5.3.8 Retain samples (US)

Representative retain samples are visually examined once a year for evidence deterioration unless visual examination would effect the integrity of the retain sample package. Any evidence of retain sample deterioration is investigated. The APR report for the product contains a brief statement of the examination/investigation results.

5.3.9 Changes effected (Change Control)

This chapter lists any changes affected associated to the product, equipment and utilities used for manufacturing and analysis.

5.3.10 Analytical data

The comparison of the particular applicable specifications and initial analysis results of all or a representative number of batches that were produced during the defined review time frame is included. These data include all critical quality parameters for a specific product and are reviewed and compared with the previous year. Quality parameters examples are assay, impurities (HPLC and GC, content uniformity, dissolution, pH, melting point, weight disintegration time, fill volume, preservative effectiveness and other critical parameters such as IPC data, bulk density, particle size, hardness, thickness appearance.

5.3.10.1 Release data

In this chapter a trending of release data is conducted.

5.3.10.2 Stability data

The APR also covers all stability parameters of all batches on stability, which represent the manufactured batches for distribution. These data is trended, reviewed and compared with data from previous year APRs to assure that no negative trend has developed and that the expiry period is still appropriate.

5.3.11 Validation review

A review of all yearly product validation activity and results is listed and summarized.

5.3.12 Recalls

Any batches withdrawn or recalled, or regulatory alerts (e.g., FDA Filed alerts) made from the marked during the time frame of the APR are listed; along with the reason for the recall or withdrawal.

5.3.13 Customer Complaints and Returns

Any technical and/or medical complaint received during the time frame of the review is listed. All complaints are evaluated by QA. If an investigation is conducted then the conclusions made as a result of the investigation are included.
Any returns that are considered complaints are evaluated.

5.3.14 Adverse Drug events (US marketed products only)

Drug safety department will provide QA post marketing Adverse Drug events (US marketed products only) with the appropriate input, which may include copies of periodic reports, periodic safety reports, product safety reviews and/ or any other required documentation/information.