.

8. **History:**

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