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# **18BP103 SCALE UP AND TECH TRANSFER**

## **1. Pilot plant design:**

Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenterals and semisolid preparations.

## **2. Scale up:**

Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenterals, NDDS products - formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

## **3. Validation:**

General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

## **4. Equipment Qualification:**

Importance, IQ, OQ, PQ for equipment - autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

## **5. Process validation:**

Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.