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| Company Name | Procedure Number: | Page 1 of 1 |
| Title: Investigation of Complaints | Implementation Date: | Version Number 3.0 |

4.1.3 Internal Notification

An internal memorandum must be send by QA Manager or designate alerting all members of the GMP/Quality committee that a complaint has been received and must be monitored by the GMP/Quality committee.

4.1.4 Complaint Tracking and follow up

The QA Manger or designate must ensure that the complaint investigation will be conducted within 30 days of receipt. The investigation time scale includes the review of the complaint by the GMP/Quality committee, laboratory investigation and any measures that must be conducted to prevent reoccurrence of the potential product deficiency. The QA Manger or designate must ensure the follow up of the assigned corrective actions and analytical testing results to close the complaint investigation within the defined time frame.

4.1.5 Complaint final decision

The QA Manger or designate must decide based on the collected information and Quality Control data the final decision on batch subject to the complaint. The competent authorities should be informed in case of faulty manufacture, product deterioration, detection of counterfeiting or any other serious quality problems with a product, that requires recalling the concerned batch(es).

4.1.6 Complaint response

The QA Manger or designate must ensure that a formal written response for the complaint is send to the customer. The QA Manger or designate must also ensure that regulatory authorities are notified as soon as possible where required or appropriate.

4.1.7 Document complaint compiling and retention

The QA Manger or designate must ensure that all relevant correspondence along with the investigation report for the complaint as well as all other associated documentation will be compiled reverencing the batch documentation. This compiled complaint documentation must be archived having the same retention time as the batch related documentation.

4.1.8 Complaint Samples storage and retention

The QA Manger or designate must ensure that complaint samples are provided to the Quality Control Laboratory.

The QA Manger or designate must ensure that complaint samples are kept under defined conditions and will be retrained as long as the associated complaint documentation.