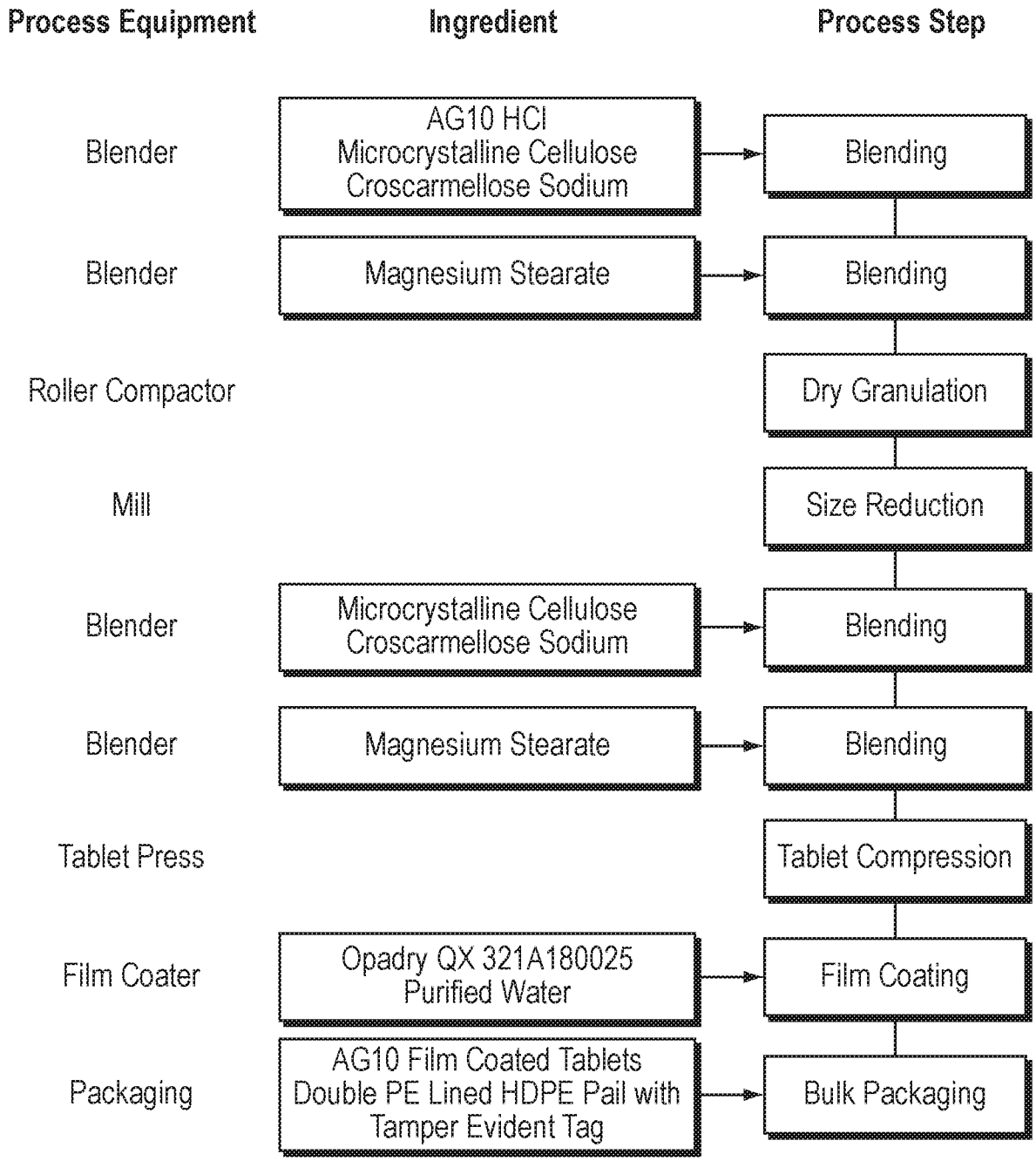
Process Equipment
Ingredient
Process Step
Blender
AG10 HCl
Microcrystalline Cellulose
Croscarmellose Sodium
Blending
Blender
Magnesium Stearate
Blending
Roller Compactor
Dry Granulation
Mill
Size Reduction
Blender
Microcrystalline Cellulose
Croscarmellose Sodium
Blending
Blender
Magnesium Stearate
Blending
Tablet Press
Tablet Compression
Film Coater
Opadry QX 321A180025
Purified Water
Film Coating
Packaging
AG10 Film Coated Tablets
Double PE Lined HDPE Pail with
Tamper Evident Tag
Bulk Packaging

FIG. 1

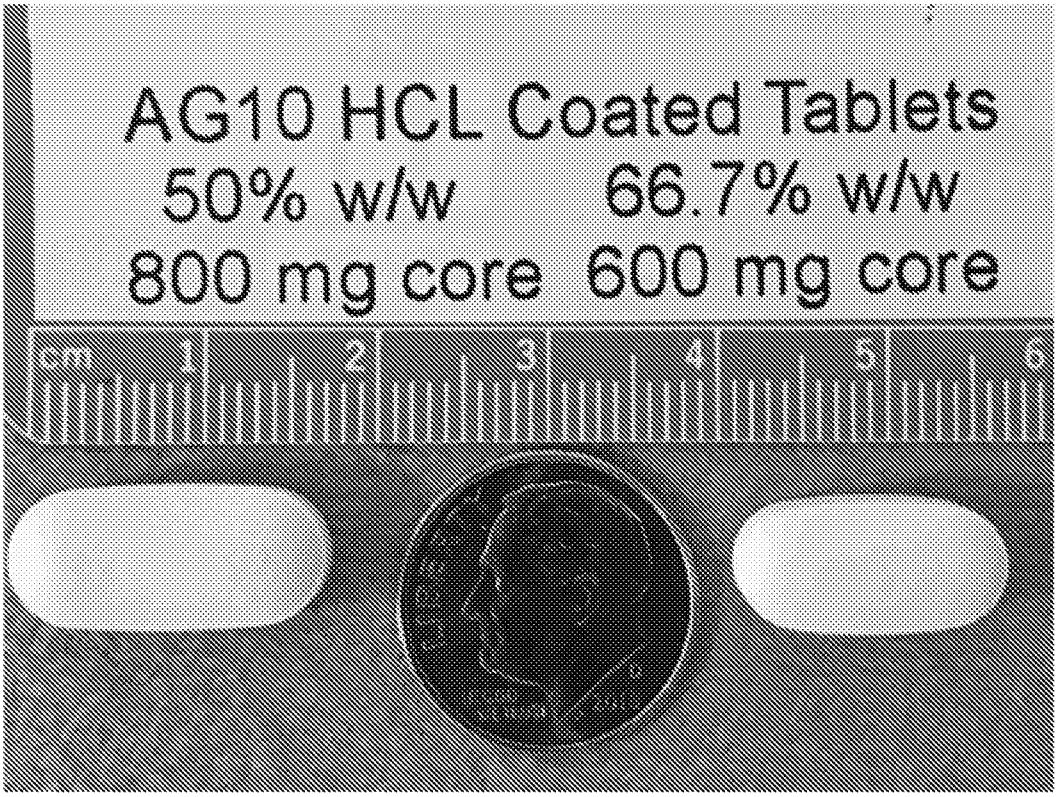
AG10 HCL Coated Tablets
50% w/w
66.7% w/w
800 mg core
600 mg core
cm
1
2
3
4
5
6

FIG. 2

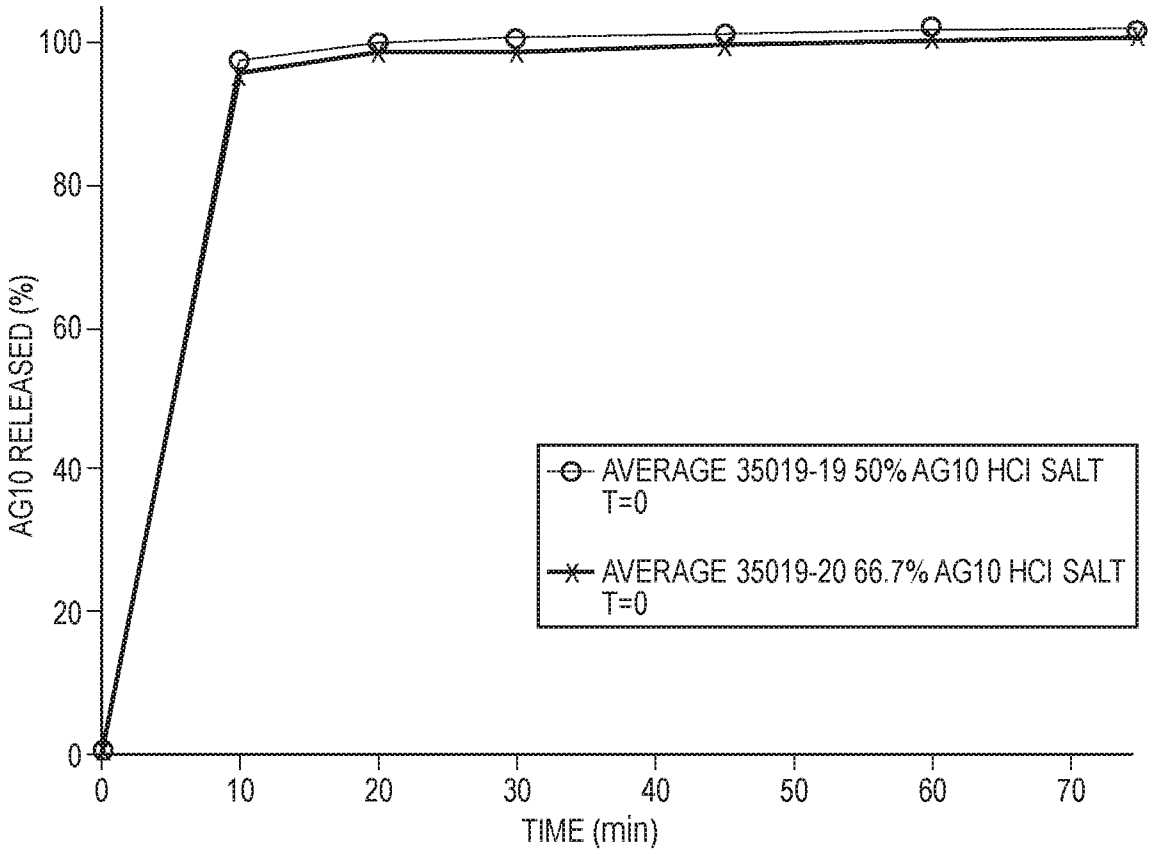
100
80
60
40
20
0
AG10 RELEASED (%)
0
10
20
30
40
50
60
70
TIME (min)
AVERAGE 35019-19 50% AG10 HCl SALT T=0
AVERAGE 35019-20 66.7% AG10 HCl SALT T=0

FIG. 3

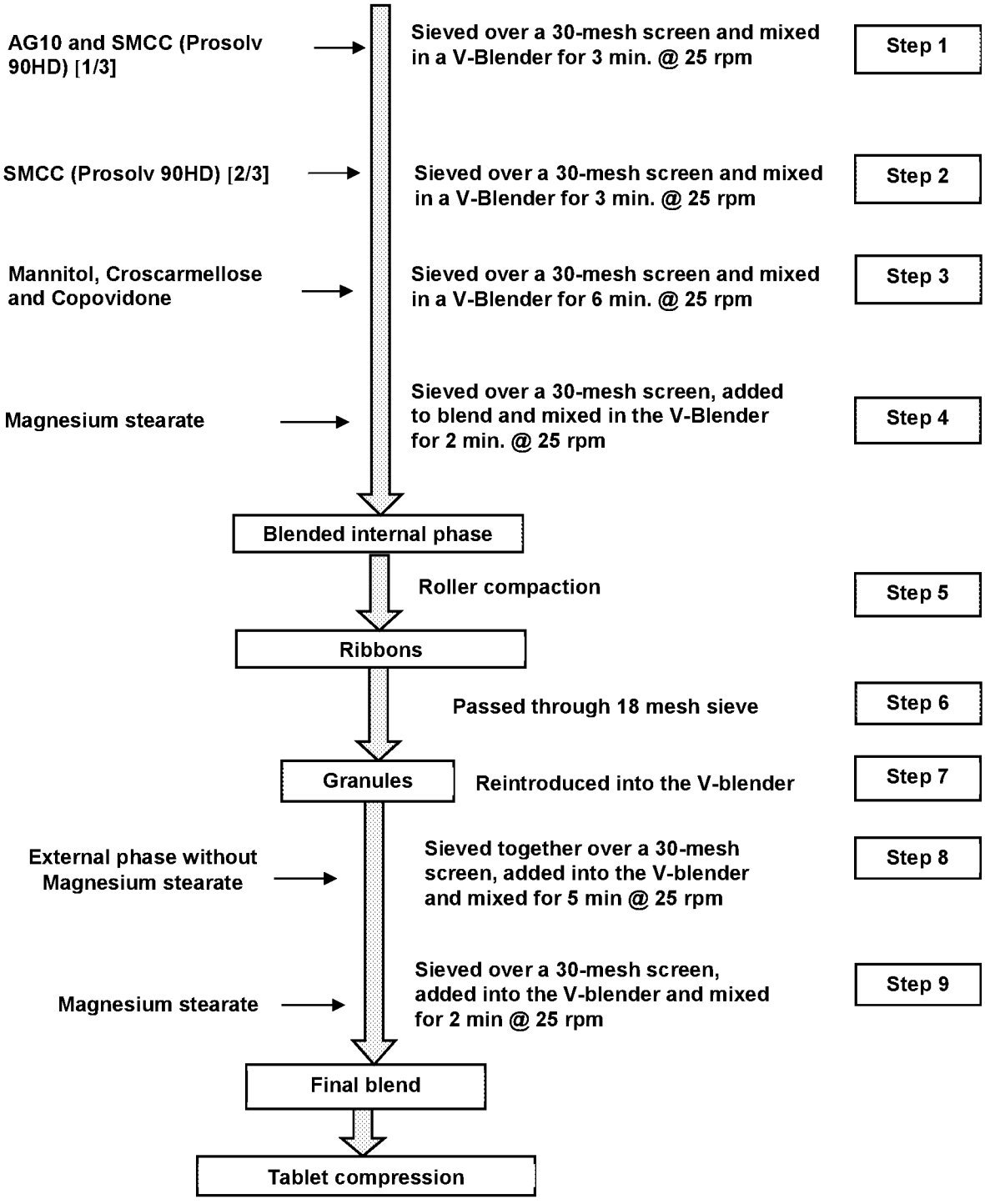
AG10 and SMCC (Prosolv 90HD) [1/3]
Sieved over a 30-mesh screen and mixed in a V-Blender for 3 min. @ 25 rpm
Step 1
SMCC (Prosolv 90HD) [2/3]
Sieved over a 30-mesh screen and mixed in a V-Blender for 3 min. @ 25 rpm
Step 2
Mannitol, Croscarmellose and Copovidone
Sieved over a 30-mesh screen and mixed in a V-Blender for 6 min. @ 25 rpm
Step 3
Magnesium stearate
Sieved over a 30-mesh screen, added to blend and mixed in the V-Blender for 2 min. @ 25 rpm
Step 4
Blended internal phase
Roller compaction
Step 5
Ribbons
Passed through 18 mesh sieve
Step 6
Granules
Reintroduced into the V-blender
Step 7
External phase without Magnesium stearate
Sieved together over a 30-mesh screen, added into the V-blender and mixed for 5 min @ 25 rpm
Step 8
Magnesium stearate
Sieved over a 30-mesh screen, added into the V-blender and mixed for 2 min @ 25 rpm
Step 9
Final blend
Tablet compression

FIG. 4

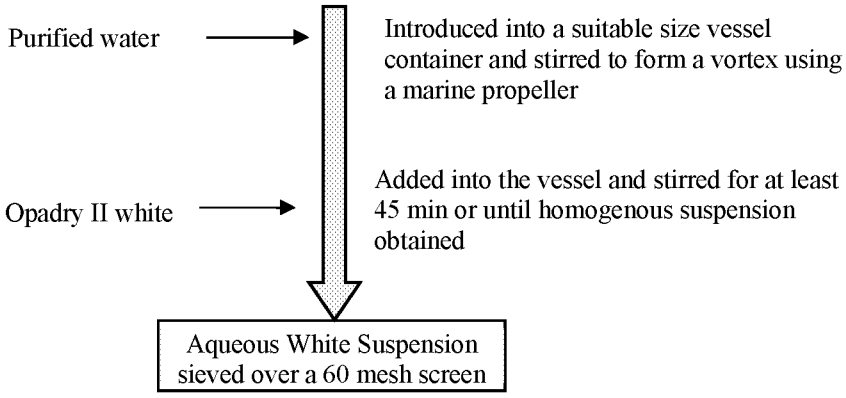
Purified water
Introduced into a suitable size vessel container and stirred to form a vortex using a marine propeller
Opadry II white
Added into the vessel and stirred for at least 45 min or until homogenous suspension obtained
Aqueous White Suspension sieved over a 60 mesh screen

FIG. 5

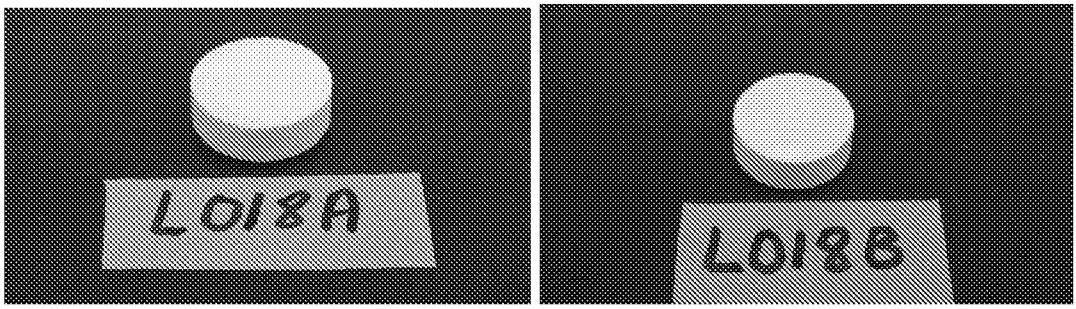

FIG. 6

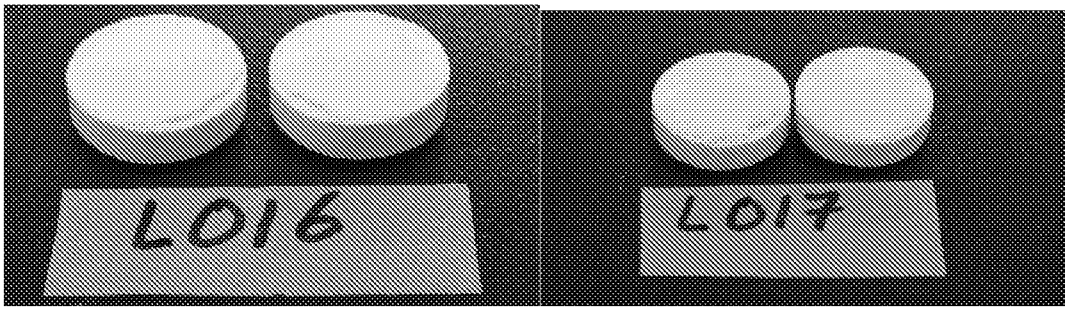

FIG. 7

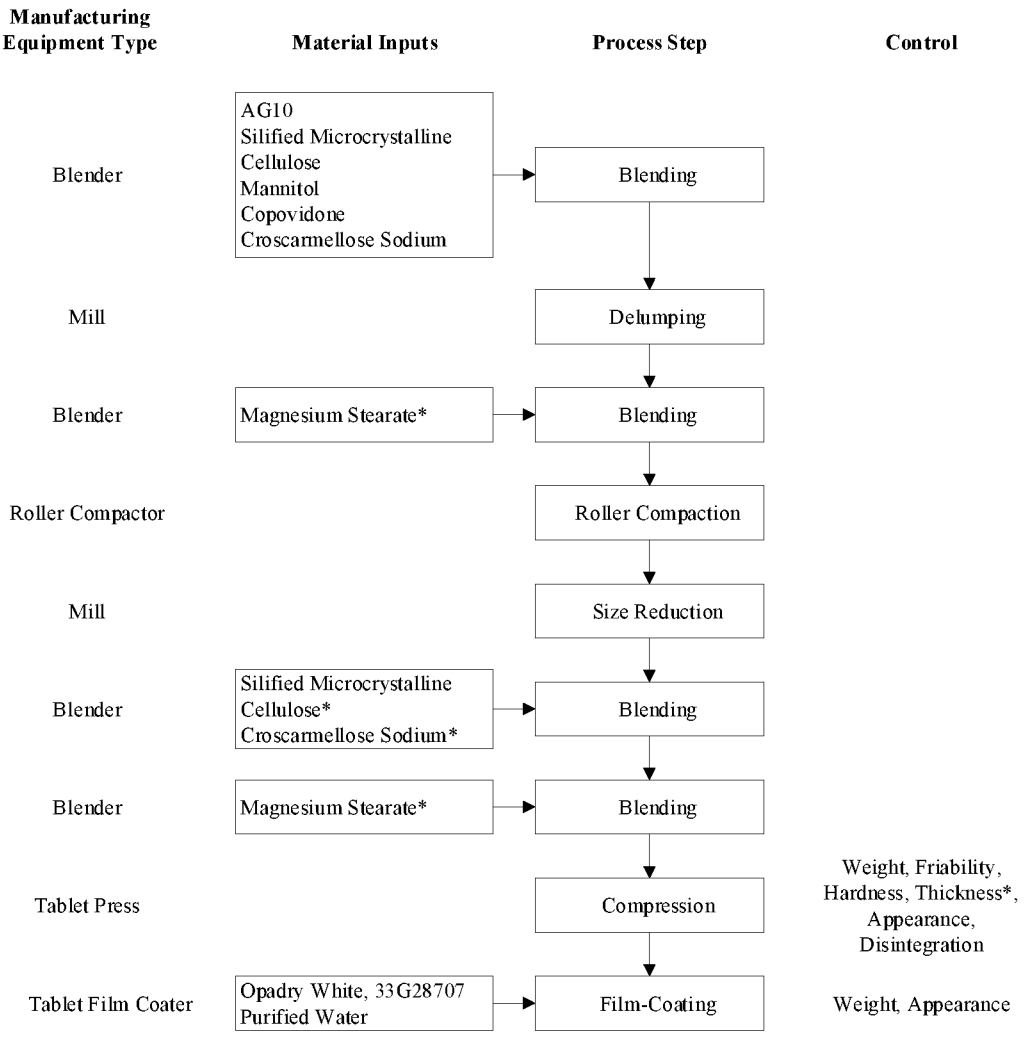
Manufacturing Equipment Type
Material Inputs
Process Step
Control
Blender
AG10
Silified Microcrystalline Cellulose
Mannitol
Copovidone
Croscarmellose Sodium
Blending
Mill
Delumping
Blender
Magnesium Stearate*
Blending
Roller Compactor
Roller Compaction
Mill
Size Reduction
Blender
Silified Microcrystalline Cellulose*
Croscarmellose Sodium*
Blending
Blender
Magnesium Stearate*
Blending
Tablet Press
Compression
Weight, Friability, Hardness, Thickness*, Appearance, Disintegration
Tablet Film Coater
Opadry White, 33G28707
Purified Water
Film-Coating
Weight, Appearance

FIG. 8

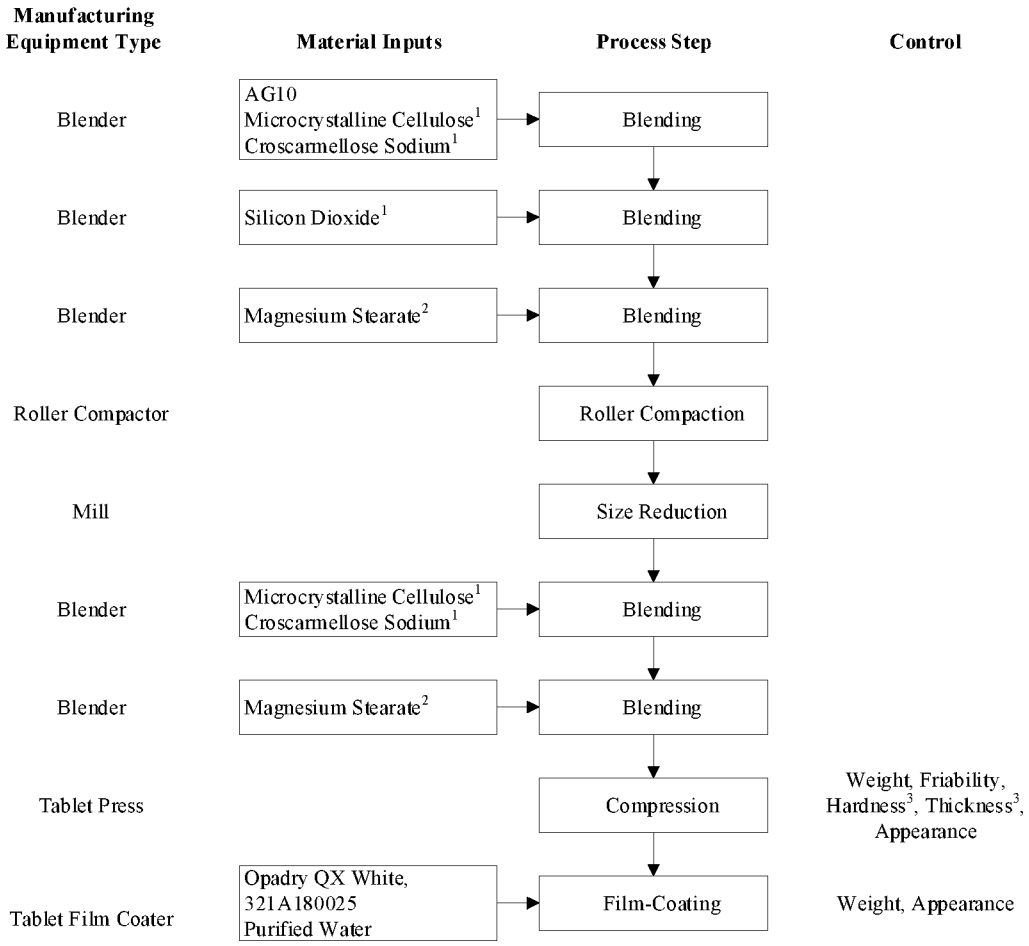
Manufacturing Equipment Type
Material Inputs
Process Step
Control
Blender
AG10
Microcrystalline Cellulose[1]
Croscarmellose Sodium[1]
Blending
Blender
Silicon Dioxide[1]
Blending
Blender
Magnesium Stearate[2]
Blending
Roller Compactor
Roller Compaction
Mill
Size Reduction
Blender
Microcrystalline Cellulose[1]
Croscarmellose Sodium[1]
Blending
Blender
Magnesium Stearate[2]
Blending
Tablet Press
Compression
Weight, Friability, Hardness[3], Thickness[3], Appearance
Tablet Film Coater
Opadry QX White, 321A180025
Purified Water
Film-Coating
Weight, Appearance

FIG. 9

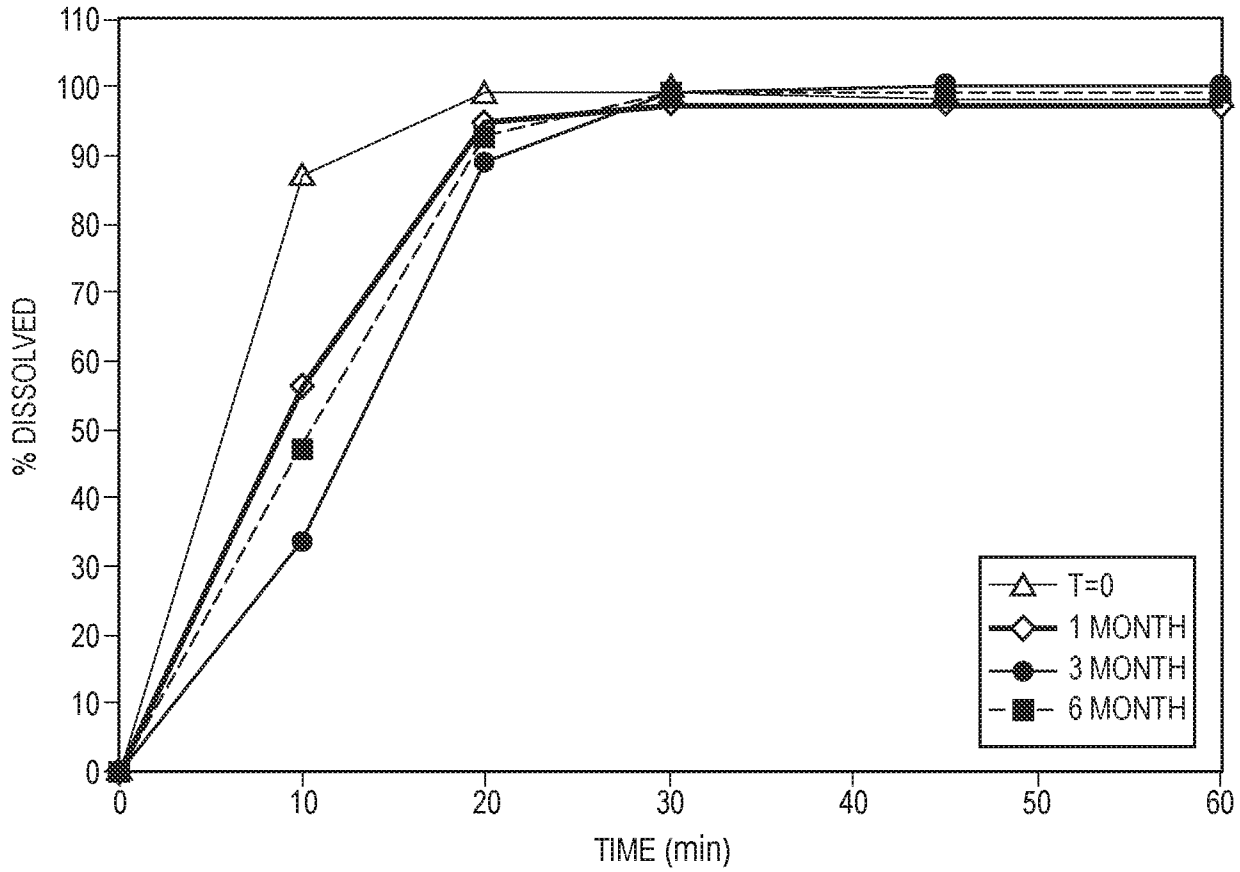
110
100
90
80
70
60
50
40
30
20
10
0
% DISSOLVED
0
10
20
30
40
50
60
TIME (min)
T=0
1 MONTH
3 MONTH
6 MONTH

FIG. 10

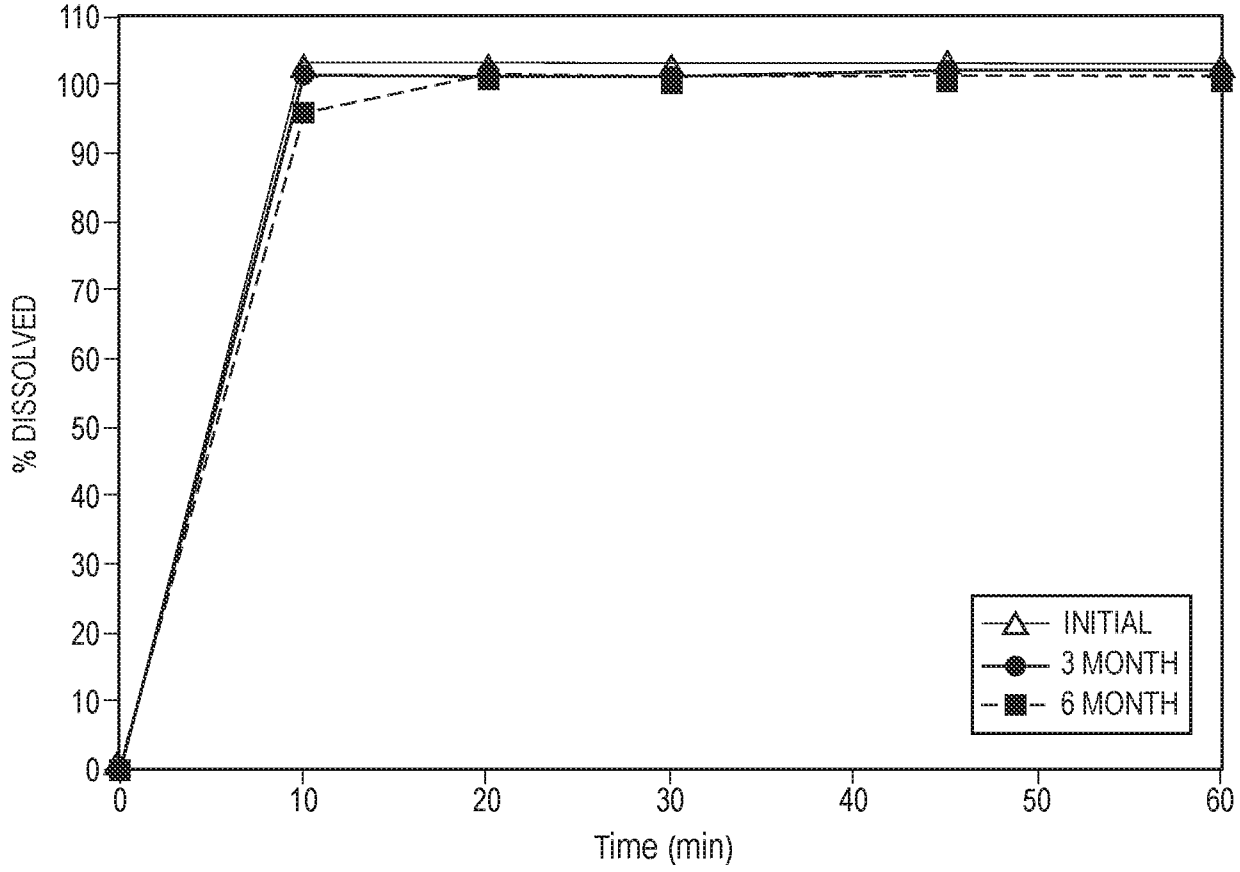
110
100
90
80
70
60
50
40
30
20
10
0
% DISSOLVED
0
10
20
30
40
50
60
Time (min)
INITIAL
3 MONTH
6 MONTH

FIG. 11