

User Requirements Specification (URS)

For Tablet Press Machine

Document Code: **QA.URS.001.01**

Basic Requirements

This document clearly defines the user requirements to ensure compliance of the system with current good manufacturing practices (C GMP) and all applicable regulation.

- Compression of pharmaceutical powders or granules into tablets at variable speed
- The equipment defined in this specification shall confirm to:

No.	Name of the product	Shape	Size (mm)	Weight (g)	RPM	Output (tablet/hr)
01	Niclosam	Caplet	25.2*10	2 ± 0.1		250,000

- Double sided, D-type tooling
- Tablets of different shapes (Round, Caplet, Oblong, Oval) and sizes ranging to 25.5 mm in diameter
- (Auto loading system) Variable speed rotary paddle granule feeder (Force feeding system for 250,000 tablet/hour)
- Machine to be equipped with 20 ton-force (Maximum)
- Automatic lubricating system with alarm
- Touch screen / operator interface including product parameter setting and monitoring system
- - All the process parameter controls should be in front of the machine.
- Dust collector is to be used for collecting extra dust form the different points of the machine. Machine should have provision to control suction pressure to control dust.
- Parts in contact with the product should SS 316 L and other will be SS 304. Surface mounted adjacent to working area should be constructed in SS construction and complete covering of the machine top is required for ensuring safety and protection.
- - Anti vibrating mounting
- - Additional lower cam to adjust depth of die fill
- Room dimension of Tablet compression is 5000 mm (L) X 4000 mm (W) X 3500 mm (H)
- - Instruction manual for installation, start up, operation, maintenance, format changeover, calibration, troubleshooting
- SOP ,DQ,IQ& OQ