Complaint Investigation Report

(Ref. SOP QMS-055)

Complaint Reference Number	**XXX-YYY-ZZ-AA**
Date Received	
Product Name	
Product Code Number	
BPN	
Packaging Type	
Process Line	
Date of Manufacture	
Date of Expiry	

Nature of complaint

Enter the following information:

- Complaint as described by the complainant
- Complainant description, e.g. end user, physician etc

Investigation Details

Include in here:

- Details relating to how the investigation was undertaken and its findings.
  - Previous occurrences
  - Testing
  - Review of documentation
  - Review of Logbooks
  - Feedback from line manager, Technician, operators etc
  - Identify current systems / controls in place that should prevent this complaint
  - Changes to process and / or equipment that have occurred
- Determination of the validity of the complaint
- Identification of potential causes and whether they can be eliminated or not (including justification).

Ensure that only facts are presented.
Photographs of samples and equipment may be included
If testing was conducted, tabulate the results and include a comparison to the specification and stability profile of the product.
Discuss the potential risks / effects that the complaint presents.

Corrective Actions

Enter details of actions required urgently to correct the assignable causes.

Preventative Actions

Enter details of actions required to prevent recurrence when the complaint is determined to be valid. Include reference to Deviation Report numbers.

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Conclusion

Provide a brief summary of the complaint, its cause(s) and preventive actions.

Authorisation		Signature	Date
Prepared by:			
Checked by:			
Approved by:			