administering, a dosage form as described herein, wherein the pharmacologically active agent is methylphenidate.

[00153a] In one aspect, the present disclosure provides a dosage form as described herein for use in therapy.

[00153b] In another aspect, the present disclosure provides a use of the dosage form as described herein in the manufacture of a medicament for the treatment of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) in a subject, wherein the medicament is to be administered orally to the subject on a once daily (QD) basis.

***IN VITRO* DISSOLUTION AND PHARMACOKINETICS**

[00154] The dosage forms of the present disclosure may be characterized by a desirable *in vitro* dissolution profile. For example, in some embodiments the % cumulative release of the pharmacologically active agent from an oral dosage form according to the present disclosure is from 5% to 40%, e.g., 10% to 30%, at T = 1 hr when assayed by USP Apparatus II using 750 mL of 1-stage 0.1 N HCl dissolution medium, a paddle speed of 50 rpm, a dissolution medium temperature of 37 °C, and a sampling volume of 1 mL.

[00155] In some embodiments, the *in vitro* % cumulative release of the pharmacologically active agent from an oral dosage form according to the present disclosure is at least 80% at T = 12 hr when assayed by USP Apparatus II using a 2-stage dissolution protocol, a paddle speed of 50 rpm, a dissolution medium temperature of 37 °C, and a sampling volume of 1 mL, wherein the 2-stage dissolution protocol includes exposing the oral dosage form to 750 mL of 0.1 N HCl for T = 0 to T = 2 hrs, adding 200 mL of 0.19 M phosphate buffer to obtain a final dissolution medium volume of 950 mL, and exposing the oral dosage form to the final dissolution medium volume from T = 2 hrs to T = 24 hr.

[00156] In some embodiments, a dosage form of the present disclosure is constituted such that initial release from the dosage form, of a pharmacologically active agent comprised by the drug composition (or ER composition), occurs at a time of 5 minutes to 120 minutes when assayed by USP Apparatus II using 750 mL of 0.1 N HCl dissolution medium, a paddle speed of 50 rpm, and a dissolution medium temperature of 37 °C. For example, in some embodiments, a dosage form of the present disclosure is consitituted such that initial release from the dosage form, of a

pharmacologically active agent comprised by the drug composition (or ER composition), occurs at a time of 10 minutes to 120 minutes, 15 minutes to 120 minutes, 20 minutes to 120 minutes, 25 minutes to 120 minutes, 30 minutes to 120 minutes, 35 minutes to 120 minutes, 40 minutes to 120 minutes, 45 minutes to 120 minutes, 50 minutes to 120 minutes, 55 minutes to 120 minutes, 60 minutes to 120 minutes, 65 minutes to 120 minutes, 70 minutes to 120 minutes, 75 minutes to 120 minutes, 80 minutes to 120 minutes, 85 minutes to 120 minutes, 90 minutes to 120

a second layer covering the first layer, the second layer comprising

MPH at about 30% to about 40% w/w relative to the total weight of the second layer, and

hydroxypropyl methylcellulose (HPMC) at about 70% to about 60% w/w relative to the total weight of the second layer; and

a third layer covering the second layer.

28. The dosage form of any one of claims 1 to 27 for use in therapy.

29. Use of the dosage form of any one of claims 1 to 27 in the manufacture of a medicament for the treatment of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) in a subject, wherein the medicament is to be administered orally to the subject on a once daily (QD) basis.