

Ans:- Validation

Scope

These guidelines focus mainly on the overall concept of Validation and are not intended to be prescriptive in specific validation requirements.

- :- General guidance only and the principles may be considered useful in its application in the manufacturing & control of starting materials and finished pharmaceutical product of starting materials and.
- :- Validation of specific processes & system for example, in sterile product manufacture, requires much more consideration and a detailed approach that is beyond the scope of this document.
- :- There are many factors that different types of validations and it is not intended to define & address all aspects related to one particular type of validation here.
- :- The general text in the main part of guidelines may be applicable to validation and qualification of premises, equipment, utilities, systems, processes & procedures.