N. 2 Machine and 4 Bin

2 bin **50 kg power**

Technical Specifications for Pharmaceutical BIN Blender (50 kg to 300 kg)

1. Materials and Surface Finishes

Product Contact Parts: Must be constructed from **AISI 316L Stainless Steel**.

Non-Contact Parts: Typically constructed from AISI 304 Stainless Steel.

Surface Finish: Internal walls must be **mirror-polished** with a roughness of **Ra ≤ 0.4 µm** (or Ra ≤ 0.8 µm) to eliminate stagnation points and facilitate **cleaning validation**.

Gaskets and Seals: Must be made of **FDA-compliant / Food Grade** materials (e.g., Silicone, EPDM, or PTFE).

2. Design and Geometry (Sanitary Compliance)

Absence of "Dead Corners": The BIN container must feature rounded corners and large radii to prevent powder entrapment.

Hermetic Sealing: The mixing process must occur under fully sealed conditions to prevent dust dispersion into the work environment (**containment**).

Discharge Valve: Must be a **sanitary-grade valve** (e.g., butterfly valve), easily strippable/removable for cleaning and inspection.

3. Control Systems and Safety

Software and Data Integrity: The system must be compliant with **FDA 21 CFR Part 11**, featuring secure access management (password

protection), **Audit Trail** for operational traceability, and electronic signatures.

Critical Process Parameters (CPPs): The PLC must monitor and record rotation speed (RPM), blending time, and BIN docking/positioning.

Safety Features: Infrared light curtains or physical perimeter fencing with safety interlocks to prevent access to the rotation radius during the cycle.

4. Operational Capacity and Validation

Fill Coefficient: For optimal blending homogeneity, the BIN should typically be loaded between **30% and 70-80%** of its total brimful volume.

Validation Documentation: The vendor must provide a complete **Validation Package**, including **DQ** (Design Qualification), **IQ** (Installation Qualification), and **OQ** (Operational Qualification) protocols to verify compliance with pharmaceutical standards.