- Perform linear regression analysis on either accelerated or long-term stability data
- p > 0.25. Yes. There is little or no a change-over-time
- Cpk > 2.5. Yes. There is little or no data variability

5.13.4 Evaluation – Change with Time

The majority of degradation processes results in an essentially linear line in this range of the label claim thus the method is generally applicable for the estimation of the expiry date at the studied storage conditions. For FPPs in semipermeable containers, loss of vehicle can result in an increase in the API concentration. In such cases, the point where the upper 95% confidence bound intersects the 105% assay value will define the conformance period.

5. 14 Release and shelf-life specifications

It may be appropriate to have justifiable differences between the shelf life and release acceptance criteria based on the stability evaluation and the changes observed on storage. Shelf-life acceptance criteria should be derived from consideration of all available stability information. Release and shelf-life dissolution acceptance criteria (Q and t) must be the same.

5.15 Stability Commitment

- For confirmation of provisional (tentative) shelf-life, real-time data are required
- First 3 production batches on stability
- Follow up stability testing (FUST) – one batch per year

5.16 Additional or New Stability Data

- Variations affecting one or more steps of the same route of synthesis of an API
- Change in the route of synthesis of an API
- Change in composition of the FPP
- Change in immediate packaging of the FPP
- Stability studies should be planned on the basis of pharmaceutical R+D and regulatory requirements.