We Claim:

1. A formulation comprising a controlled-release portion and an immediate-release portion,

wherein the formulation comprises Drotaverine or a salt thereof, a polymer or mixture of polymers, and at least one pharmaceutically acceptable excipient, wherein said formulation comprises at least one acidifying agent and from 0 to 10% by weight of antioxidants.

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

3. The formulation of claim 2, wherein the Drotaverine salt is Drotaverine hydrochloride.

4. The formulation of claim 1, 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, a Carbomer, a Methacrylic acid, a Polyethylene Oxide, and a combination thereof.

5. The formulation of claim 4, wherein the polymer or mixture of polymers comprises hydroxypropyl methylcellulose.

6. The formulation of any one of claims 1-5, wherein the formulation comprises controlled-release polymer in the range of 5% to 30% (w/w) of the formulation.

7. The formulation of claim 5, wherein the hydroxypropyl methylcellulose has a viscosity from 100-150,000 cP.

8. The formulation of claim 4, wherein the polymer or mixture of polymers comprises K100, K4M, K15M, K100M, E4M, E10M, or Methocel K100M CR.

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

10. The formulation of claim 1, wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of a gum, a filler, a flow aid, a lubricant, a disintegrant, a diluent, a binder, or a glidant, and a combination thereof.

11. The formulation of claim 1, comprising up to 10% by weight of the antioxidants.

12. The formulation of claim 11, wherein the antioxidant is chosen from butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), sodium metabisulfite, sodium thiosulfate, propyl gallate, ascorbic acid, or cysteine or combinations thereof.

13. The formulation of any one of claims 1-12, wherein the formulation optionally comprises a functional or non-functional coating.

14. The formulation of any one of claims 1-13, wherein the formulation has a dissolution release profile *in vitro*, when measured using the USP II Method, at 75rpm, in 1000ml, 0.1 N HCl (pH 1.2), at 37±0.5, 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, and not less than about 85% after 16 hours.

15. The formulation of claim 1, wherein the formulation comprises Drotaverine hydrochloride, HPMC K4M, Methacrylic acid, citric acid, and sodium metabisulphite.

16. A direct compression method of preparing a single or multilayer controlled-release tablet comprising the formulation of claim 1, the method comprising:

(a) sieving and dry mixing Drotaverine or salt thereof with an acidifying agent, polymer and excipient to obtain a drug-polymer-excipient blend;
(b) sieving and mixing extra-granular ingredients with the drug-polymer-excipient blend to obtain a formulation of claim 1; and
(c) compressing the formulation to form the tablet.

17. A wet granulation method of preparing a single or multi-layer controlled-release tablet comprising the formulation of claim 1, the method comprising:

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

(b) granulating the blend of step (a) 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 the formulation of claim 1; and compressing the formulation to form the tablet.

18. Use of the formulation as claimed in claim 1 in the manufacture of a medicament for the treatment of at least one symptom of disorders such as gastrointestinal, biliary, urological, or gynecological 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.

19. The use of claim 18, wherein the disorder comprises irritable bowel syndrome, biliary colics, cholecystolithiasis, cholecystitis, cholangitis, renal colics, nephrolithiasis, ureterolithiasis, pyelitis, cystitis, dysmenorrhoea, imminent abortion, or uterine tetanus.

20. Use of the formulation as claimed in claim 15 in the manufacture of a medicament for the treatment of at least one symptom of disorders such as gastrointestinal, biliary, urological, or gynecological characterized by spastic conditions of smooth muscles in a subject in need thereof.

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.