Claims

1. A solid oral pharmaceutical dosage form comprising at least one active pharmaceutical ingredient or a pharmaceutical acceptable salt, an isomeric form, a prodrug, or metabolite thereof, wherein the solid oral pharmaceutical dosage form comprises:

    (i) an immediate release active core
    (ii) a first delayed-release layer comprising an enteric coating
    (iii) a second sustained release layer comprising a retard polymer, and
    (iv) a third immediate release layer comprising an active pharmaceutical ingredient

    wherein the solid oral pharmaceutical dosage form exhibits a bi-modal release profile of the at least one active pharmaceutical ingredient, and wherein the active pharmaceutical ingredient in the active core is the same or different than the active pharmaceutical ingredient in the third layer and
    wherein the core is a pellet and each layer is applied onto the core leading to a coated pellet.

2. A solid oral pharmaceutical dosage form according to claim 1, wherein the solid dosage form is a tablet.

3. A solid oral pharmaceutical dosage form according to claims 1, wherein the solid dosage form is a capsule.

4. A solid oral pharmaceutical dosage form according to any of the previous claims, wherein there are one or more additional layers between the layers or on top of the third layer.

5. A solid oral pharmaceutical dosage form according to any of the previous claims, wherein the first delayed-release layer comprises an enteric polymer selected from the group comprising esters of cellulose and its derivatives (cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate), polyvinyl acetate phthalate, pH-sensitive methacrylic acid copolymers and shellac.

6. A solid oral pharmaceutical dosage form according to any of the previous claims, wherein the second sustained-release layer comprises one or more pH-independent pharmaceutically acceptable excipients.

7. A solid oral pharmaceutical dosage form according to any of the preceding claims, wherein the retard polymer is selected from the group comprising cellulose derivatives, sodium carboxymethylcellulose, hydoxyalkylcelluloses such as hydroxypropylmethylcellulose and hydroxypropylcellulose, polyethylene oxide, alkylcelluloses such as methylcellulose and ethylcellulose, polyethylene glycol, cellulose acetate, cellulose acetate butyrate, ammonio methacrylate copolymer, polyacrylate dispersion, polyvinylpyrrolidone polyvinyl acetate and mixture thereof.

8. A solid oral pharmaceutical dosage form according to any of the preceding claims, wherein each individual layer may further comprise of excipients like binder, lubricant, plasticizer, pore builder, solvent, or a buffer solution for pH adjustment.

9. A solid oral pharmaceutical dosage form according to any of the preceding claims, wherein bi-modal release profile means an immediate release of 30-50% of the active pharmaceutical ingredient, and a second delayed release of the remaining 70-50% of the active pharmaceutical ingredient.

10. A solid oral pharmaceutical dosage form according to any of the preceding claims, wherein the dosage form is to be administered once per day.

11. A solid oral pharmaceutical dosage form according to any of the preceding claims, additionally comprising compounds selected from the group of viscosity increasing agents, emetic, irritative substances, and/or antagonists of the active ingredient.

12. A solid oral pharmaceutical dosage form according to any of the preceding claims for use in therapy.

13. A solid oral pharmaceutical dosage form according to any of the previous claims, wherein the at least one active pharmaceutical ingredient is methylphenidate or a pharmaceutical acceptable salt thereof, wherein the methylphenidate is a racemic mixture of d-and l-threo enantiomers or the d-threo enantiomer of methylphenidate or a pharmaceutical salt thereof.

14. A solid oral pharmaceutical dosage form according to any of the preceding claims, wherein the dosage form comprises 5 – 100 mg methylphenidate or the hydrochloride salt thereof.