Vacuum Static Tray Dryer

Equipment: Vacuum Static Tray Dryer (VTD)
Capacity: 100 kg Granules / Batch

1. Functional Requirements (Process)

Batch Capacity: 100 kg to 120 kg of wet granulate.

Drying Technology: Vacuum-assisted thermal conduction through heated shelves.

Operating Temperature: Ambient to **100°C/120°C** with a temperature uniformity of **±2°C** across all shelves.

Vacuum Level: Final vacuum depth of **10-20 mbar**.

Drying Efficiency: Must be optimized for heat-sensitive active pharmaceutical ingredients (APIs).

2. Technical Specifications & Materials

Materials of Construction (MOC):

- **Contact Parts:** Stainless Steel **AISI 316L**, mirror-polished (Ra < 0.5 µm).
- **Non-Contact Parts:** Stainless Steel **AISI 304**, matt/satin finish.

Trays & Shelves: 48 to 60 trays configuration. Shelves must be hollow for fluid circulation (hot water or thermal oil) to ensure direct heat transfer.

Door Gaskets: Food-grade **Silicone or Viton** (FDA compliant).

Condenser: Integrated shell-and-tube condenser for solvent recovery with a dedicated receiver tank.

3. Control System & Compliance

Automation: PLC-based control system (e.g., Siemens S7 or Allen-Bradley).

Data Integrity: Fully compliant with **FDA 21 CFR Part 11** (Audit Trail, Electronic Signatures, Multi-level Password Access).

Instrumentation: High-precision PT100 sensors for both shelf and product temperature monitoring, plus a digital vacuum transmitter.

Alarms: High-temperature cutoff, vacuum leak detection, and emergency stop.

4. Utilities & Safety

Vacuum Pump: Dry-running vacuum pump (oil-free) recommended to prevent cross-contamination.

Filtration: 0.2 µm hydrophobic HEPA filter on the vacuum break line.

Explosion Protection: ATEX certification required if processing flammable solvents.

5. Validation & Documentation

Documentation Package: FAT (Factory Acceptance Test), SAT (Site Acceptance Test), and **IQ/OQ/PQ** protocols.

Certifications: Material certificates (3.1), calibration certificates for all instruments, and welding logs