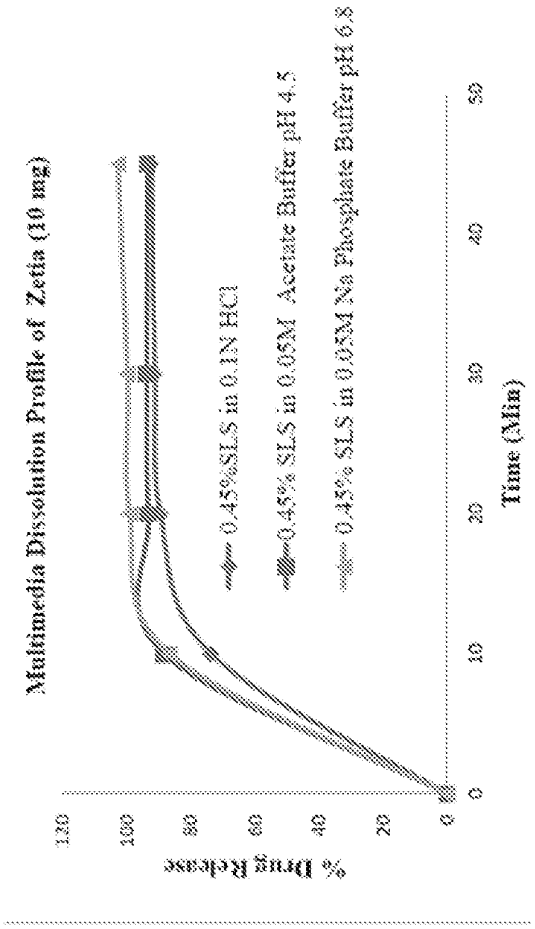

Multimedia Dissolution Profile of Zetia (10 mg)
% Drug Release
120
100
80
60
40
20
0
0
10
20
30
40
50
Time (Min)
0.45%SLS in 0.1N HCl
0.45% SLS in 0.05M Acetate Buffer pH 4.5
0.45% SLS in 0.05M Na Phosphate Buffer pH 6.8

FIG. 1

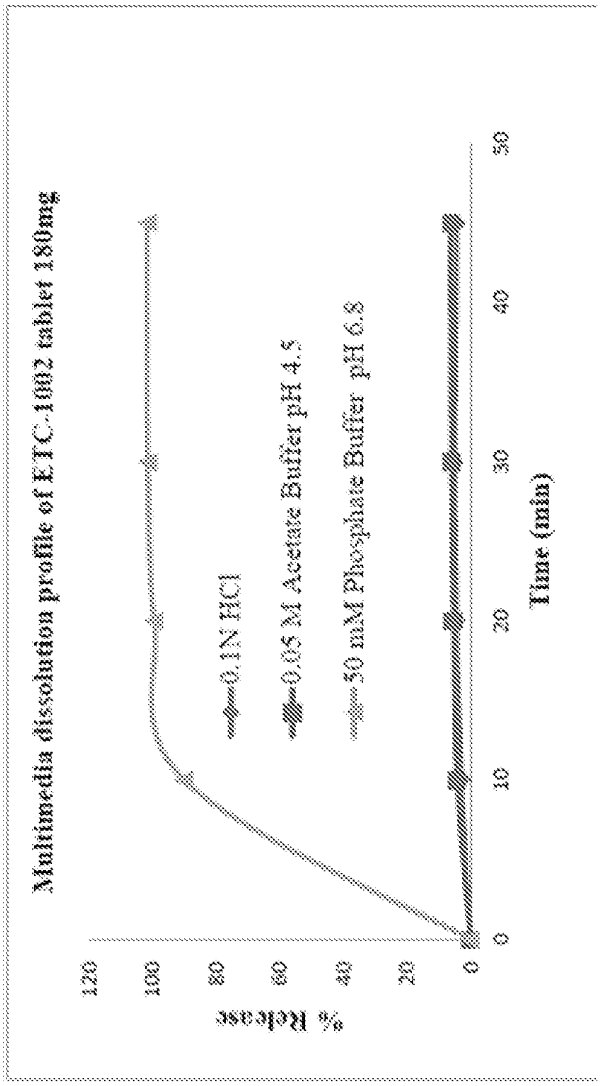

Multimedia dissolution profile of ETC-1002 tablet 180mg
% Release
120
100
80
60
40
20
0
0
10
20
30
40
50
Time (min)
0.1N HCl
0.05 M Acetate Buffer pH 4.5
50 mM Phosphate Buffer pH 6.8

FIG. 2

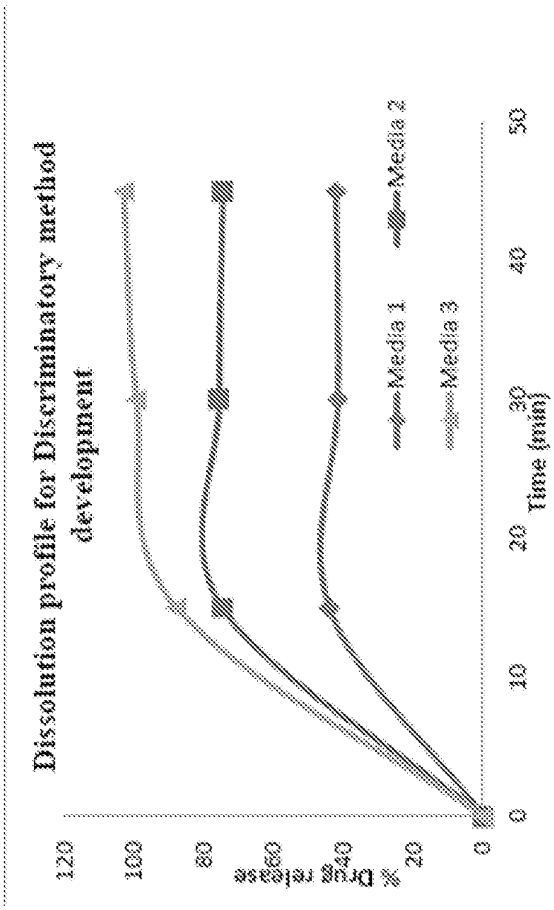

Dissolution profile for Discriminatory method development
% Drug release
120
100
80
60
40
20
0
0
10
20
30
40
50
Time (min)
Media 1
Media 2
Media 3

FIG. 3

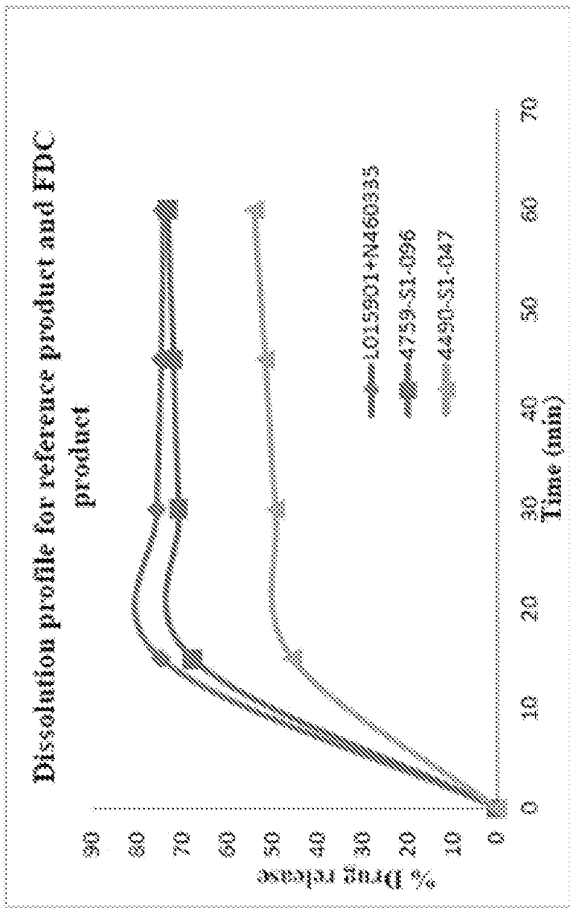

Dissolution profile for reference product and FDC product
% Drug release
Time (min)
0
10
20
30
40
50
60
70
80
90
LO159031+N4680333
4759-51-096
4490-51-047

FIG. 4

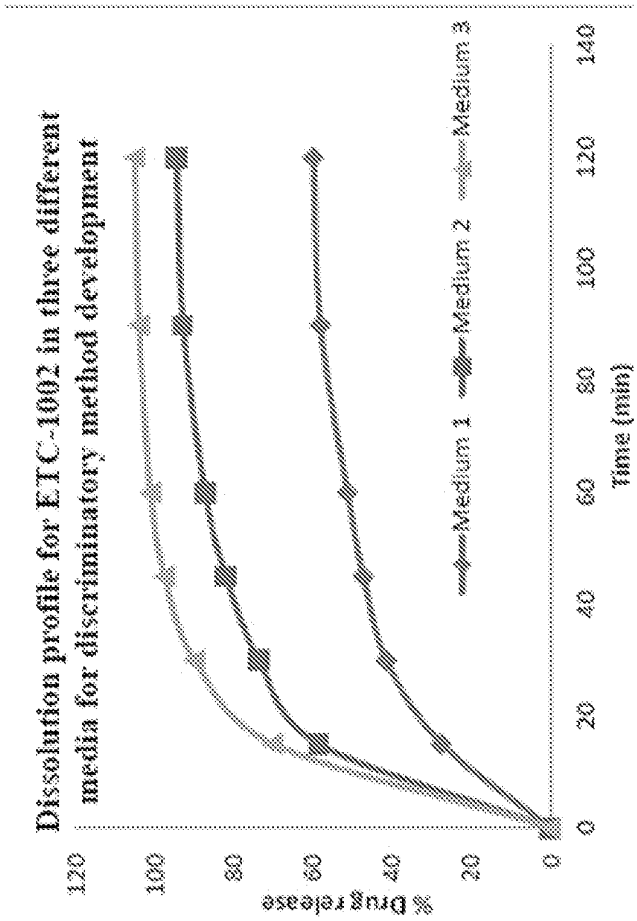

Dissolution profile for ETC-1002 in three different media for discriminatory method development
% Drug release
Time (min)
Medium 1
Medium 2
Medium 3
0
20
40
60
80
100
120
140

FIG. 5

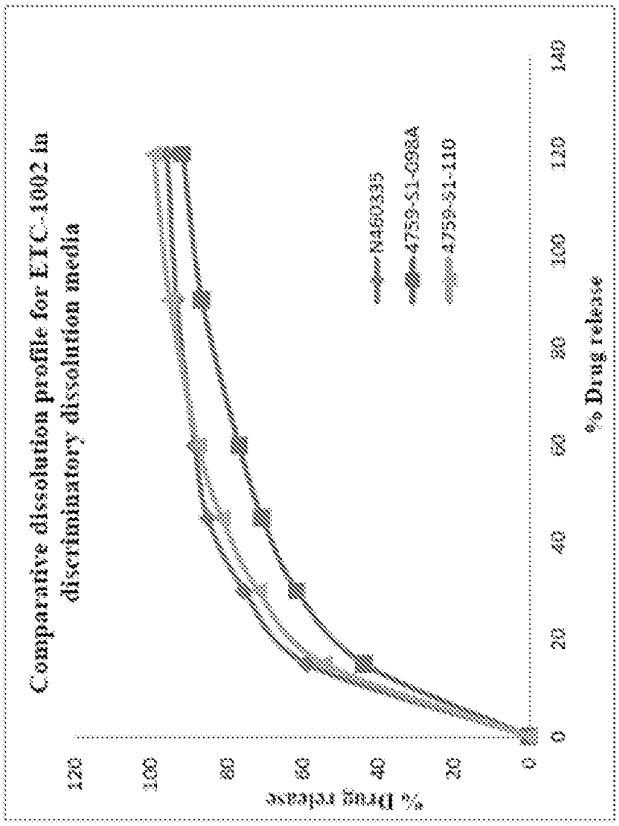

Comparative dissolution profile for ETC-1002 in discriminatory dissolution media
% Drug release
% Drug release
0
20
40
60
80
100
120
140
N4600335
4759-51-698A
4759-31-110

FIG. 6

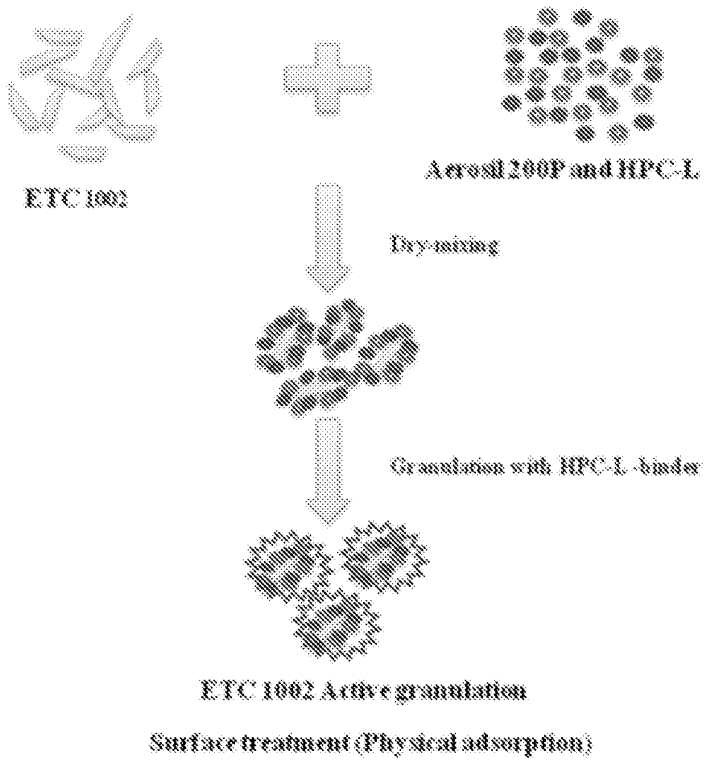

ETC 1002
Aerosil 200P and HPC-L
Dry-mixing
Granulation with HPC-L -binder
ETC 1002 Active granulation
Surface treatment (Physical adsorption)

FIG. 7

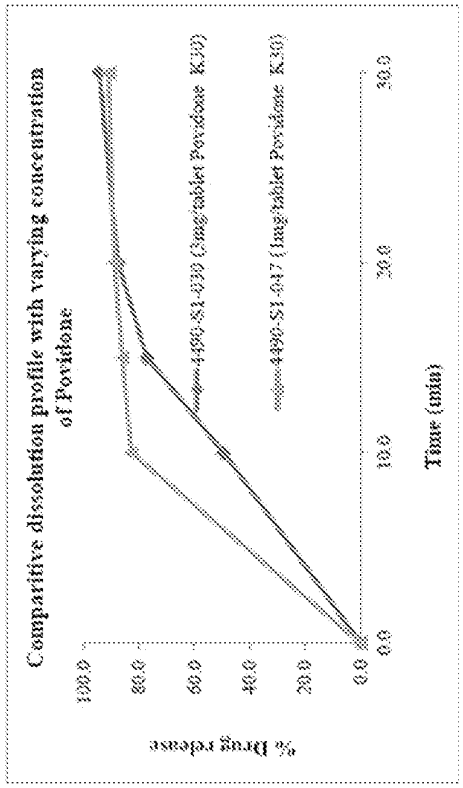

Comparitive dissolution profile with varying concentration of Povidone
% Drug release
100.0
80.0
60.0
40.0
20.0
0.0
0.0
10.0
20.0
30.0
Time (min)
4490-S1-039 (5mg/tablet Povidone K30)
4490-S1-047 (1mg/tablet Povidone K30)

FIG. 8

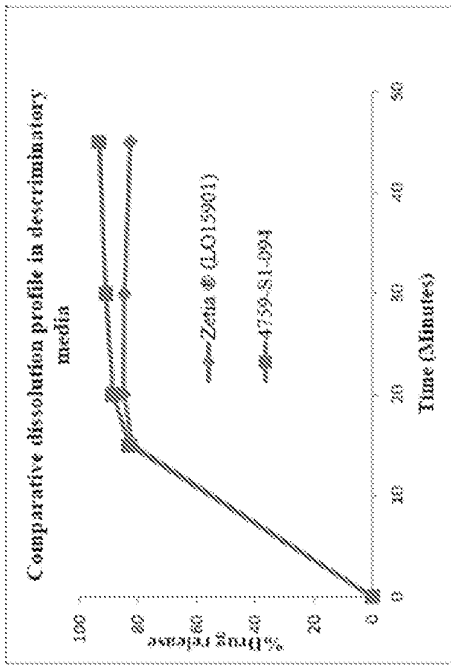

Comparative dissolution profile in descriminatory media
% Drug release
100
80
60
40
20
0
0
10
20
30
40
50
Time (Minutes)
Zeta ® (LO15901)
4759-81-094

FIG. 9

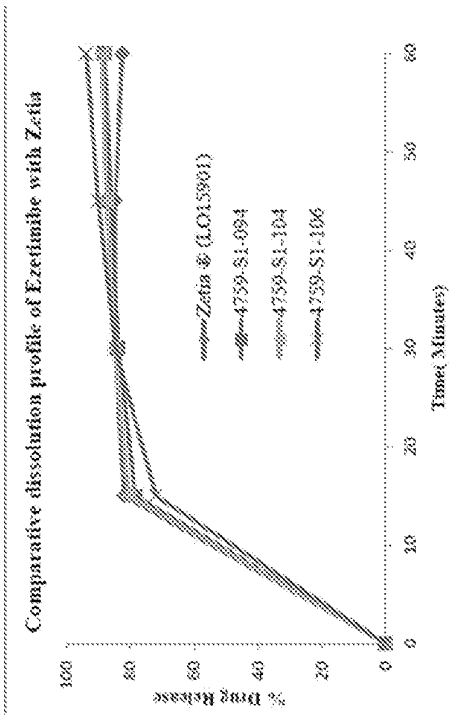

Comparative dissolution profile of Ezetimibe with Zetia
% Drug Release
Time(Minutes)
Zetia ® (LOT:5901)
4759-S1-094
4759-S1-104
4759-S1-106
0
20
40
60
80
100
0
10
20
30
40
50
60

FIG. 10

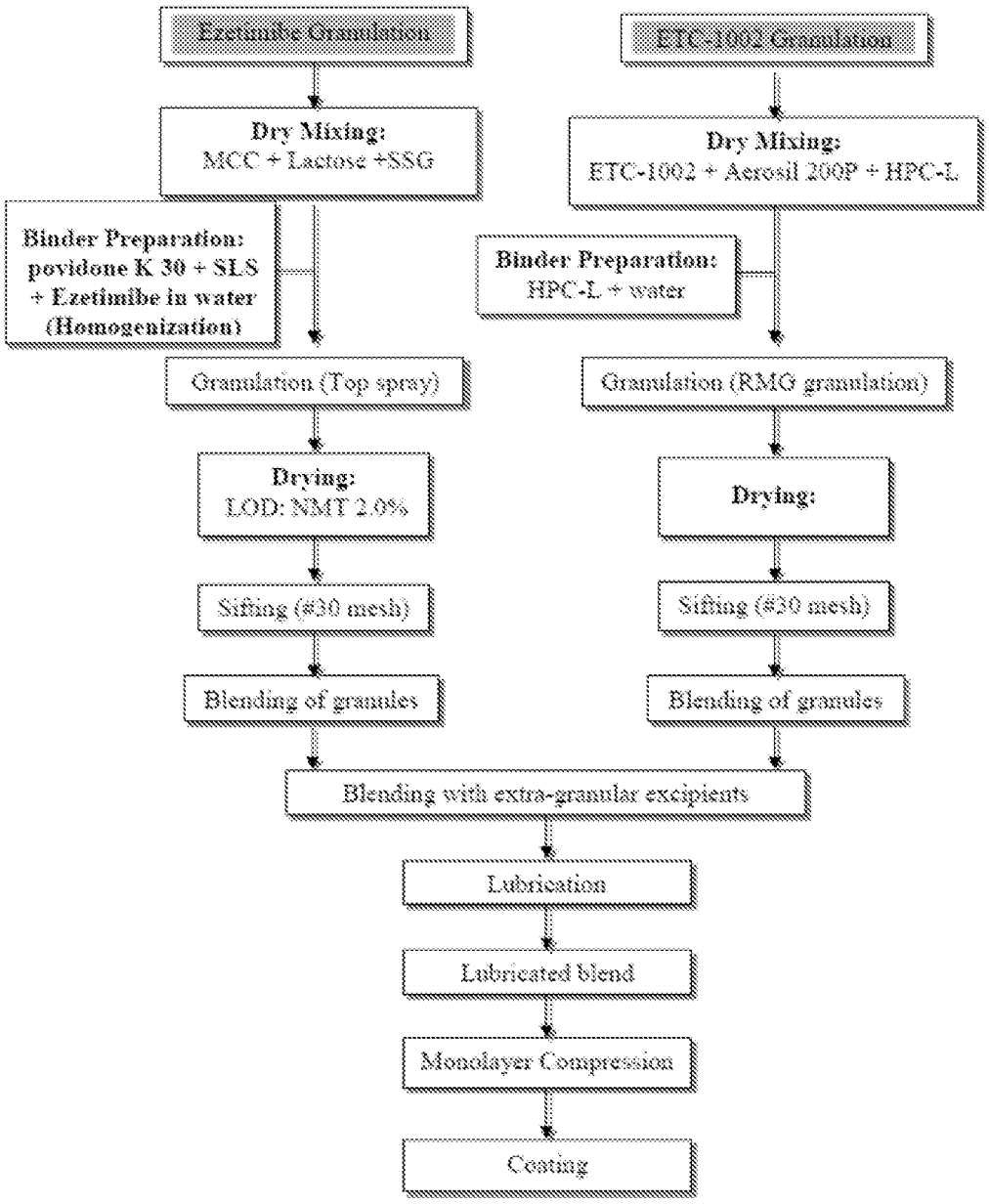

Ezetimibe Granulation
Dry Mixing:
MCC + Lactose +SSG
Binder Preparation:
povidone K 30 + SLS
+ Ezetimibe in water
(Homogenization)
Granulation (Top spray)
Drying:
LOD: NMT 2.0%
Sifting (#30 mesh)
Blending of granules
ETC-1002 Granulation
Dry Mixing:
ETC-1002 + Aerosil 200P + HPC-L
Binder Preparation:
HPC-L + water
Granulation (RMG granulation)
Drying:
Sifting (#30 mesh)
Blending of granules
Blending with extra-granular excipients
Lubrication
Lubricated blend
Monolayer Compression
Coating

FIG.11

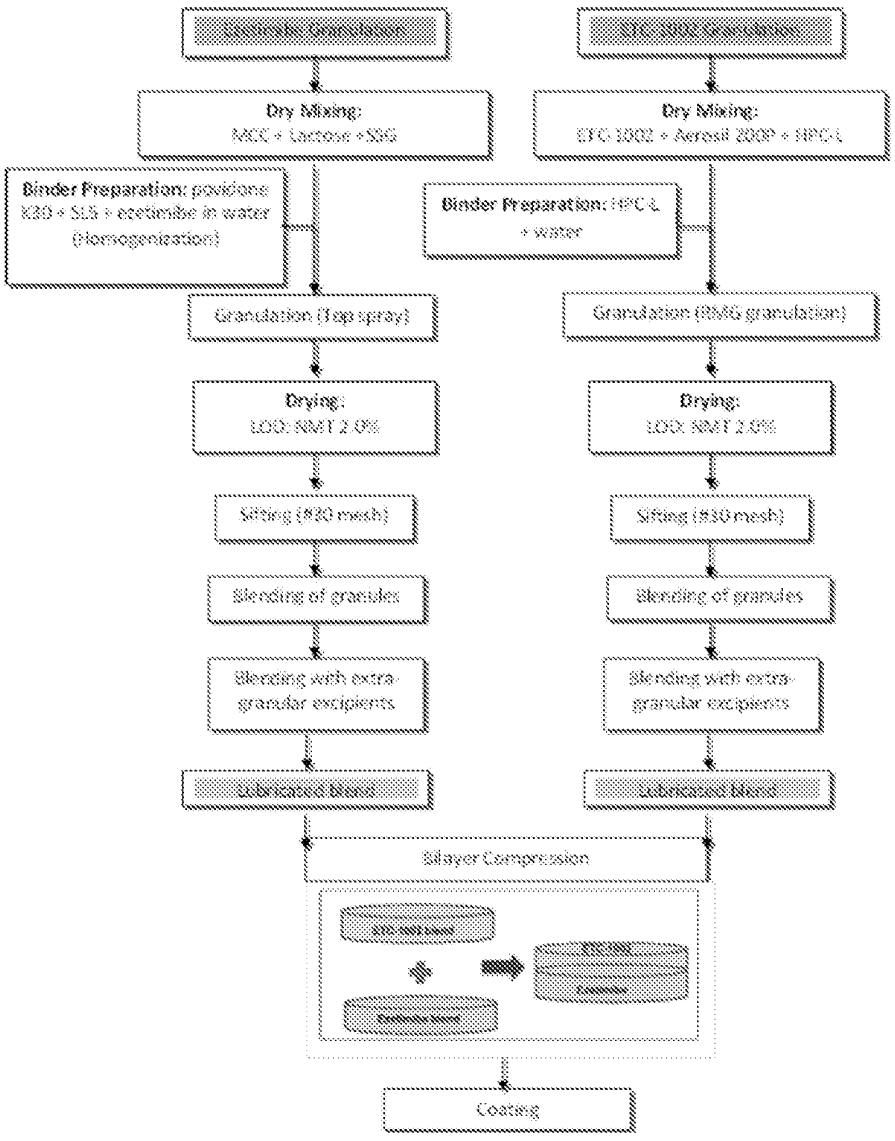

Dry Mixing:
MCC + Lactose +SSG
Dry Mixing:
EFC 1002 + Aerosil 200P + HPC-L
Binder Preparation: povidone K30 + SLS + ecetinibe in water (Homogenization)
Binder Preparation: HPC-L + water
Granulation (Top spray)
Granulation (RMG granulation)
Drying:
LOD: NMT 2.0%
Drying:
LOD: NMT 2.0%
Sifting (#30 mesh)
Sifting (#30 mesh)
Blending of granules
Blending of granules
Blending with extra-granular excipients
Blending with extra-granular excipients
Lubricated blend
Lubricated blend
Bilayer Compression
Coating

FIG.12

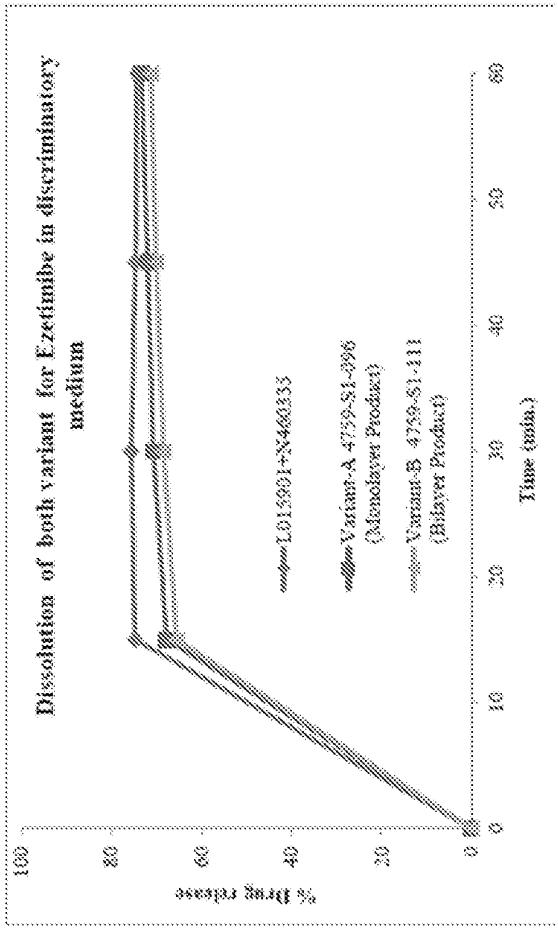

Dissolution of both variant for Ezetimibe in discriminatory medium
% Drug release
Time (min.)
0
10
20
30
40
50
60
0
20
40
60
80
100
LD15901+X460335
Variant-A 4739-51-096 (Monolayer Product)
Variant-B 4739-51-111 (Bilayer Product)

FIG. 13

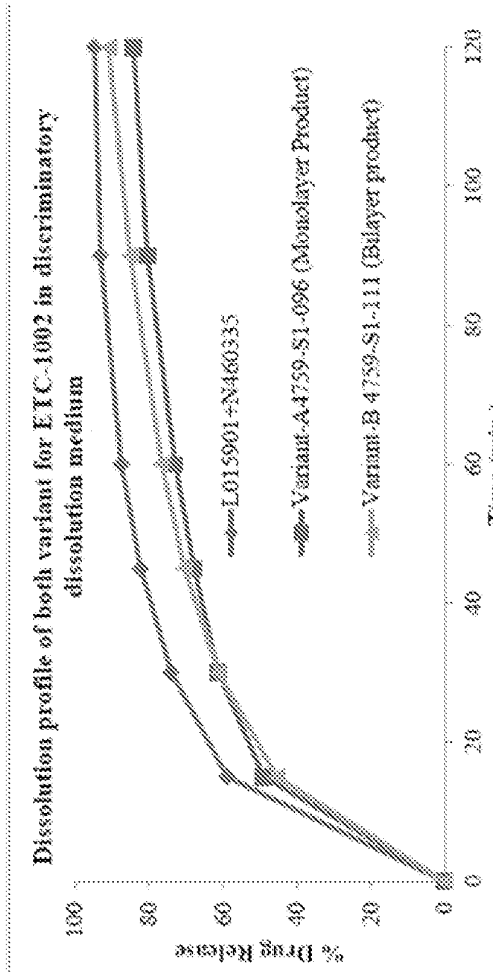

Dissolution profile of both variant for ETC-1002 in discriminatory dissolution medium
% Drug Release
Time (min.)
0
20
40
60
80
100
120
L015901+N460335
Variant-A4759-S1-096 (Monolayer Product)
Variant-B 4759-S1-111 (Bilayer product)

FIG. 14

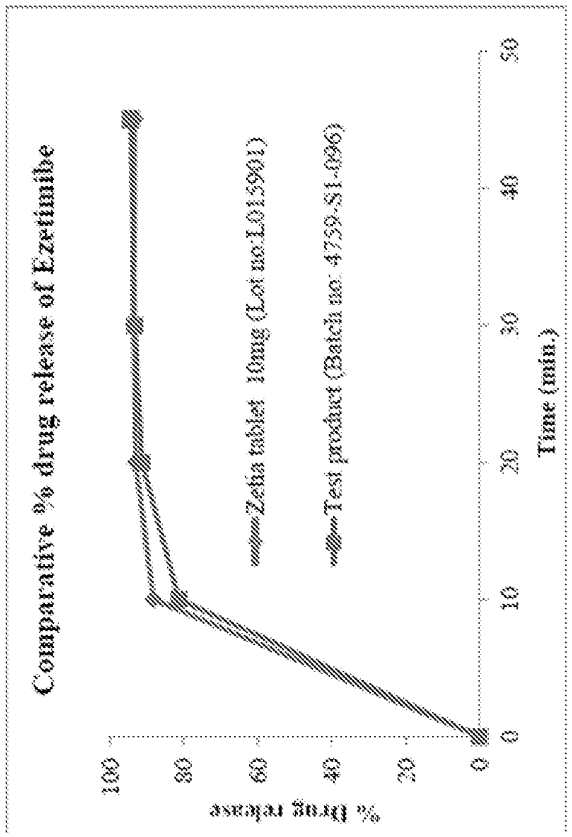

Comparative % drug release of Ezetimibe
Zeba tablet 10mg (Lot no L015901)
Test product (Batch no 4759-S1-096)
% Drug release
Time (min.)
0
20
40
60
80
100
0
10
20
30
40
50

FIG. 15

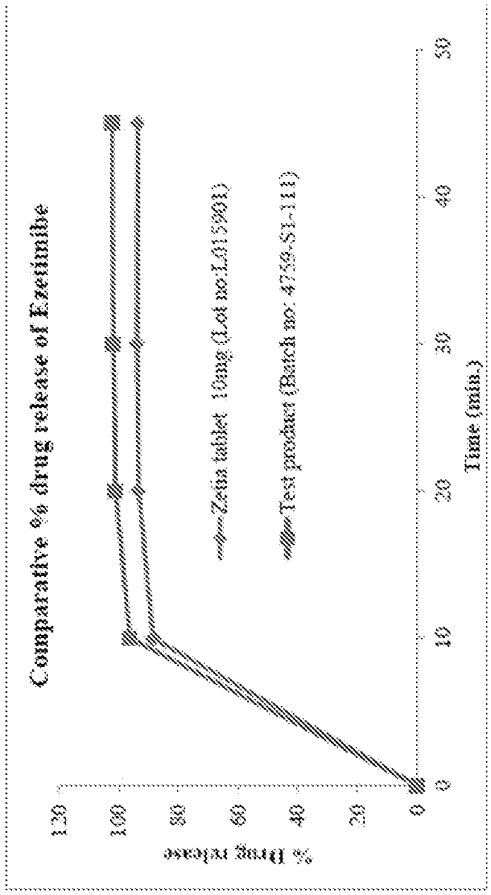

Comparative % drug release of Ezetimibe
% Drug release
120
100
80
60
40
20
0
0
10
20
30
40
50
Time (min.)
Zetia tablet 10mg (Lot no:LG015901)
Test product (Batch no: 4759-51-111)

FIG. 16

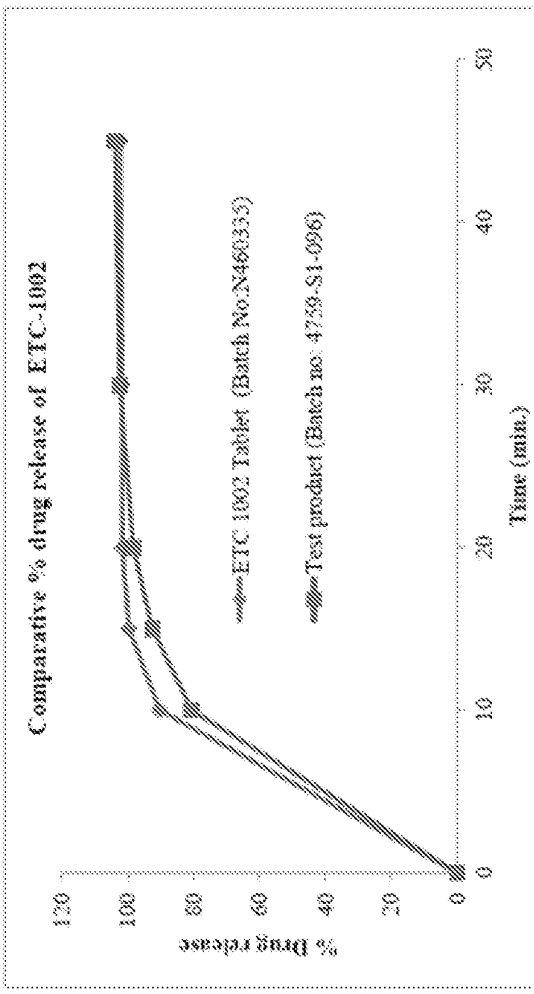

Comparative % drug release of ETC-1002
ETC 1002 Tablet (Batch No:N460353)
Test product (Batch no: 4759-S1-096)
% Drug release
Time (min.)
0
20
40
60
80
100
120
0
10
20
30
40
50

FIG. 17

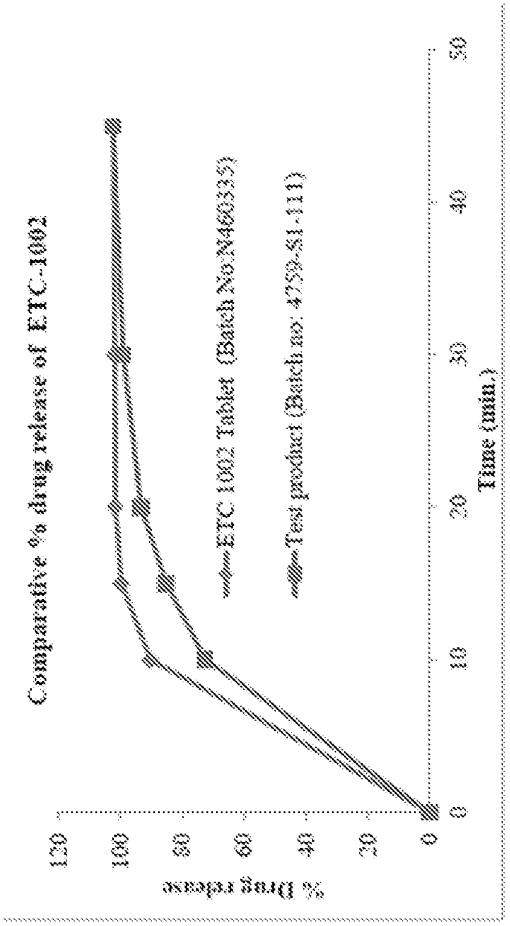

Comparative % drug release of ETC-1002
% Drug release
120
100
80
60
40
20
0
0
10
20
30
40
50
Time (min.)
ETC 1002 Tablet (Batch No:N460335)
Test product (Batch no: 4759-81-111)

FIG. 18