6.1.3 Adverse Drug Event (ADE) Complaints

Any adverse event associated with the use of a drug product or active pharmaceutical ingredient in humans, being or not being considered product related.

6.2 Complaint Investigation

The complaint investigation must include but is not limited to:

1. Review of the complaint records to evaluate if similar complaints have been received on this batch or on other batches manufactured.
2. The potential for other batches to be affected by the same defect.
3. An attempt to obtain the complaint sample.
4. The evaluation of returned product must include as minimum:
    a. An assessment of the integrity of the packaging.
    b. A determination of the length of time that the product was out on the market.
    c. Assessment of shipping conditions.
    d. Evidence of the storage conditions of the material and the compliance with the labeled storage conditions.
5. A review of the manufacturing and analytical documentation associated with the complaint batch, in consultation with the manufacturing personnel in the relevant area.
6. Where appropriate analytical examination of any returned samples(s) to the appropriate specification and any additional tests that may be deemed to investigate the complaint.
7. Where appropriate the examination of reserve samples of the batch subject to the complaint.
8. Special attention should be given to establishing if this complaint was caused because of counterfeiting.
9. Measures to be taken to prevent reoccurrence.

6.3 Complaint Investigation details

6.3.1 Complaint information

All received complaints must be investigated

a) Name and Address of complaint

b) Telephone number of the person submitting the complaint

c) Date complaint is received

d) Who received the complaint

e) Mode of complaint (Fax, Verbal, e-mail, letter etc.)

f) Nature of complaint