The Annual Product review provides the basis to evaluate the overall quality and the need for improvements. The Annual Product Review must include all Batches of Product whether they were accepted or rejected and/or stability testing performed during the last 12 months period.

The Annual Product Review must cover a one-year period, but does not have to coincide with the calendar year. The review must be completed within thirty (30) business days of the close of the period.

A report for the Annual Product Review must address the assessment of data, documents and electronic records reviewed.

7.2 Statistic

7.2.1 Trending

Statistical analyses should be performed to assess batch uniformity and integrity of drug substances and products. The process evaluation retrospectively, (e.g., control, acceptance, charts, etc.) is useful to study the historical behaviour patterns of the process and aid in the visual evaluation of out of specification values and/or trends that may translate into abnormal variation.

7.2.2 Mean Charts

Consistent mean values indicate that he process is stable, and could be a problem if these values are close to pass/fail limit, or the values consistently all fall above or below mean.

Inconsistent values may be indicative of a change such as different machines, differences in the granulation, etc., and should be investigated.

Mean assay values consistently below or above 100% could suggest a possible processing problem, as products are formulated to 100%.

Steady increases or decreases in values indicate trends over all or part of the evaluation, and they should be noted. Whether these trends are problematic needs to be determined by considering several factors:

- Magnitude of the increase or decrease
- New or historical trend
- Number of quality parameters affected
- Proximity to the pass/fail limit

7.2.3 Range Evaluation

Erratic values or high range values may indicate a process problem, especially if this is not consistent with prior product behaviour. An investigation should be conducted to determine whether there has been a process change, test method change or continued deviation that may affect the parameter in question.

A value or values outside the control limits may not be indicative of a problem if this is normal for the product and there is no history with this parameter. The emphasis is on the process in control rather than a direct evaluation of whether the result of test satisfies specifications.