FIG. 1

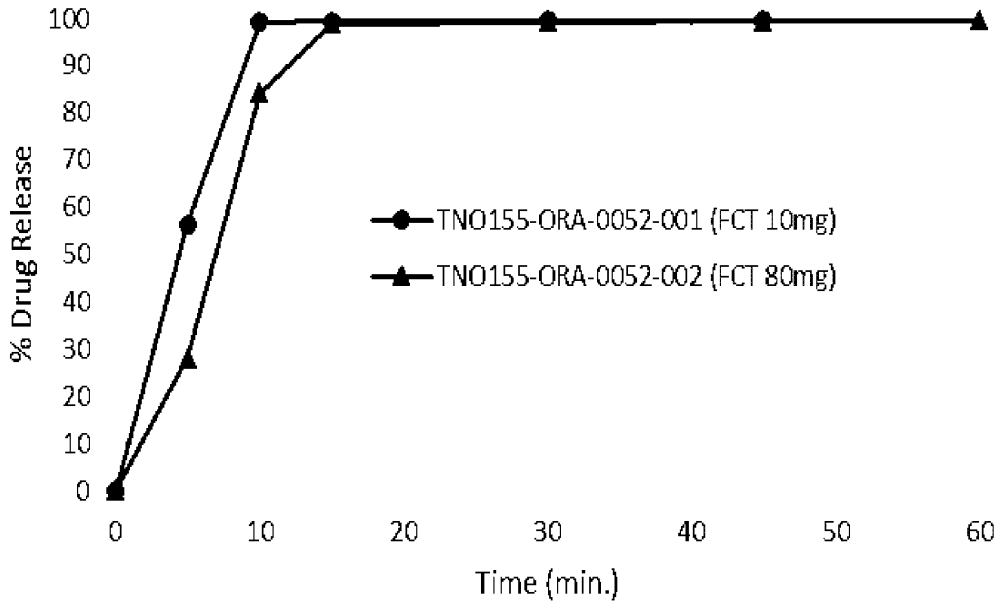

100
90
80
70
60
50
40
30
20
10
0
% Drug Release
0
10
20
30
40
50
60
Time (min.)
TNO155-ORA-0052-001 (FCT 10mg)
TNO155-ORA-0052-002 (FCT 80mg)

FIG. 2

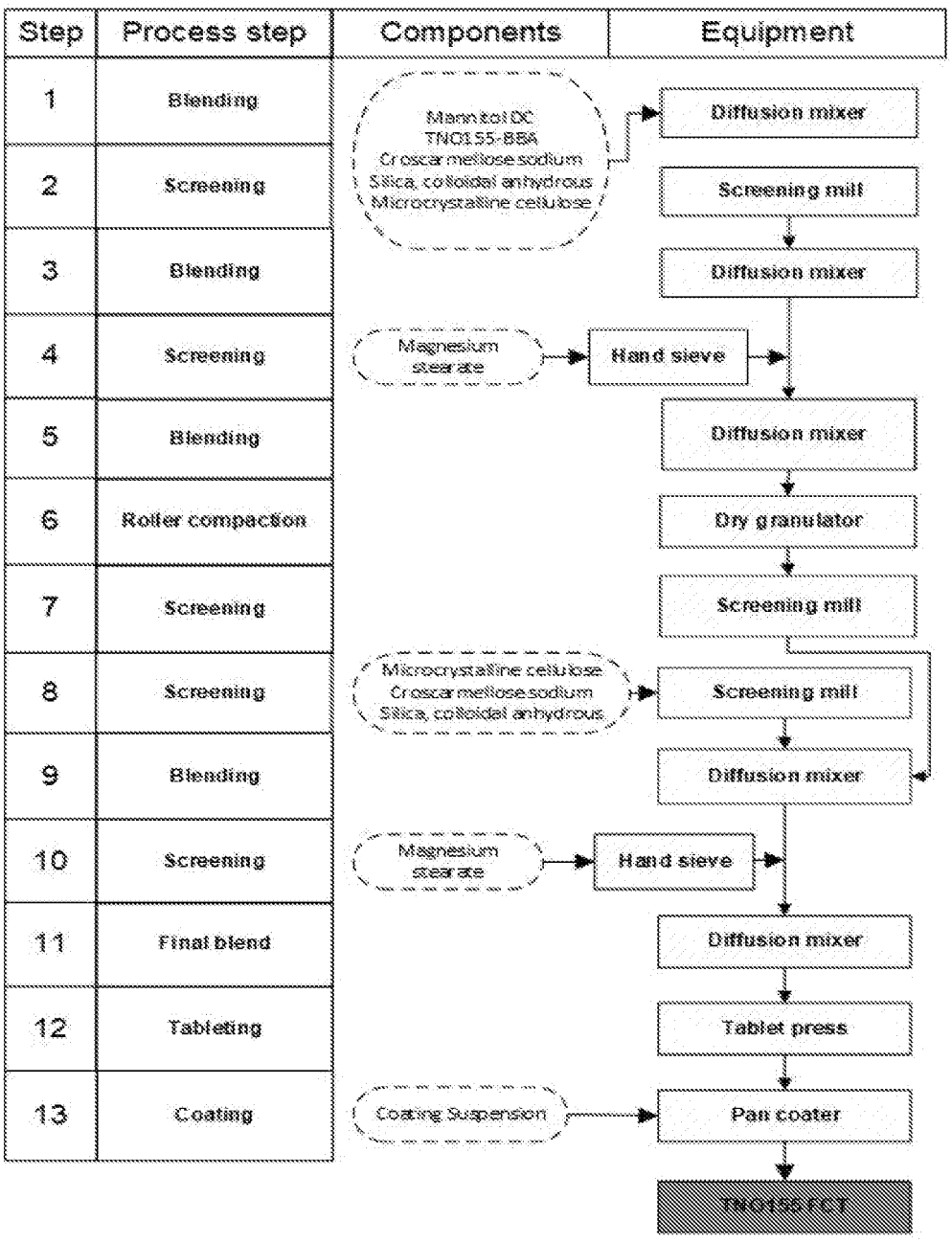

Step
Process step
Components
Equipment
1
Blending
2
Screening
3
Blending
4
Screening
5
Blending
6
Roller compaction
7
Screening
8
Screening
9
Blending
10
Screening
11
Final blend
12
Tableting
13
Coating
Mannitol DC
TN01155-BBA
Croscarmellose sodium
Silica, colloidal anhydrous
Microcrystalline cellulose
Diffusion mixer
Screening mill
Diffusion mixer
Magnesium stearate
Hand sieve
Diffusion mixer
Dry granulator
Screening mill
Microcrystalline cellulose
Croscarmellose sodium
Silica, colloidal anhydrous
Screening mill
Diffusion mixer
Magnesium stearate
Hand sieve
Diffusion mixer
Tablet press
Coating Suspension
Pan coater
TN01155 FCT

FIG. 3

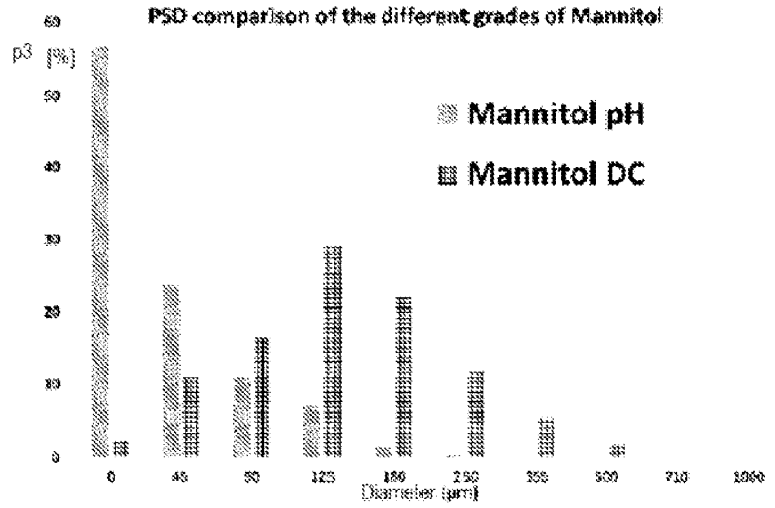

PSD comparison of the different grades of Mannitol
Mannitol pH
Mannitol DC
Diameter (µm)

FIG. 4

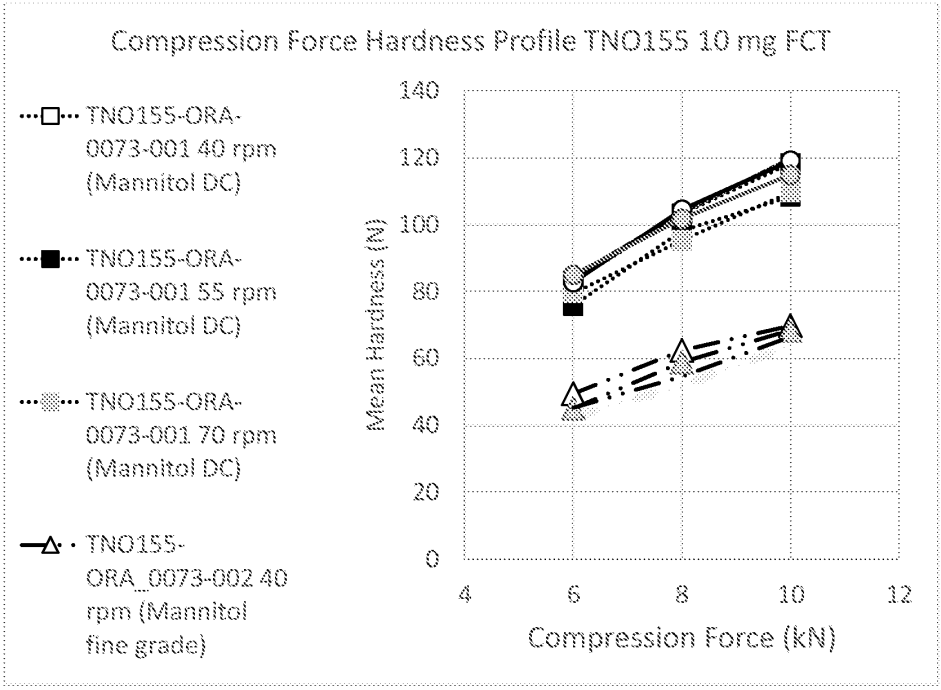
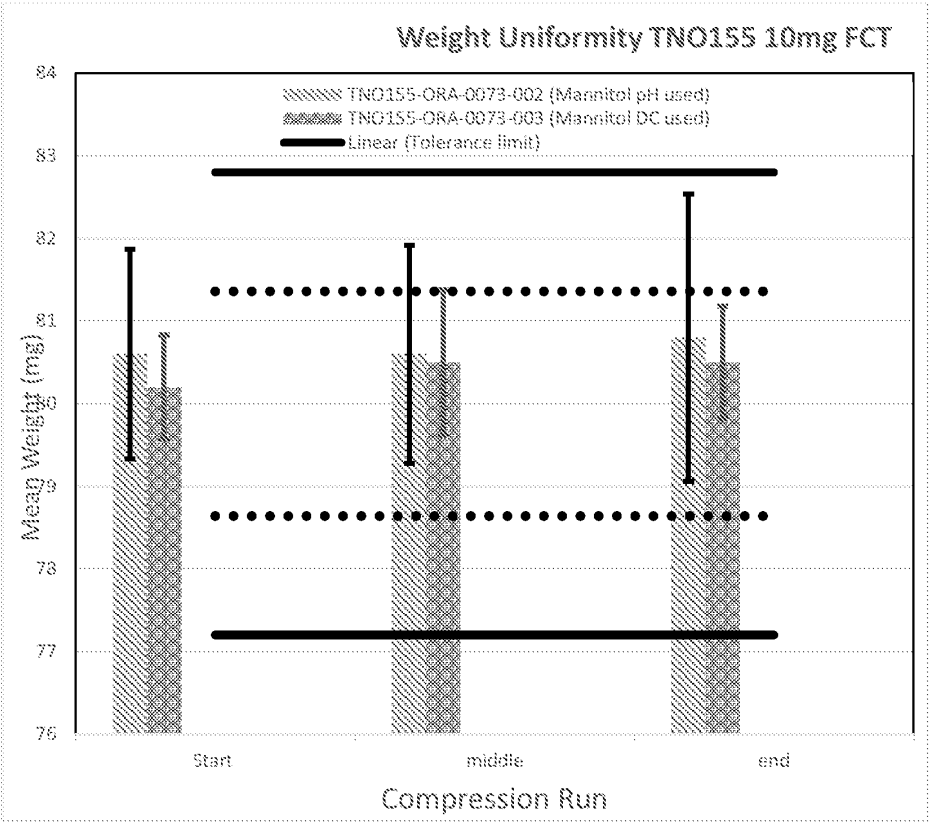

Compression Force Hardness Profile TNO155 10 mg FCT
TNO155-ORA-0073-001 40 rpm (Mannitol DC)
TNO155-ORA-0073-001 55 rpm (Mannitol DC)
TNO155-ORA-0073-001 70 rpm (Mannitol DC)
TNO155-ORA_0073-002 40 rpm (Mannitol fine grade)
Mean Hardness (N)
140
120
100
80
60
40
20
0
4
6
8
10
12
Compression Force (kN)

FIG. 5


Weight Uniformity TNO155 10mg FCT
TNO155-ORA-0073-002 (Mannitol pH used)
TNO155-ORA-0073-003 (Mannitol DC used)
Linear (Tolerance limit)
Mean Weight (mg)
84
83
82
81
80
79
78
77
76
Start
middle
end
Compression Run