We Claim:

1. A ~~controlled-release~~ formulation comprising a controlled-release portion comprising Drotaverine or a salt thereof, at least one polymer ~~or mixture of polymers~~, at least one acidifying agent, and at least one pharmaceutically acceptable excipient~~, wherein said formulation comprises at least one acidifying agent and from 0 to 10% by weight of anti-oxidants~~.

2. The formulation of claim 1, further comprising an immediate release portion comprising drotaverine or a salt thereof.

3. The formulation of claim 1, further comprising an antioxidant.

4~~2~~. The formulation of claim 1, wherein the formulation comprises ~~about~~ 10 mg to ~~about~~ 300 mg of Drotaverine or salt thereof.

~~3. The formulation of claim 1 or 2, wherein the formulation comprises Drotaverine or salt thereof in the range of 15% to 60% (w/w) of the formulation.~~

5~~4~~. The formulation of claim 4~~any of the preceding claims~~, wherein the Drotaverine salt is Drotaverine hydrochloride.

~~5. The formulation of claim 1, wherein said at least one acidifying agent is selected from the group consisting of Citric acid, Fumaric acid, Lactic acid, Maleic acid, Malic acid, Tartaric acid, and a combination thereof.~~

6. The formulation of claim 4~~1~~, wherein the at least one polymer ~~or mixture of polymers~~ is chosen ~~selected~~ from ~~the group consisting of Hypromellose,~~ Hydroxyethyl Cellulose, Hydroxypropyl Cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose, methyl cellulose, sodium carboxymethyl cellulose or salts thereof, Ethyl Cellulose, a Carbomer~~s~~, a Methacrylic acid~~s~~, a Polyethylene Oxide~~s (PEO)~~, or~~and~~ a combination thereof.

7. The formulation of claim 6, wherein the at least one polymer comprises hydroxypropyl methylcelluloseis Polyethylene oxide (PEO).

8. The formulation of claim 6, wherein the at least one polymer or combination thereof comprises 5-30% (w/w) of the formulation.

9. The formulation of claim 7, wherein the hydroxypropyl methylcellulose has a viscosity from 100-150,000 cP.

108. The formulation of claim 6, wherein the polymer or mixture of polymers is hydroxypropyl methylcellulose having an apparent viscosity ranging from about 100-150,000 cP, wherein, optionally, the at least one polymer or mixture of polymers iscomprises K100, K4M, K15M, K100M, E4M, E10M, or Methocel K100M CR, or a combination thereof.

9. The formulation of any one of the preceding claims, wherein the formulation comprises controlled-release polymer in the range of 05% to 30% (w/w) of the formulation.

11. The formulation of claim 4, wherein the at least one acidifying agent is chosen from Citric acid, Fumaric acid, Lactic acid, Maleic acid, Malic acid, or Tartaric acid, or a combination thereof.

1210. The formulation of claim 41, wherein the at least one pharmaceutically acceptable excipient is chosen from selected from the group consisting of a gums, a fillers, a flow aids, a lubricants, a disintegrants, a diluents, a binders, lubricants,or a glidants, and or a combination thereof.

13. The formulation of claim 3, wherein the antioxidant comprises up to 10% w/w of the controlled-release formulation.

14. The formulation of claim 13, wherein the antioxidant is chosen butylated hydroxyanisole, butylated hydroxytoluene, sodium metabisulfite, sodium thiosulfate, propyl gallate, ascorbic acid, or cysteine.

~~11. The formulation of claim 10, wherein:~~

~~the gums are selected from the group consisting of xanthan gum, karaya gum, locust bean gum, alginic acid, sodium alginate, acrylic polymers, and a combination thereof;~~
~~the diluents are selected from the group consisting of microcrystalline cellulose, lactose, dicalcium phosphate, starch, and a combination thereof;~~
~~the binders are selected from the group consisting of starch, polyvinylpyrrolidone, natural or synthetic gum, cellulosic polymers, and a combination thereof;~~
~~the lubricants and glidants are selected from the group consisting of talc, colloidal silicon dioxide, magnesium stearate, and a combination thereof; and~~
~~the disintegrants are selected from the group consisting of Sodium Starch Glycollate, Croscarmellose Sodium, Crospovidone, and a combination thereof.~~

~~12. The formulation of any one of the preceding claims, wherein the formulation is for oral delivery.~~

~~13. The formulation of claim 12, wherein the formulation is a tablet, mini-tablet, MUPS (Multiple-Unit Pellet System) tablet or capsule.~~

~~14. The formulation of claim 13, wherein the formulation is in the form of single layered, bi-layered, multi-layered, coated, uncoated, or multi-coated pellets, granulates, or beads, which can be filled into capsules or compressed to tablets.~~

~~15. The formulation of any of the preceding claims, wherein the formulation comprises a controlled release portion and an immediate release portion.~~

15~~6~~. The formulation of claim 4~~any of the preceding claims~~, further ~~wherein the formulation optionally~~ comprisinge~~s~~ a ~~functional or non-functional~~ coating.

~~17. The formulation of any one of claims 13 to 16, wherein the tablet or capsule is prepared by a wet granulation, dry granulation/slugging or direct compression process.~~

~~18. The formulation of any one of claims 13 to 17, wherein the capsule comprises shells prepared by gelatin or non-gelatin based materials.~~

~~19. The formulation of any one of the preceding claims, wherein the formulation releases Drotaverine or salt thereof for at least 24 hours.~~

~~20. The formulation of any one of the preceding claims, wherein the formulation elicits a minimum effective concentration in plasma of a subject similar to immediate release dosage form within about 1 hour and the rest of the drug is gradually released over a period of about 12-24 hours to maintain the drug concentration within the therapeutic window of Drotaverine.~~

16~~21~~. The formulation of claim 4~~any one of the preceding claims~~, wherein the formulation has a dissolution release profile *in vitro* using the USP II Method of 25% to 40% after ~~about~~ 1 hour, 30% to 50% after ~~about~~ 2 hours, 40% to 65% after ~~about~~ 4 hours, 60% to 85% after ~~about~~ 8 hours, or ~~and~~ not less than about 85% after ~~about~~ 16 hours.

17~~22~~. A ~~controlled-release~~ formulation comprising Drotaverine hydrochloride~~or a salt thereof~~, HPMC K4M, Methacrylic acid~~a polymer or mixture of polymers~~, citric acid, and sodium metabisulphite~~at least one pharmaceutically acceptable excipient~~.

~~23. A formulation of claim 22 wherein the formulation comprises about 10 to about 300 mg of Drotaverine or salt thereof.~~

~~24. The formulation of claim 23, wherein the formulation comprises Drotaverine or salt thereof in the range of 15% to 60% (w/w) of the formulation.~~

~~25. The formulation of any one of claims 22 to 24, wherein the Drotaverine salt is Drotaverine hydrochloride.~~

~~26. The formulation of claim 22, wherein the polymer or mixture of polymers is selected from the group consisting of Hypromellose, Hydroxyethyl Cellulose, Hydroxypropyl~~

~~Cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose, methyl cellulose, sodium carboxymethyl cellulose or salts thereof, Ethyl Cellulose, Carbomers, Methacrylic acids, Polyethylene Oxides (PEO), and a combination thereof.~~

~~27. The formulation of claim 26, wherein the polymer or mixture of polymers is hydroxypropyl methylcellulose having an apparent viscosity ranging from about 100-150,000 cP, wherein, optionally, the polymer or mixture of polymers is K100, K4M, K15M, K100M, E4M, E10M, Methocel K100M CR, or a combination thereof.~~

~~28. The formulation of any one of claims 22 to 27, wherein the formulation comprises controlled-release polymer in the range of 05% to 30% (w/w) of the formulation.~~

~~29. The formulation of claim 22, wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of gums, fillers, flow aids, lubricants, disintegrants, diluents, binders, lubricants, glidants, and a combination thereof.~~

~~30. The formulation of claim 29, wherein:~~

~~the gums are selected from the group consisting of xanthan gum, karaya gum, locust bean gum, alginic acid, sodium alginate, acrylic polymers, and a combination thereof;~~
~~the diluents are selected from the group consisting of microcrystalline cellulose, lactose, dicalcium phosphate, starch, and a combination thereof;~~
~~the binders are selected from the group consisting of starch, polyvinylpyrrolidone, natural or synthetic gum, cellulosic polymers, and a combination thereof;~~
~~the lubricants and glidants are selected from the group consisting of talc, colloidal silicon dioxide, magnesium stearate, and a combination thereof; and~~
~~the disintegrants are selected from the group consisting of Sodium Starch Glycollate, Croscarmellose Sodium, Crospovidone, and a combination thereof.~~

~~31. The formulation of any one of claims 22 to 30, wherein the formulation is for oral delivery.~~

~~32. The formulation of claim 31, wherein the formulation is a tablet, mini-tablet, MUPS (Multiple-Unit Pellet System) tablet or capsule.~~

~~33. The formulation of claim 32, wherein the formulation is in the form of single layered, bi-layered, multi-layered, coated, uncoated, or multi-coated pellets, granulates, or beads, which can be filled into capsules or compressed to tablets.~~

~~34. The formulation of any of one of claims 22 to 33, wherein the formulation comprises a controlled release portion and an immediate release portion.~~

~~35. The formulation of any of claims 22 to 34, wherein the formulation optionally comprises a functional or non-functional coating.~~

~~36. The formulation of any one of claims 22 to 35, wherein the formulation elicits a minimum effective concentration in plasma of a subject similar to immediate release dosage form within about 1 hour and the rest of the drug is gradually released over a period of about 12-24 hours to maintain the drug concentration within the therapeutic window of Drotaverine.~~

~~37. The formulation of any one of claims 22 to 36, wherein the formulation has a dissolution release profile *in vitro* of 25% to 40% after about 1 hour, 30% to 50% after about 2 hours, 40% to 65% after about 4 hours, 60% to 85% after about 8 hours and not less than about 85% after about 16 hours.~~

18~~38~~. A method of preparing a single-layer controlled-release tablet comprising Drotaverine or a salt thereof, the method comprising:

(a) sieving and dry mixing Drotaverine or salt thereof with an acidifying agent, polymer and excipient to obtain a drug-excipient blend;

(b) sieving and mixing extra-granular ingredients with the drug-excipient blend to obtain a formulation; and

(c) compressing the formulation to form the tablet.

19~~39~~. A method of preparing a single or multi-layer controlled-release tablet comprising Drotaverine or a salt thereof, the method comprising:

(a) sieving and dry mixing Drotaverine or salt thereof with an acidifying agent, polymer and excipient to obtain a drug-excipient blend~~dry mix~~;

(b) granulating the blend ~~dry mix~~ with a binder solution comprising at least polyvinylpyrrolidone and isopropyl alcohol to obtain granules;

(c) drying the granules to obtain ~~a desired Loss-on Drying of the~~ dried granules;

(d) milling the dried granules followed by sieving to obtain granules of specific size; and

~~(e)~~ sieving extra-granular ingredients followed by mixing with the granules of specific size to obtain a formulation; and

~~(f)~~(e) compressing the formulation to form the tablet.

~~40. The method of claim 38 or 39, further comprising coating the tablet with one or more functional or non-functional coatings.~~

20~~41~~. Use of the formulation as claimed in claim 1 in the manufacture of a medicament for the treatment of ~~A method of treating~~ at least one symptom of gastrointestinal, biliary, urological, ~~and~~ or gynecological disorder~~s~~ characterized by spastic conditions of smooth muscles~~, for instance, irritable bowel syndrome, biliary colics, cholecystolithiasis, cholecystitis, cholangitis, renal colics, nephrolithiasis, ureterolithiasis, pyelitis, cystitis, dysmenorrhoea, imminent abortion, or uterine tetanus~~ in a subject in need thereof, comprising the formulation as claimed in claim 1 to be administered~~ing~~ to the subject ~~the formulation as claimed in any one of the claims 1 to 21 or 22 to 37~~ .

~~42. The method of claim 41, wherein the formulation is administered as single layer, bi-layered, multi-layered, uncoated, coated or multicoated pellets, beads, or granules in tablet or capsule form.~~

~~43. Use of a formulation of any of claims 1 to 21, or 22 to 37 for treating at least one symptom of a gastrointestinal, biliary, urological or gynecological disorder characterized by spastic conditions of smooth muscles in a subject, comprising administering the formulation to the subject.~~

21. The use of claim 20, wherein the disorder comprises irritable bowel syndrome, biliary colics, cholecystolithiasis, cholecystitis, cholangitis, renal colics, nephrolithiasis, ureterolithiasis, pyelitis, cystitis, dysmenorrhoea, imminent abortion, or uterine tetanus.

22. Use of the formulation as claimed in claim 17 in the manufacture of a medicament for the treatment of at least one symptom of gastrointestinal, biliary, urological, or gynecological disorder characterized by spastic conditions of smooth muscles in a subject in need thereof, comprising the formulation as claimed in claim 17 to be administered to the subject.

23. The use of claim 22, wherein the disorder comprises irritable bowel syndrome, biliary colics, cholecystolithiasis, cholecystitis, cholangitis, renal colics, nephrolithiasis, ureterolithiasis, pyelitis, cystitis, dysmenorrhoea, imminent abortion, or uterine tetanus.