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## *Uncoated, Dispersible and Coated Tablets Technologies*

### **Fundamental principles of uncoated, dispersible tablets \*\*/Coated tablet formulation**

1. Weight of drug (in metric system) ..... (Direct compression method)
2. Drug dry slugging (small pieces)
3. Dry granules ..... (dry granulation method) ..... Compression
4. Weight of excipients ..... wet granulation method
5. Shifting (to shift raw material in polythene bags)
6. Milling (to make smaller particle)
7. Dispersible tablets\*\* Sweetening agent milled sugar 97% w/w or aspartame 1% to 2%, colour ponceau 4 R 0.03% w/w and opicifier titanium dioxide 0.001% w/w, Flavour raspberry 0.21% w/w, Buffering agent citric acid 0.1% w/w.
8. (Wet granulation) ..... wet mixing (starch paste~ + drug)~ binding agent starch paste = 120% w/v starch powder in cool water or 3 to 5% w/v, starch in RO water, then boiling at 60 degrees/CMC 2 to 4% w/v in cool RO water or acacia 1 to 2% w/v in boiling water at 60°C.  
\*\*Binding agent ethanol 50% v/v and RO water 50% v/v to make polyvinylpyrrolidone K-30 paste 1 to 2% w/v
9. Wet material drying (at 60°C)
10. **Multi Mill:** Breaking big lumps
11. Drying at 60°C
12. Wet granulation (making wet granules)

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13. Dry granulation (making dry granules at 60°C)
14. **Lubrication:** Dry mixing (mixing dry granules and anti-adhesive magnesium stearate 0.2 to 2% w/w, \*\*Disintegrator starch powder 5 % to 10% w/w, lubricant talcum powder 0.2% to 5% w/w, diluent colloidal silicon dioxide 1% to 2%, surfactant sodium lauryl sulphate 0.01% to 0.05% w/w, other pharmaceutical excipients if needed)
15. Compression (to make uncoated tablets)
16. Coating (Film\*, enteric \*\*\*, sugar) film coating\* suspension, spray and drying at 35°C of film coating material hydroxypropyl methylcellulose 1% w/v in vehicle isopropyl alcohol 70% v/v, glidant talc 1% w/w, plasticizer triethyl citrate 0.5% w/w, opicifier titanium dioxide 0.001% w/v, colour ponceau 4 R 0.03% w/v, sustain release coating suspension, spray and drying at 35°C, hydroxypropyl methylcellulose 1% w/v, ethyl cellulose 0.5% w/v in vehicle isopropyl alcohol 70% v/v, glidant talc 1%, plasticizer triethyl citrate 0.5% w/w, opicifier titanium dioxide 0.001% w/v, colour ponceau 4 R 0.03% w/v, enteric coating \*\*\*suspension, spray and drying at 35°C of enteric coating cellulose acetate phthalate (soluble at pH > 6) 1% w/v in isopropyl alcohol 70% v/v, glidant talc 1% w/w, plasticizer triethyl citrate 0.5% w/w, colours ponceau 4 R 0.03% w/v and opicifier titanium dioxide 0.001% w/v sustain release coating can be controlled release coating or sodium CMC high viscosity 2 to 4 % w/v. Sugar coating contain solution of sugar syrup 68% w/v, citric acid 0.1% w/v, sodium benzoate 0.1% w/v, colour ponceau 4 R 0.1% w/v is sprayed on uncoated tablets and sugar coating tablets are dried at 60°C. All types of coating must be only 1 mm in thickness to avoid wastage and production loss during strip, blister and alu packing.
17. Packing (strip, blister, alu, 15 kg HMHDPE drums)  
Quality control and quality assurance for 20 tablets is:
  - Weight variation = Weight of tablet  $\pm$  5% in mg
  - Thickness = Size of tablet  $\pm$  5 % in mm
  - Hardness = 4 kg/cm<sup>2</sup>. No tablet breaking while transport.

- Friability = Chamber rotation for 4 minutes @ 25 rpm.  
Weight loss limit not more than (NMT) 0.8 % w/w .

**Clean tablets:** No mobilile oil.

**Rate of disintegration time:** At 35°C uncoated tablets (within 30 minutes) must disintegrate and coated tablets (within 1 hour) must disintegrate and pass through the sieve.

**Dissolution test time:** 100% tablet must dissolve and weight of drug must be equivalent to the label claim by chemical analysis (within 1 hour)

**Storage:** Airtight packing.

Yield% = Obtained weight/supplied weight \* 100.

Yield% must be above 92% to obtain profit in business.

**Tablets produced by direct compression:** Aspirin, chlorine, ferrous sulphate.

**Tablets produce by dry granulation:** Calcium lactate, riboflavin, alprazolam.

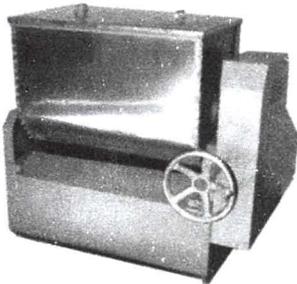
**Tablets produced by wet granulation:** Paracetamol, sodium bicarbonate. 70% of drugs are produced by wet granulation method.

### **Machines used**

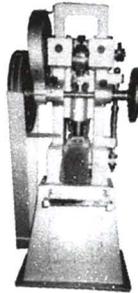
1. Sifter
2. Mass mixer
3. Hot air drier
4. Multi mill
5. Hammer mill or motar and pestle of iron
6. Oscillating granulator
7. Drum mixer
8. Tablet making machine
9. Coating pan
10. Tablet disintegration
11. Tablet dissolution machine
12. Tablet hardness tester
13. Tablet friability machine
14. Strip or blister machine

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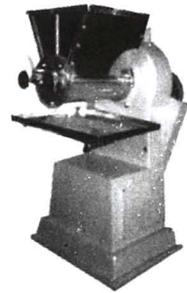
15. Batch printing machine
16. Label gumming machine
17. Taping and sealing cartons
18. Digital balance
19. Measuring cylinder
20. Compactor



Mass mixer



Tablet machine with 13 stations (die sets)



Oscillating granulator



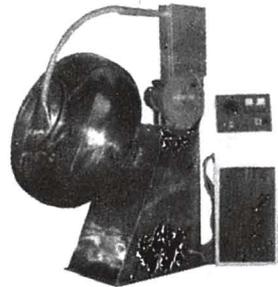
Digital balance for weighing in milligrams



Digital balance for weighing in kilograms



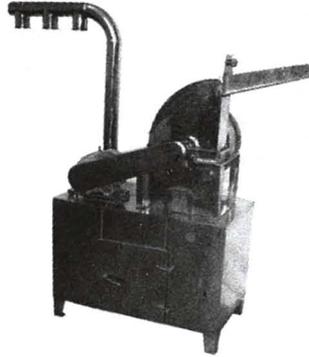
Drier 24 trays



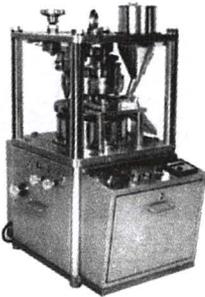
Coating pan for coating tablets



Polishing pan for sugar coating tablets



Hammer mill for milling hard materials like herbal powder, homeopathic tablets



Rotary tablet machine with 51 stations



Roll compactor for dry granulation with quality s.s 306



Multi mill for wet granulation of tablets



Punches and dies of tablet machine



Sifter

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Disintegrator

**AT7**  
*Smart*



Dissolution



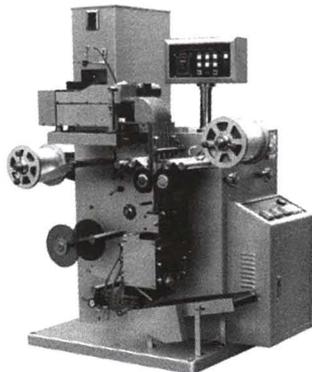
Tablet hardness tester



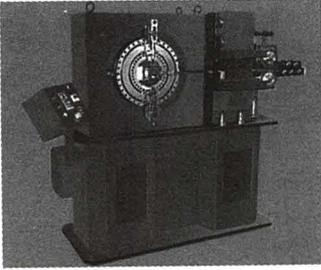
Friability



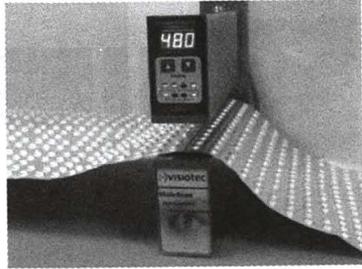
Tablet defoiler



Blister machine



Strip machine



Pin hole detector



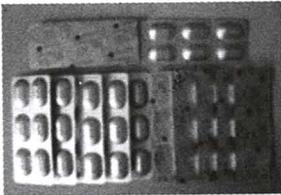
Blister leak tester



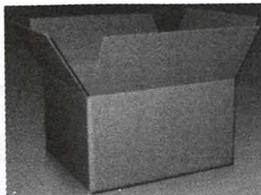
Blister pack of film coated tablets



Show box



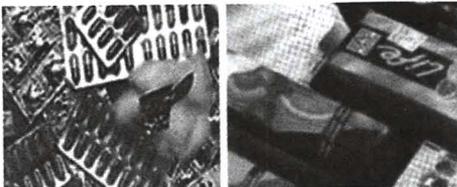
Alu pack of tablets



5 ply carton



HMHDPE drums

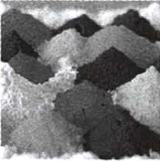


Strip and blister pack and show box

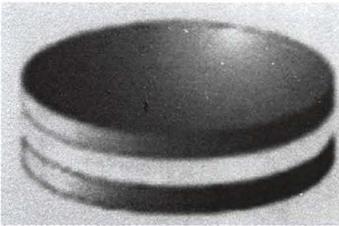


Fiber drums

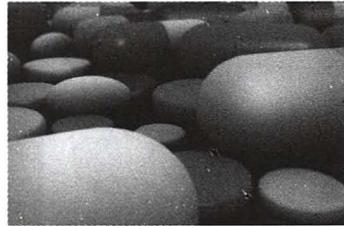
## 8 Drugs and Cosmetics Formulations



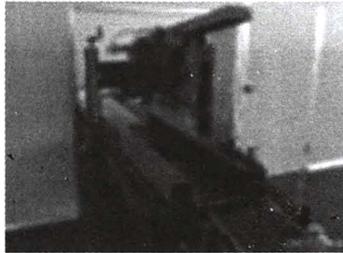
Dry powder to finished products



Bilayer tablet



Uncoated, coated tablets and capsule



Carton sealing machine