We Claim:

1. A formulation comprising a controlled-release portion comprising Drotaverine or a salt thereof, at least one polymer, at least one acidifying agent, and at least one pharmaceutically acceptable excipient.

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

5. The formulation of claim 4, wherein the Drotaverine salt is Drotaverine hydrochloride.

6. The formulation of claim 4, wherein the at least one polymer is chosen from Hydroxyethyl Cellulose, Hydroxypropyl Cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose, methyl cellulose, sodium carboxymethyl cellulose or salts thereof, Ethyl Cellulose, a Carbomer, a Methacrylic acid, a Polyethylene Oxide, or a combination thereof.

7. The formulation of claim 6, wherein the at least one polymer comprises hydroxypropyl methylcellulose.

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.

10. The formulation of claim 6, wherein the at least one polymer comprises K100, K4M, K15M, K100M, E4M, E10M, or Methocel K100M CR.

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.

12. The formulation of claim 4, wherein the at least one pharmaceutically acceptable excipient is chosen from a gum, a filler, a flow aid, a lubricant, a disintegrant, a diluent, a binder, or a glidant, 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.

15. The formulation of claim 4, further comprising a coating.

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

17. A formulation comprising Drotaverine hydrochloride, HPMC K4M, Methacrylic acid, citric acid, and sodium metabisulphite.

18. 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. 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;
(b) granulating the blend with a binder solution comprising at least polyvinylpyrrolidone and isopropyl alcohol to obtain granules;
(c) drying the granules to obtain 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 compressing the formulation to form the tablet.

20. Use of the formulation as claimed in claim 1 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 1 to be administered 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.