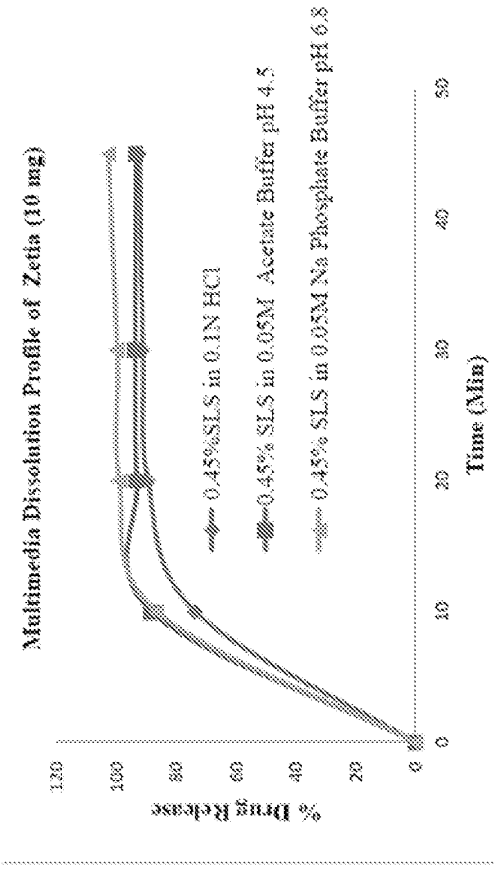

Multimedia Dissolution Profile of Zetia (10 mg)
0.45%SLS in 0.1N HCl
0.45% SLS in 0.05M Acetate Buffer pH 4.5
0.45% SLS in 0.05M Na Phosphate Buffer pH 6.8
% Drug Release
Time (Min)
0
20
40
60
80
100
120
0
10
20
30
40
50

FIG. 1

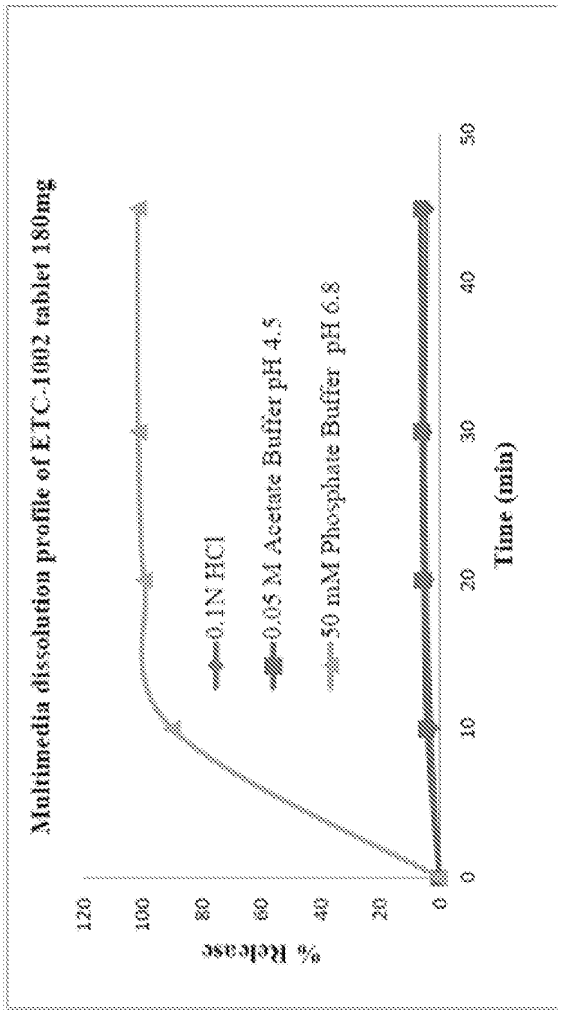

Multimedia dissolution profile of ETC-1002 tablet 180mg
0.1N HCl
0.05 M Acetate Buffer pH 4.5
50 mM Phosphate Buffer pH 6.8
% Release
Time (min)
0
20
40
60
80
100
120
0
10
20
30
40
50

FIG. 2

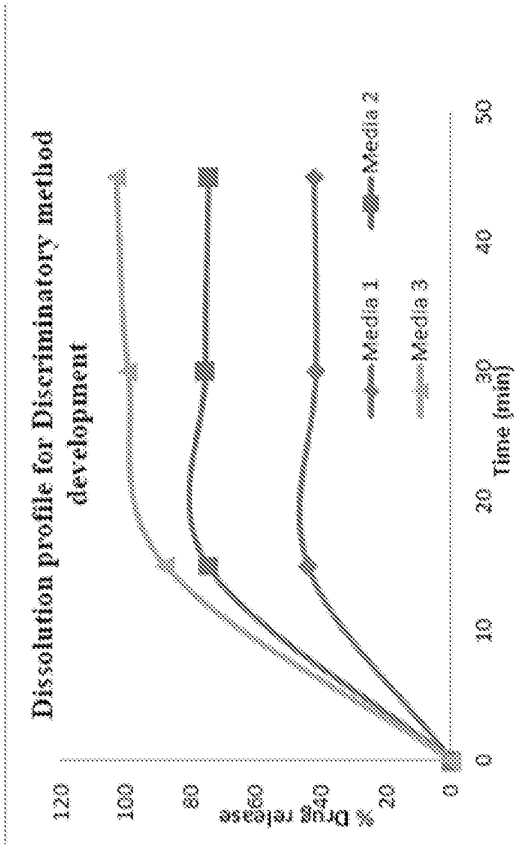

Dissolution profile for Discriminatory method development
% Drug release
Time (min)
0
20
40
60
80
100
120
0
10
20
30
40
50
Media 1
Media 2
Media 3

FIG. 3

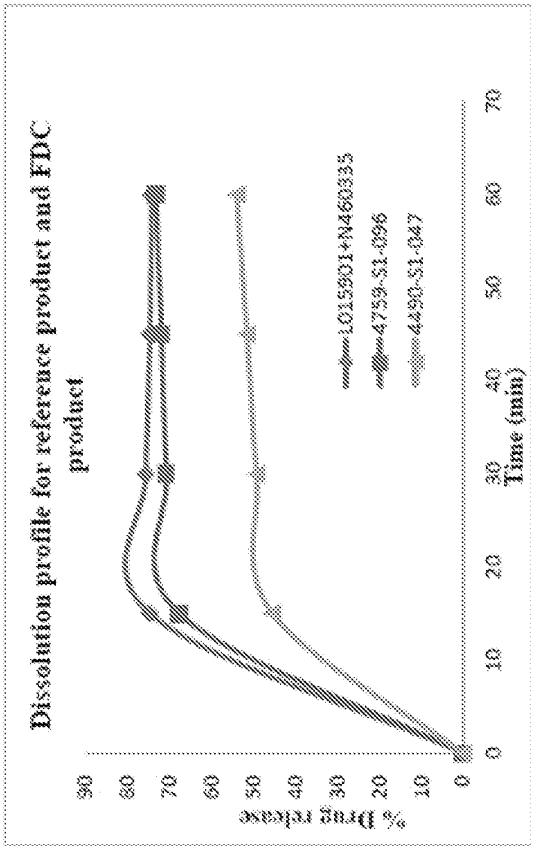

Dissolution profile for reference product and FDC product
% Drug release
Time (min)
0
10
20
30
40
50
60
70
80
90
LO15901+N460335
4759-S1-096
4490-S1-047

FIG. 4

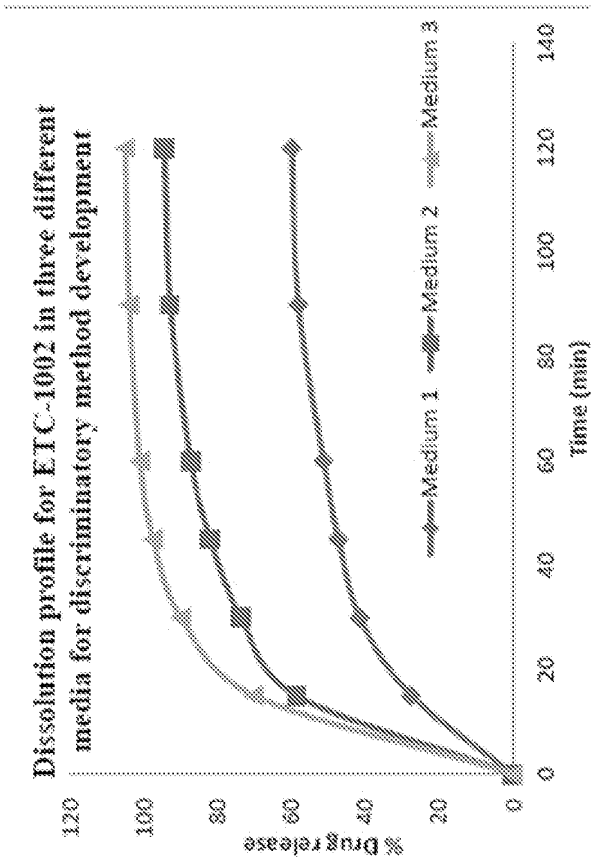

Dissolution profile for ETC-1002 in three different media for discriminatory method development
% Drug release
Time (min)
Medium 1
Medium 2
Medium 3
0
20
40
60
80
100
120
140

FIG. 5

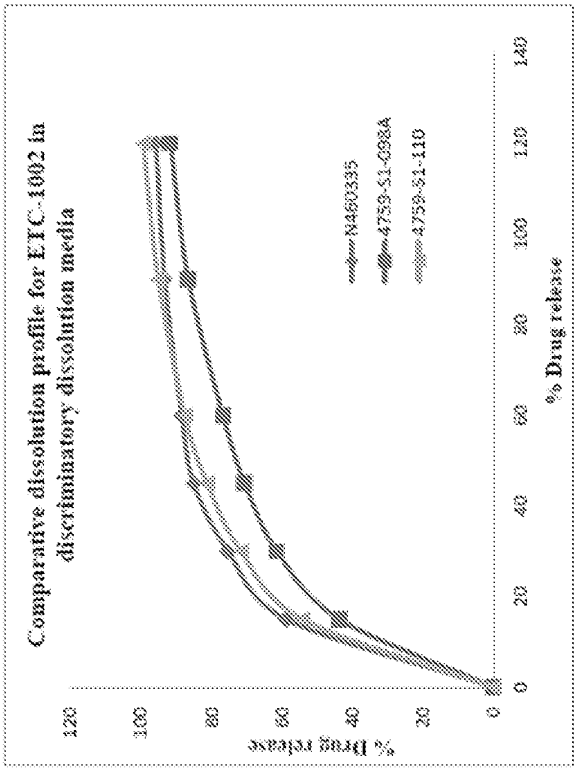

Comparative dissolution profile for ETC-1002 in discriminatory dissolution media
% Drug release
% Drug release
0
20
40
60
80
100
120
140
M460335
4759-51-6984
4759-51-110

FIG. 6

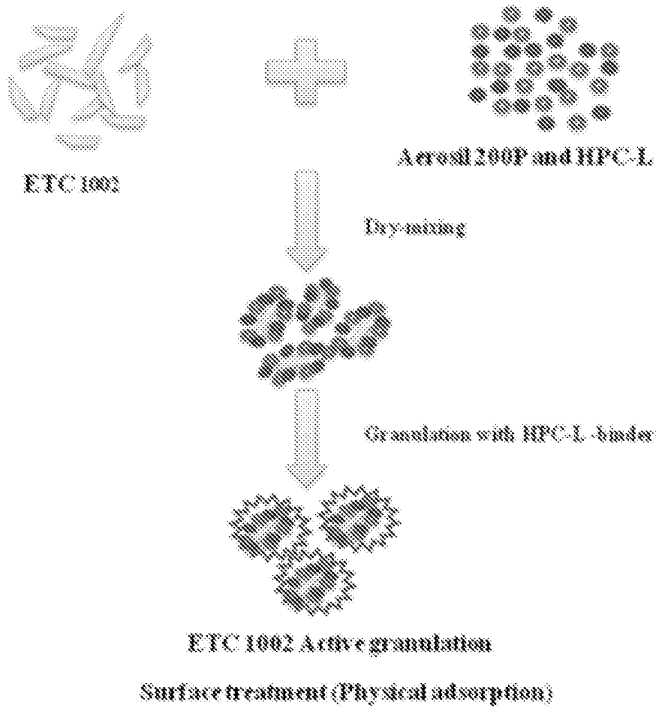

ETC 1002
Aerosil 200P and HPC-L
Dry-mixing
Granulation with HPC-L-binder
ETC 1002 Active granulation
Surface treatment (Physical adsorption)

FIG. 7

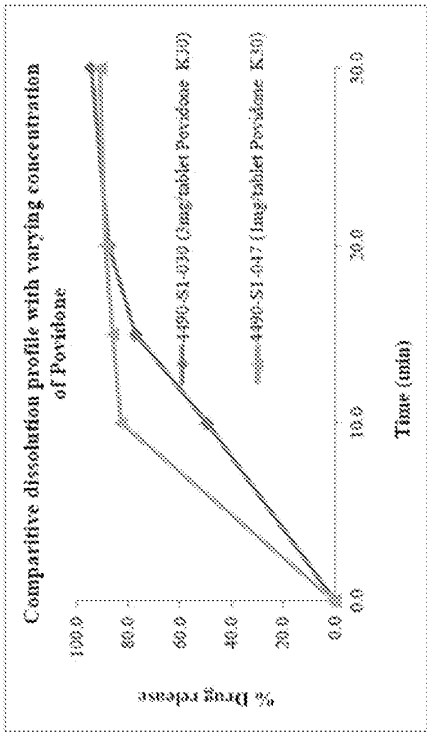

Comparitive dissolution profile with varying concentration of Povidone
% Drug release
100.0
80.0
60.0
40.0
20.0
0.0
0.0
10.0
20.0
30.0
Time (min)
4496-S1-030 (5mg tablet Povidone K30)
4496-S1-047 (1mg tablet Povidone K30)

FIG. 8

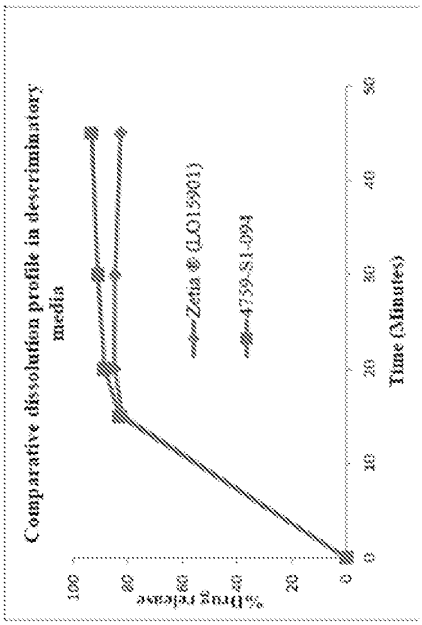

Comparative dissolution profile in descriminatory media
% Drug release
Time (Minutes)
Zeta ® (L0159001)
4739-84-099
0
20
40
60
80
100
0
10
20
30
40
50

FIG. 9

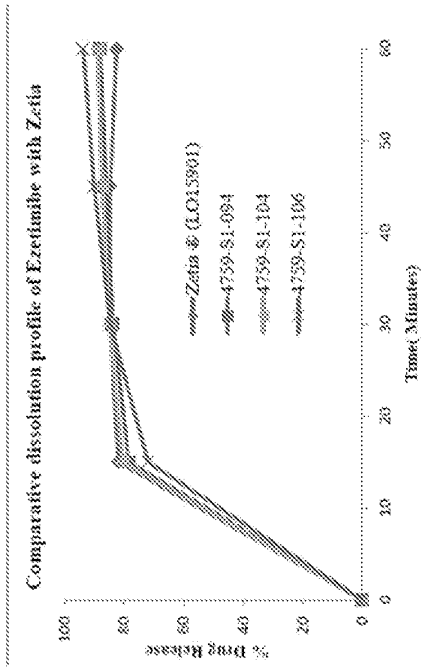

Comparative dissolution profile of Ezetimibe with Zetia
Zetia @ (LOT5901)
4759-81-094
4759-81-104
4759-81-106
% Drug Release
Time(Minutes)
0
20
40
60
80
100
0
10
20
30
40
50
60

FIG. 10

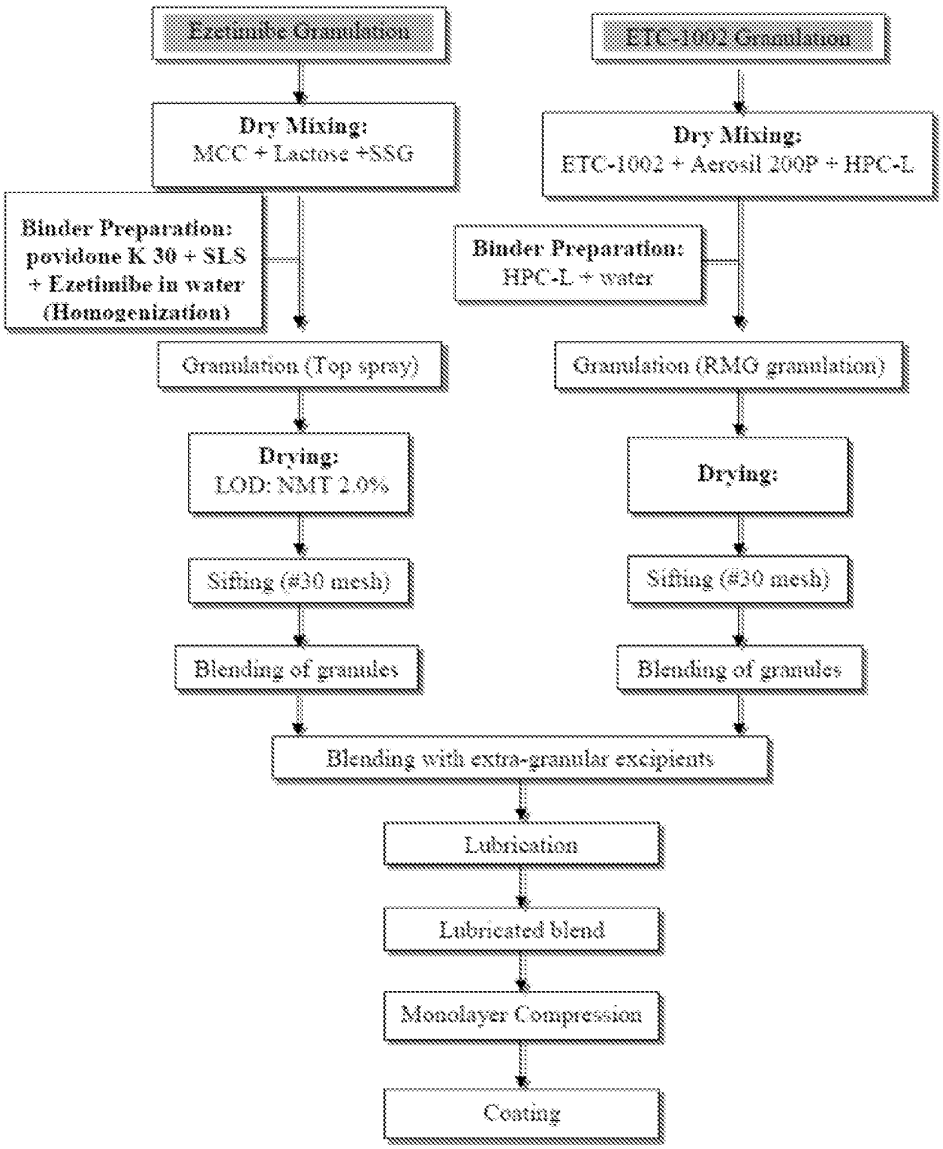

Ezetimibe Granulation
ETC-1002 Granulation
Dry Mixing:
MCC + Lactose +SSG
Dry Mixing:
ETC-1002 + Aerosil 200P + HPC-L
Binder Preparation:
povidone K 30 + SLS
+ Ezetimibe in water
(Homogenization)
Binder Preparation:
HPC-L + water
Granulation (Top spray)
Granulation (RMG granulation)
Drying:
LOD: NMT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

FIG.11

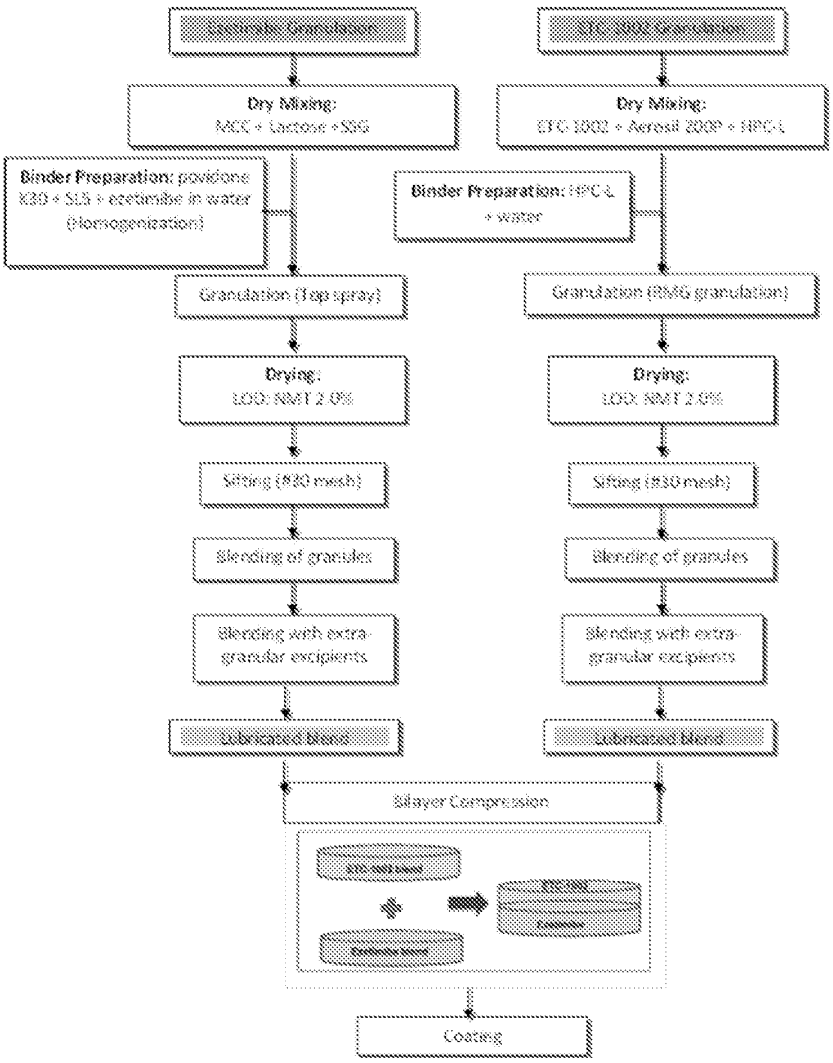

Dry Mixing:
MCC + Lactose + SSG
Dry Mixing:
Binder Preparation: povidone
Binder Preparation: HPC-L
+ water
Granulation (Top spray)
Granulation (RMG granulation)
Drying:
LOD: NMT 2.0%
Drying:
LOD: NMT 2.0%
Sifting (#20 mesh)
Sifting (#30 mesh)
Blending of granules
Blending of granules
Blending with extra-granular excipients
Blending with extra-granular excipients
Lubricated Blend
Lubricated Blend
Bilayer Compression
Coating

FIG.12

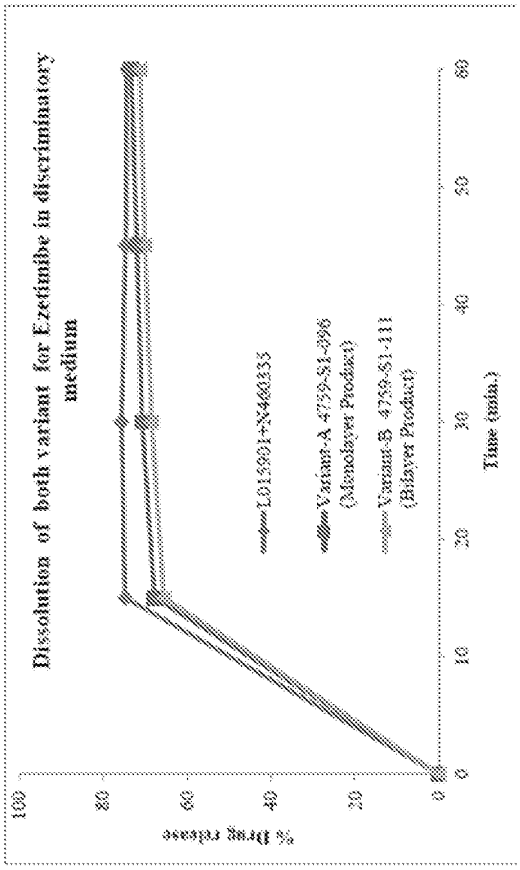

Dissolution of both variant for Ezetimibe in discriminatory medium
% Drug release
Time (min.)
0
20
40
60
80
100
0
10
20
30
40
50
60
L015901+X460335
Variant-A 4759-81-096 (Mendeyn Product)
Variant-B 4759-81-111 (Bayer Product)

FIG. 13

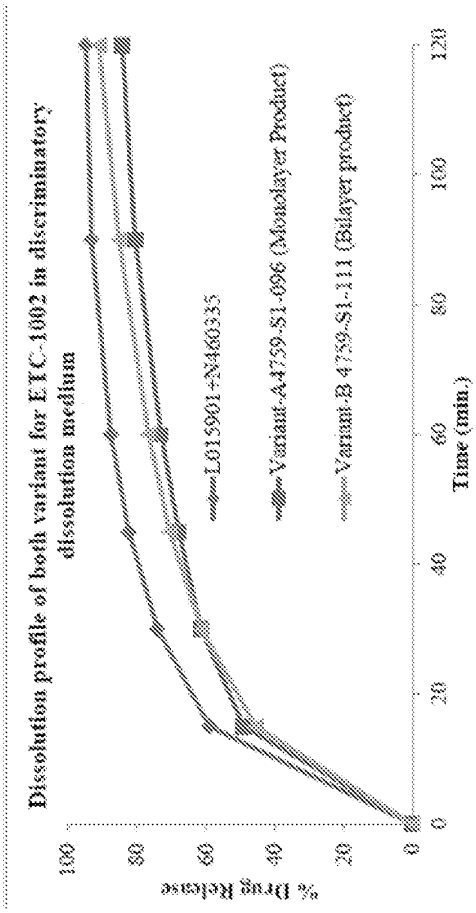

Dissolution profile of both variant for ETC-1002 in discriminatory dissolution medium
% Drug Release
Time (min.)
0
20
40
60
80
100
120
L015901+N460335
Variant-A4759-S1-096 (Monolayer Product)
Variant-B 4759-S1-111 (Bilayer product)

FIG. 14

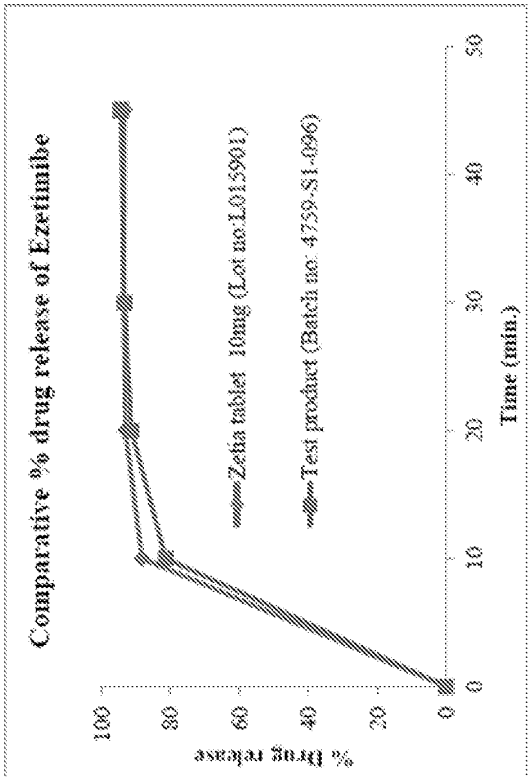

Comparative % drug release of Ezetimibe
% drug release
Time (min.)
Zeba tablet 10mg (Lot no:L015901)
Test product (Batch no: 4759-81-096)
0
20
40
60
80
100
0
10
20
30
40
50

FIG. 15

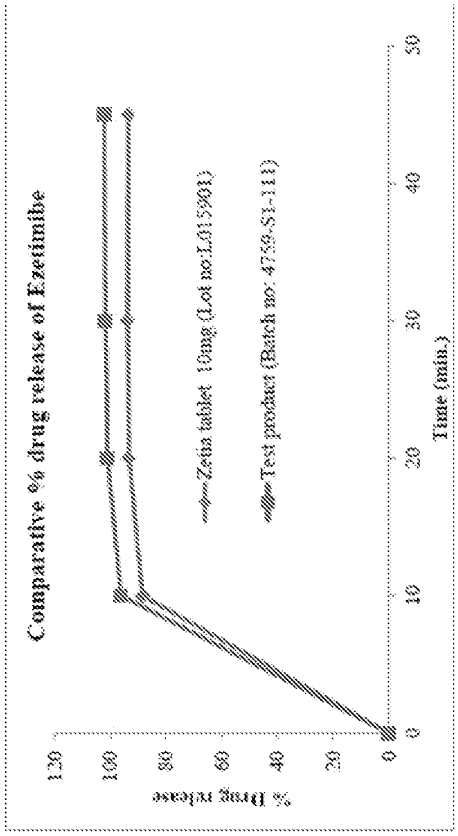

Comparative % drug release of Ezetimibe
Zetia tablet 10mg (Lot no:L015901)
Test product (Batch no: 4759-S1-111)
% Drug release
Time (min.)
0
20
40
60
80
100
120
0
10
20
30
40
50

FIG. 16

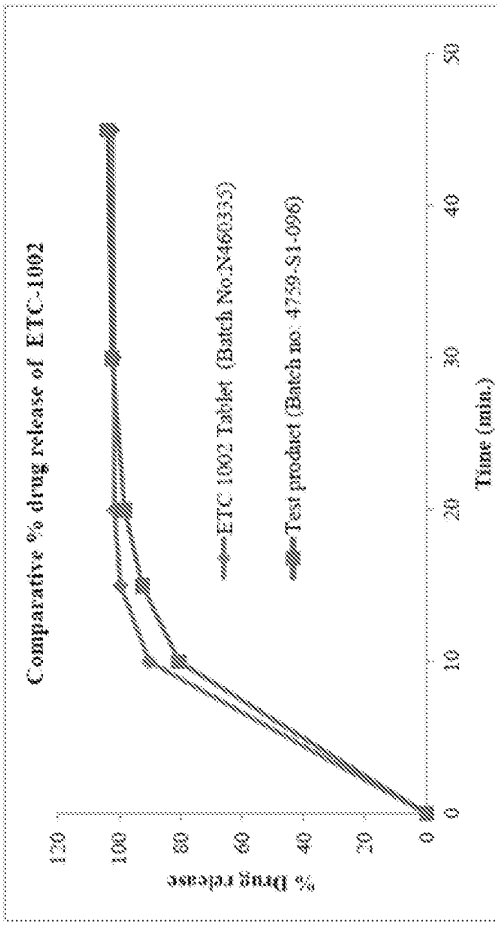

Comparative % drug release of ETC-1002
% Drug release
Time (min.)
ETC 1002 Tablet (Batch No:N460335)
Test product (Batch no: 4759-S1-096)
0
20
40
60
80
100
120
0
10
20
30
40
50

FIG. 17

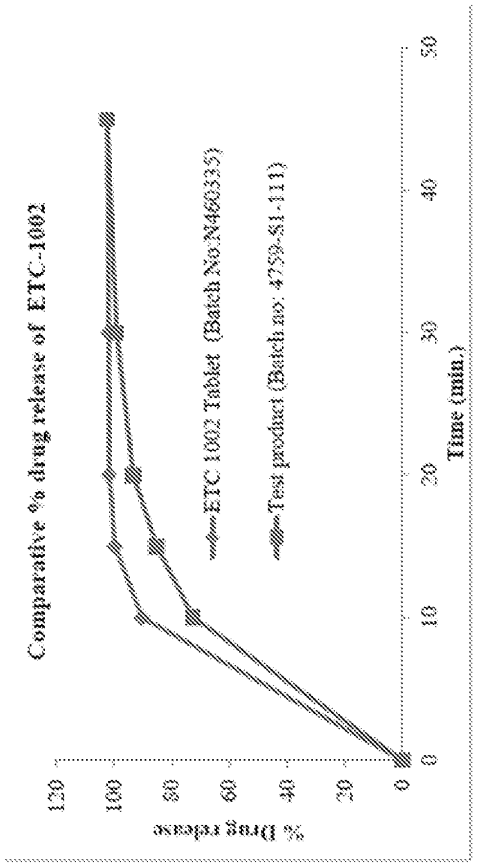

Comparative % drug release of ETC-1002
ETC 1002 Tablet (Batch No.N460335)
Test product (Batch no: 4759-81-111)
% Drug release
Time (min.)
0
20
40
60
80
100
120
0
10
20
30
40
50

FIG. 18