AGRINI EXPORT PVT LTD

DEFINATION OF COMPLAINT:-

•"Complaint is defined as statement that is something wrong or not good enough, which shows customer dissatisfaction about the company and the product".

Example: Complaint about packaging materials, Concerning about the product etc.

NEED FOR COMPLAINT HANDLING SYSTEM

•It gives the company an opportunity to improve the quality of the product

•It is helpful to maintain cGMP

•It maintains committed relationship between the customer and company

•It is the regulatory obligation.

SOP on Complaint Handling

•OBJECTIVE: To lay out the procedure for investigation and reporting the market complaints.

•RESPONSIBILITY: The quality assurance manager along withmanager of the complaint related department.

PROCEDURE:

•Complaints shall be classified in following categories to facilitate investigation:

•Product quality complaints

•Packaging complaints (shortages and packaging error).

•Market complaints :

Time period for investigation after receipt of complaints:
•Product quality complaints –within 5days.

•Packaging and quality complaints –within10 days.

• complaint –within 3days.

Complaint records shall be maintained at least one year after expiration date of medicines.
Complaint records shall be reviewed and a monthly summary shall be prepared for the management.

Product complaint data sheet

Product complaint data sheet should have the following details:

•Serial number assigned to the complaints.

•Exact nature of the complaints.

•Name of the complainants.

•Address of the complainants.

•Date of complaint received.

•If verbal, name of the person who received the complaint.

•Name of the product, strength and batch number of

Quantity involved in the complaint.

•Size of sample obtained from the complainant.

•Evaluation of complaint by QC department.

•Materials and records used to perform evaluation.

•Other possible effected materials, product sand results of their investigation.

•Name and signature of the investigator(s) and date.

•Action taken by the company.

•Copy of reply sent to complainant.

Steps in handling of complaints

The proposed handling system is in compliance with the GMP Guidelines of EU, USA and Brazil and is presented in four steps:

2. Receiving complaints.

3. Technical investigation.

4. Corrective actions/feed back to Customers.

4. Monthly reports/trend analysis.

Receiving Complaints

It is important to have open channels with customers in order to receive their suggestions, doubts and complaints. Generally, these channels are toll-free numbers, e-mails, chat-rooms and P.O. boxes.

•The most flexible channels are toll-free numbers and chat-rooms.

•A person must be appointed in charge of receiving complaints and inputting the min to appropriate investigation form that shall be addressed.

The investigation form must include:

•Information about the complainant:
-Name

-Address

-Phone no.

-Email
•Information about the Box Product
-Product name

-Batch No:-

-MFG & Exp date

-Amount of the product with the problem.
-Detailed description of the complaint.

Technical investigation

Upon receipt of the investigation form, the QA unit is able to start the investigation.

It is divided into two phases:
•Documentation based investigation.

•Laboratory analysis.

Documentation based investigation:
The primary documentation to be reviewed consists of:
Complaintfiles:
Thisisconstitutedtocheckhowmanyothercomplaintsofthesamenature hadoccurredtoaspecificlotandhowtheywerehandled.

Batch records must be verified in order to see if there was any non-conformance during the production.

Laboratory analysis phase

It consists of requesting the Quality Control (QC) laboratory to analyze.

•Complaint samples.

•Retained samples.

Complaint samples are the customer sample.
Retained samples –the reserve samples representative of the lot manufactured (which were kept under appropriate conditions of temperature, humidity and light so that the drug product was not affected).
The Company elects a person in the QA unit to be in charge of technical investigation of each complaint,

E.g. a Complaint Officer.

There are three possible conclusions, as follows:

•Confirmed complaints.

•Non confirmed complaints.

•Counterfeit/ tamper suspicion.

CONFIRMEDCOMPLAINTS:

•When both complaint and retained samples showed out-of-specification (OOS) results or when only the complaint sample showed OOS results.

Example:

•a single unexplained failure may be when one Box is missing in the intact blister Bundle in the complaint sample, but no deviation was found in the retained samples or during the in-process controls and final QC

Analysis recorded in the batch record.

NON-CONFIRMEDCOMPLAINTS:

•When both complaint and retained samples showed results in compliance with specifications or when only the complaint sample showed OOSresults.

•OOS results in a complaint sample can be attributed to misuse or mishandling, when the drug product was not kept under appropriate conditions of temperature, humidity and light so that the identity, strength, quality and purity of the drug product could be affected.

Example:

Boxes of the complaint sample show a change in their appearance that is characteristic of a light, humidity or high temperature exposure.

COUNTERFEIT / TAMPERSUSPICION:

•When the retained sample is within the specification but the complaint sample isclearly OOS with no reason for that, such as a counterfeit or tampered

Example:
•When Bundled material is different from the original; an example of tampering is when the colour of the Box product is completely different from the original or when any foreign substance was added to the product.

The Complaint Officer must also check if the complaint represents a serious and unexpected adverse Box experience.

The Complaint Officer and the QA Manager must sign off the investigation form once the investigation is completed.

30 days is a reasonable time to conclude an investigation.

Complaint files should be retained for at least 1yeara

CORRECTIVE ACTIONS AND FEEDBACK TOCUSTOMERS

For all confirmed complaints, corrective actions must be implemented. These actions can range from a simple and quick training to some employees to a formal Corrective Action and Preventive Action (CAPA) handling.

•If a CAPA is opened, a multidisciplinary team consisting of representatives of QA, QC, Regulatory Affairs and Production Management must be established.

Concerning non-confirmed complaints originating from misuse or inadequate handling of the drug product. The customer should receive a written response together with scientific information on the correct use and

Handling.

As feedback to the customer, the company must write a response letter to the complainant to explain the investigation approach taken, the results obtained and any implications, in case the quality problem was confirmed.

The customer should be sent a free replacement product together with the response letter, since the customer returned the product (the 'complaint sample') to the company for analysis and a quality problem was found.

MONTHLY REPORTS AND TREND ANALYSIS

•Monthly reports should be elaborated in order to evaluate the amount and the nature of the complaints received and to perform a trend analysis of these complaints.

The monthly reports must answer the following questions:
How many complaints did the company receive in the period?

How many were confirmed?

How many were non-confirmed or we recounterfe it/tamper suspicion?

•Graphic methods of displaying data are important adjuncts to data analysis and presentation.

•The report must be readily available mainly during GMP inspections.

Documentation final product complaint report

P.O#--------
Control no: ----------
•Nature of the complaint-------------------------

•Date------------------

•Complaint: ----------

•Originator of the complaint & title----------

•Distribution contact person & title----------

•Method of notification----------

•Name----------

•Phone No. ----------

•Date shipped----------Invoice#-------

•Product name: ----------

•EXP date: ----------Quantity involved----------

Quantity shipped----------

•Reason for complaint return request----------

•Complaint#----------Product----------

•Evaluation of complaints:
1. Physical characteristics----------
2. Sign of deterioration----------
3. Other observation----------
•Quality control Findings:

1. Returned sample----------
2. Returned sample re assay----------
3. Initial data----------

4. Quality control comments &suggestions

--

- Quality control----------, Date----------
- Complaint#
- Product
- Packaging/Labelling/Inserts

Evaluation
- Remarks

Resultant action taken:
- 1.Method, Date of customer notification & authorized action
- 2.Comments
- 3.Completion date for action taken
- 4.Quality assurance evaluation