and dosing up to 120 mg is well-tolerated. The program has also collected preliminary efficacy data in an early Phase 2 trial in participants with ET.

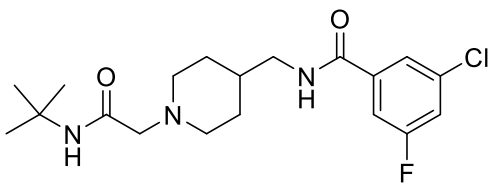
With a modified release (MR) formulation that supports once daily (QD) dosing over a 24-fold well-tolerated dose range that exhibits robust pharmacodynamic effects, in combination with preliminary efficacy data, there is a clear clinical rationale to support further study of the safety and efficacy of PRAX-944 for addressing the unmet need in ET.

However, certain challenges associated with the use of the currently available PRAX-944 MR formulations (*i.e.,* placebo, 5 mg, and 20 mg tablets) have been identified during clinical trials. For example, for clinical blinding purposes, different dose strengths of PRAX-944 are provided in multi-tablet combinations (*e.g.,* including one or more of placebo, 5 mg, and 20 mg tablets) packaged in blisters. It has been found that opening blister packages, handling small, round tablets, and taking many pills is especially challenging for patients struggling with movement disorders, such as essential tremor (ET). Accordingly, there is a need to develop new single unit dose tablets of , suitable strengths to improve usability for patients, reduce the total number of dosage units (*e.g.*, tablets) needed to deliver a specific dosage strength to a patient, and reduce or eliminate the risk of dosing errors.

SUMMARY

This disclosure provides compositions, including single-unit dosage forms and pharmaceutical compositions, comprising the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl). In certain embodiments and examples, the compositions described herein are bioequivalent to currently available oral dosage forms, such as the current PRAX-944 dosage form which is a modified release (MR) formulation available as 5-mg and 20-mg tablets that are round and small in size (*e.g.,* about 6 mm in diameter). The present disclosure further comprises methods useful for treating a disease or condition relating to aberrant function or activity of a T-type calcium channel, such as tremor (*e.g.,* essential tremor). The present disclosure further comprises methods useful for preventing and/or treating a disease or condition relating to aberrant function or activity of a T-type calcium channel, such as tremor, such as essential tremor.

In one aspect, the present disclosure provides a single-unit dosage form, comprising the compound of Formula (I):



(I),

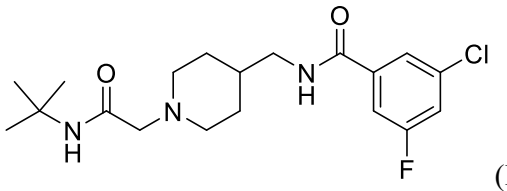
or a pharmaceutically acceptable salt thereof, in an amount equivalent to about 15 mg to about 25 mg of freebase form of the compound of Formula (I), wherein:

(a) the single-unit dosage form comprises a length of about 10 to about 20 mm and a width of about 1 mm to about 10 mm; and/or

(b) the single-unit dosage form has a total weight of from about 200 mg to about 600 mg; and/or

(c) the single-unit dosage form comprises from about 1% by weight to about 10% by weight of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

In another aspect, the present disclosure provides a single-unit dosage form, comprising the compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof, in an amount equivalent to about 60 mg to about 70 mg of freebase form of the compound of Formula (I), wherein:

(a) the single-unit dosage form comprises a length of about 10 to about 20 mm and a width of about 1 mm to about 10 mm; and/or

(b) the single-unit dosage form has a total weight of from about 200 mg to about 600 mg; and/or

(c) the single-unit dosage form comprises from about 10% by weight to about 15% by weight of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

In one example, the present disclosure provides a single-unit dosage form, comprising: the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl), wherein the single-unit dosage form is bioequivalent to a reference composition of the same dosage strength administered as one or more dosage forms, such as multiple small, round 20-mg PRAX-944 tablets.

In some examples, the single-unit dosage form and the reference composition have: (i) a different size; (ii) a different shape; (iii) both a different size and a different shape; (iv) the same shape but different sizes; or (v) the same size but different shapes. In certain examples, the single-

unit dosage form is larger than the reference composition. In some examples, the reference composition comprises smaller, round 20-mg PRAX-944 tablets.

In some examples, the single-unit dosage form is a larger tablet that exhibits bioequivalence upon administration to a subject in a fed state and/or fasted state as compared to administration of a reference composition of the same dosage strength administered as one or more smaller dosage forms, optionally one or more small, round 20-mg PRAX-944 tablets, to a subject in a fed and/or fasted state; wherein bioequivalency is established by: (a) a 90% Confidence Interval for AUC which is between about 80% and about 125% (e.g., about 80%, about 81%, about 82%, about 83%, about 84%, about 85%, about 86%, about 87%, about 88%, about 89%, about 90%, about 91%, about 92%, about 93%, about 94%, about 95%, about 96%, about 97%, about 98%, about 99%, about 100%, about 101%, about 102%, about 103%, about 104%, about 105%, about 106%, about 107%, about 108%, about 109%, about 110%, about 111%, about 112%, about 113%, about 114%, about 115%, about 116%, about 117%, about 118%, about 119%, about 120%, about 121%, about 122%, about 123%, about 124%, or about 125%), and (b) a 90% Confidence Interval for Cmax, which is between about 80% and about 125% (e.g., about 80%, about 81%, about 82%, about 83%, about 84%, about 85%, about 86%, about 87%, about 88%, about 89%, about 90%, about 91%, about 92%, about 93%, about 94%, about 95%, about 96%, about 97%, about 98%, about 99%, about 100%, about 101%, about 102%, about 103%, about 104%, about 105%, about 106%, about 107%, about 108%, about 109%, about 110%, about 111%, about 112%, about 113%, about 114%, about 115%, about 116%, about 117%, about 118%, about 119%, about 120%, about 121%, about 122%, about 123%, about 124%, or about 125%). In some examples, the 90% confidence interval for the AUC and/or Cmax may be contained within tighter confidence limits, e.g., about 90% to about 120%, about 90% to about 115%, about 90% to about 110%, or about 90% to about 100%.

In some examples, the single-unit dosage form (i) reduces the total number of dosage units (*e.g.*, tablets) needed to deliver a specific dosage strength to a subject; (ii) is characterized by a physical size and shape, (*e.g.,* tablet size and shape) which makes it easier and more convenient for subjects with a movement disorder, such as essential tremor (ET), to grasp; (iii) can be formulated as single-unit dose strengths for 5 mg, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg; and/or (iv) does not require titration to reach doses >40 mg. In certainexamples, titration may reduce and/or eliminate adverse events. In some examples, titration may comprise the administration of one or more single-unit dosages forms described herein. In some examples, at least about 50% (e.g., at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 85%, at least about 90%, at least about 95%, or about 100%) of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within a predetermined time period upon administration to a subject. In certain examples, the predetermined time period may range from about 1 hour to about 12 hours (e.g., about 1 hour, about 2 hours, about 3 hours, about 4

hours, about 5 hours, about 6 hours, about 7 hours, about 8 hours, about 9 hours, about 10 hours, about 11 hours, or about 12 hours).

In some examples, at least about 50% (e.g., at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 85%, at least about 90%, at least about 95%, or about 100%) of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 1 hour to about 12 hours (e.g., about 1 hour, about 2 hours, about 3 hours, about 4 hours, about 5 hours, about 6 hours, about 7 hours, about 8 hours, about 9 hours, about 10 hours, about 11 hours, or about 12 hours) upon administration to a subject.

In some examples, about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, or about 100% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 1 hour to about 12 hours (e.g., about 1 hour, about 2 hours, about 3 hours, about 4 hours, about 5 hours, about 6 hours, about 7 hours, about 8 hours, about 9 hours, about 10 hours, about 11 hours, or about 12 hours) upon administration to a subject.

In some examples, about 5% to about 25% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 1 to about 2 hours upon administration to a subject.

In some examples, about 25% to about 50% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 2 hours to about 4 hours upon administration to a subject.

In some examples, about 50% to about 75% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 3 hours to about 7 hours upon administration to a subject.

In some examples, about 75% to about 100% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 6 hours to about 10 hours upon administration to a subject.

In some examples, about 80% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 7 hours upon administration to a subject.

In some examples, about 90% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within about 9 hours to about 12 hours upon administration to a subject.

In some examples, at least about 50% (e.g., at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 85%, at least about 90%, at least about 95%, or about 100%) of the compound of Formula (I) or

a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released within a predetermined time period using USP apparatus type-I, media containing 900 mL 0.1 M HCl, and a paddle speed of 100 rpm. In certain examples, the predetermined time period may range from about 1 hour to about 12 hours (e.g., about 1 hour, about 2 hours, about 3 hours, about 4 hours, about 5 hours, about 6 hours, about 7 hours, about 8 hours, about 9 hours, about 10 hours, about 11 hours, or about 12 hours).

In some examples, at least about 50% (e.g., at least about 50%, at least about 55%, at least about 60%, at least about 65%, at least about 70%, at least about 75%, at least about 80%, at least about 85%, at least about 90%, at least about 95%, or about 100%) of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released in about 1 hour to about 12 hours (e.g., about 1 hour, about 2 hours, about 3 hours, about 4 hours, about 5 hours, about 6 hours, about 7 hours, about 8 hours, about 9 hours, about 10 hours, about 11 hours, or about 12 hours) using USP apparatus type-I, media containing 900 mL 0.1 M HCl, and a paddle speed of 100 rpm.In some examples, about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, or about 100% of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl) is released in about 1 hour to about 12 hours (e.g., about 1 hour, about 2 hours, about 3 hours, about 4 hours, about 5 hours, about 6 hours, about 7 hours, about 8 hours, about 9 hours, about 10 hours, about 11 hours, or about 12 hours) using USP apparatus type-I, media containing 900 mL 0.1 M HCl, and a paddle speed of 100 rpm.

In some examples, the single-unit dosage form comprises from about 1 mg to about 200 mg of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl). In some examples, the single-unit dosage form comprises from about 1% by weight to about 70% by weight of the compound of Formula (I) or a pharmaceutically acceptable salt thereof (*e.g.,* the compound of Formula (II), *e.g.,* PRAX-944 HCl).

In some examples, the single-unit dosage form further comprises a modified-release polymer. In some examples, the modified-release polymer comprises a matrix polymer, optionally selected from the group consisting of a hydrophilic matrix polymer, a hydrophobic matrix polymer, a polyacrylate polymer, and combinations thereof. In some examples, the modified-release polymer comprises (i) a hydrophilic matrix polymer, optionally selected from the group consisting of hypromellose, HPMC (hydroxyl-propyl methylcellulose), and combinations thereof, optionally wherein the HPMC (hydroxyl-propyl methylcellulose) is selected from the group consisting of Methocel K4M, Methocel K100LV, Methocel E50LV, and combinations thereof; (ii) a hydrophobic matrix polymer, optionally selected from the group consisting of ethyl cellulose, ethocel, and combinations thereof; and/or (iii) a polyacrylate polymer, optionally selected from the group consisting of Eudragit RL100, Eudragit RS100, and combinations thereof. In some examples, the

single-unit dosage form comprises from about 5 mg to 300 mg of a modified-release polymer. In some examples, the single-unit dosage form comprises from about 10% by weight to about 70% by weight of the modified-release polymer. In some examples, the modified-release polymer is hypromellose.

In some examples, the single-unit dosage form further comprises a diluent, optionally a soluble diluent. In some examples, the diluent comprises: (i) a cellulose derivative, optionally a microcrystalline cellulose, optionally a silicified microcrystalline cellulose; (ii) a starch, optionally selected from the group consisting of a hydrolyzed starch, a pregelatinized starch, and combinations thereof); (iii) an anhydrous lactose; (iv) a lactose monohydrate; (v) a di-calcium phosphate (DCP); and/or (vi) a sugar alcohol, optionally selected from the group consisting of sorbitol, xylitol, mannitol, and combinations thereof. In some examples, the single-unit dosage form comprises from about 5 mg to about 300 mg of diluent. In some examples, the single-unit dosage form comprises from about 5% by weight to about 50% by weight of diluent. In some examples, the diluent is microcrystalline cellulose, optionally silicified microcrystalline cellulose. In some examples, the diluent is a sugar alcohol, optionally mannitol.

In some examples, the single-unit dosage form further comprises a glidant. In some examples, the glidant is selected from the group consisting of fumed silica, optionally colloidal silicon dioxide, talc, magnesium carbonate, and combinations thereof. In some examples, the single-unit dosage form comprises about 1 mg to about 10 mg of glidant. In some examples, the single-unit dosage form comprises from about 1% by weight to about 10% by weight of glidant. In some examples, the glidant is fumed silica, optionally colloidal silicon dioxide.

In some examples, the single-unit dosage form further comprises a lubricant. In some examples, lubricant is selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, talc, silica, a fat, optionally vegetable stearin, and combinations thereof. In some examples, the single-unit dosage form comprises from about 1 mg to about 10 mg of lubricant. In some examples, the single-unit dosage form comprises from about 1% by weight to about 10% by weight of lubricant. In some examples, the lubricant comprises magnesium stearate.

In some examples, the single-unit dosage form further comprises a coating. In some examples, the coating comprises a film coating agent. In some examples, the coating comprises compendial grade polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, and/or talc. In some examples, the single-unit dosage form comprises from about 1 mg to about 20 mg of coating. In some examples, the single-unit dosage form comprises from about 1% by weight to about 10% by weight of coating. In some examples, the coating comprises Opadry® II white 85F18422.

In some examples, the single-unit dosage form comprises a tablet, optionally formulated for oral administration. In some examples, the single-unit dosage form comprises an oblong tablet, an oval tablet, or a capsule-shaped tablet, optionally wherein the tablet is not a round tablet. In

some examples, opening blister packages of oblong, oval, or capsule-shaped tablets, handling oblong, oval, or capsule-shaped tablets, and taking one or more oblong, oval, or capsule-shaped tablets is less challenging and move convenient for patients struggling with movement disorders, such as essential tremor (ET), *e.g.,* as compared to a small, round tablet (*e.g.,* about 6 mm in diameter).

In some examples, the single-unit dosage form comprises a total weight from about 200 mg to about 600 mg per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises about 1% to about 100% by weight of PRAX-944 HCl, optionally wherein the total weight of the dosage unit (e.g., per tablet) is from about 200 mg to about 600 mg (e.g., about 200 mg, about 205 mg, about 210 mg, about 215 mg, about 220 mg, about 225 mg, about 230 mg, about 235 mg, about 240 mg, about 245 mg, about 250 mg, about 255 mg, about 260 mg, about 265 mg, about 270 mg, about 275 mg, about 280 mg, about 285 mg, about 290 mg, about 295 mg, about 300 mg, about 305 mg, about 310 mg, about 315 mg, about 320 mg, about 325 mg, about 330 mg, about 335 mg, about 340 mg, about 345 mg, about 350 mg, about 355 mg, about 360 mg, about 365 mg, about 370 mg, about 375 mg, about 380 mg, about 385 mg, about 390 mg, about 395 mg, about 400 mg, about 405 mg, about 410 mg, about 415 mg, about 420 mg, about 425 mg, about 430 mg, about 435 mg, about 440 mg, about 445 mg, about 450 mg, about 455 mg, about 460 mg, about 465 mg, about 470 mg, about 475 mg, about 480 mg, about 485 mg, about 490 mg, about 495 mg, about 500 mg, about 505 mg, about 510 mg, about 515 mg, about 520 mg, about 525 mg, about 530 mg, about 535 mg, about 540 mg, about 545 mg, about 550 mg, about 555 mg, about 560 mg, about 565 mg, about 570 mg, about 575 mg, about 580 mg, about 585 mg, about 590 mg, about 595 mg, or about 600 mg).

In some examples, the single-unit dosage form comprises a length of about 1 mm to about 30 mm (e.g., a length of about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm, about 5 mm, about 5.5 mm, about 6 mm, about 6.5 mm, about 7 mm, about 7.5 mm, about 8 mm, about 8.5 mm, about 9 mm, about 9.5 mm, about 10 mm, about 10.5 mm, about 11 mm, about 11.5 mm, about 12 mm, about 12.5 mm, about 13 mm, about 13.5 mm, about 14 mm, about 14.5 mm, about 15 mm, about 15.5 mm, about 16 mm, about 16.5 mm, about 17 mm, about 17.5 mm, about 18 mm, about 18.5 mm, about 19 mm, about 19.5 mm, about 20 mm, about 20.5 mm, about 21 mm, about 21.5 mm, about 22 mm, about 22.5 mm, about 23 mm, about 23.5 mm, about 24 mm, about 24.5 mm, about 25 mm, about 25.5 mm, about 26 mm, about 26.5 mm, about 27 mm, about 27.5 mm, about 28 mm, about 28.5 mm, about 29 mm, about 29.5 mm, or about 30 mm).

In some examples, the single-unit dosage form comprises a width of about 1 mm to about 30 mm (e.g., a width of about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm, about 5 mm, about 5.5 mm, about 6 mm, about 6.5 mm, about 7 mm, about 7.5 mm, about 8 mm, about 8.5 mm, about 9 mm, about 9.5 mm, about 10 mm, about 10.5 mm, about 11 mm, about 11.5 mm, about 12 mm, about 12.5 mm, about 13 mm, about 13.5 mm, about 14 mm, about 14.5 mm, about 15 mm, about 15.5 mm, about 16 mm, about 16.5 mm, about 17

mm, about 17.5 mm, about 18 mm, about 18.5 mm, about 19 mm, about 19.5 mm, about 20 mm, about 20.5 mm, about 21 mm, about 21.5 mm, about 22 mm, about 22.5 mm, about 23 mm, about 23.5 mm, about 24 mm, about 24.5 mm, about 25 mm, about 25.5 mm, about 26 mm, about 26.5 mm, about 27 mm, about 27.5 mm, about 28 mm, about 28.5 mm, about 29 mm, about 29.5 mm, or about 30 mm).

In some examples, the single-unit dosage form comprises a width of about 1 mm to about 10 mm (e.g., a width of about 1 mm, about 1.1 mm, about 1.2 mm, about 1.3 mm, about 1.4 mm, about 1.5 mm, about 1.6 mm, about 1.7 mm, about 1.8 mm, about 1.9 mm, about 2 mm, about 2.1 mm, about 2.2 mm, about 2.3 mm, about 2.4 mm, about 2.5 mm, about 2.6 mm, about 2.7 mm, about 2.8 mm, about 2.9 mm, about 3 mm, about 3.1 mm, about 3.2 mm, about 3.3 mm, about 3.4 mm, about 3.5 mm, about 3.6 mm, about 3.7 mm, about 3.8 mm, about 3.9 mm, about 4 mm, about 4.1 mm, about 4.2 mm, about 4.3 mm, about 4.4 mm, about 4.5 mm, about 4.6 mm, about 4.7 mm, about 4.8 mm, about 4.9 mm, about 5 mm, about 5.1 mm, about 5.2 mm, about 5.3 mm, about 5.4 mm, about 5.5 mm, about 5.6 mm, about 5.7 mm, about 5.8 mm, about 5.9 mm, about 6 mm, about 6.1 mm, about 6.2 mm, about 6.3 mm, about 6.4 mm, about 6.5 mm, about 6.6 mm, about 6.7 mm, about 6.8 mm, about 6.9 mm, about 7 mm, about 7.1 mm, about 7.2 mm, about 7.3 mm, about 7.4 mm, about 7.5 mm, about 7.6 mm, about 7.7 mm, about 7.8 mm, about 7.9 mm, about 8 mm, about 8.1 mm, about 8.2 mm, about 8.3 mm, about 8.4 mm, about 8.5 mm, about 8.6 mm, about 8.7 mm, about 8.8 mm, about 8.9 mm, about 9 mm, about 9.1 mm, about 9.2 mm, about 9.3 mm, about 9.4 mm, about 9.5 mm, about 9.6 mm, about 9.7 mm, about 9.8 mm, about 9.9 mm, or about 10 mm).

In some examples, the single-unit dosage form comprises a length of about 14 to about 16 mm (e.g., a length of about 14 mm, about 14.1 mm, about 14.2 mm, about 14.3 mm, about 14.4 mm, about 14.5 mm, about 14.6 mm, about 14.7 mm, about 14.8 mm, about 14.9 mm, about 15 mm, about 15.1 mm, about 15.2 mm, about 15.3 mm, about 15.4 mm, about 15.5 mm, about 15.6 mm, about 15.7 mm, about 15.8 mm, about 15.9 mm, or about 16 mm), and a width of about 5 mm to about 7 mm (e.g., a width of about 5 mm, about 5.1 mm, about 5.2 mm, about 5.3 mm, about 5.4 mm, about 5.5 mm, about 5.6 mm, about 5.7 mm, about 5.8 mm, about 5.9 mm, about 6 mm, about 6.1 mm, about 6.2 mm, about 6.3 mm, about 6.4 mm, about 6.5 mm, about 6.6 mm, about 6.7 mm, about 6.8 mm, about 6.9 mm, or about 7 mm).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 5 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 1 mg to about 10 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 10 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 5 mg to about 15 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 15 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 10 mg to about 20 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 20 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 15 mg to about 25 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 25 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 20 mg to about 30 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 30 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 25 mg to about 35 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 35 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 30 mg to about 40 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 40 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 35 mg to about 45 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 45 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 40 mg to about 50 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 50 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 45 mg to about 55 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 55 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 50 mg to about 60 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 60 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 55 mg to about 65 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 65 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 60 mg to about 70 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 70 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 65 mg to about 75 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 75 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 70 mg to about 80 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 80 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 75 mg to about 85 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 85 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 80 mg to about 90 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 90 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 85 mg to about 95 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 95 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 90 mg to about 100 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 100 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 95 mg to about 105 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 105 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 100 mg to about 110 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 110 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 105 mg to about 115 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 115 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 110 mg to about 120 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 120 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 115 mg to about 125 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 125 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 120 mg to about 130 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 130 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 125 mg to about 135 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 135 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 130 mg to about 140 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 140 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 135 mg to about 145 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 145 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 140 mg to about 150 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 150 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 145 mg to about 155 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 155 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 150 mg to about 160 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 160 mg of PRAX-944 free base per dosage unit (e.g., per tablet), optionally from about 155 mg to about 165 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 1.0 mg to about 200 mg (e.g., about 1 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, about 120 mg, about 125 mg, about 130 mg, about 135 mg, about 140 mg, about 145 mg, about 150 mg, about 155 mg, about 160 mg, about 165 mg, about 170 mg, about 175 mg, about 180 mg, about 185 mg, about 190 mg, about 195 mg, or about 200 mg) of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 1% by weight to about 50% (e.g., about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, or about 50%) by weight of PRAX-944 HCl, optionally wherein the total dosage unit (e.g., tablet) weight is from about 50 mg to about 500 mg (e.g., about 50 mg, about 60 mg, about 70 mg, about 80 mg, about 90 mg, about 100 mg, about 110 mg, about 120 mg, about 130 mg, about 140 mg, about 150 mg, about 160 mg, about 170 mg, about 180 mg, about 190 mg, about 200 mg, about 210 mg, about 220 mg, about 230 mg, about 240 mg, about 250 mg, about 260 mg, about 270 mg, about 280 mg, about 290 mg, about 300 mg, about 310 mg, about 320 mg, about 330 mg, about 340 mg, about 350 mg, about 360 mg, about 370 mg, about 380 mg, about 390 mg, about 400 mg, about 410 mg, about 420 mg, about 430 mg, about 440 mg, about 450 mg, about 460 mg, about 470 mg, about 480 mg, about 490 mg, or about 500 mg).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 5.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 1% by weight to about 5% by

weight of PRAX-944 HCl, optionally from about 1 mg to about 10 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 10.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 1% by weight to about 10% by weight of PRAX-944 HCl, optionally from about 5 mg to about 15 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 20.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 1% by weight to about 10% by weight of PRAX-944 HCl, optionally from about 15 mg to about 25 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 40.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 5% by weight to about 15% by weight of PRAX-944 HCl, optionally from about 25 mg to about 50 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 60.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 5% by weight to about 20% by weight of PRAX-944 HCl, optionally from about 50 mg to about 75 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 80.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 15% by weight to about 25% by weight of PRAX-944 HCl, optionally from about 75 mg to about 100 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 100.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 20% by weight to about

25% by weight of PRAX-944 HCl, optionally from about 75 mg to about 125 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises the compound of Formula (I) or a pharmaceutically acceptable salt thereof (e.g., the compound of Formula (II), e.g., PRAX-944 HCl) in an amount equivalent to about 120.0 mg of PRAX-944 free base per dosage unit (e.g., per tablet). In some examples, the single-unit dosage form comprises from about 25% by weight to about 35% by weight of PRAX-944 HCl, optionally from about 110 mg to about 135 mg of PRAX-944 HCl per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form further comprises one or more of (i) a modified-release polymer, optionally from about 35% by weight to about 45% by weight of modified-release polymer, optionally from about 175 mg to about 185 mg of modified-release polymer per dosage unit (e.g., per tablet); (i) a soluble diluent, optionally from about 6% by weight to about 10% by weight of soluble diluent, optionally from about 34 mg to about 38 mg of soluble diluent per dosage unit (e.g., per tablet); (iii) a glidant, optionally from about 1% by weight to about 3% by weight of glidant, optionally from about 6 mg to about 8 mg of glidant per dosage unit (e.g., per tablet); (iv) a lubricant, optionally from about 0.5% by weight to about 2% by weight of lubricant, optionally from about 3 mg to about 6 mg of lubricant per dosage unit (e.g., per tablet); and (v) a coating, optionally from about 12% by weight to about 15% by weight of coating, optionally from about 1 mg to about 5 mg of coating per dosage unit (e.g., per tablet).

In some examples, the single-unit dosage form comprises: (i) large tablet prototype 01 (58% K4M Round) (DC); (ii) large tablet prototype 01 (58% K4M Caplet) (DC); (iii) large tablet prototype 04 (58% K4M) (DG); (iv) large tablet prototype 23 (50% K4M); (v) large tablet prototype 28 (58% K100LV); (vi) large tablet prototype 34 (50% K100LV, 8% Mannitol EG); (vii) large tablet prototype 36 (50% K100LV, 8% Mannitol IG); (viii) large tablet prototype 52 (28% K100LV, 30% E50LV); (ix) large tablet prototype 53 (40% K100LV, 8% Mannitol IG); or (x) large tablet prototype 54 (46% K100LV, 12% Mannitol IG). In some examples, the single-unit dosage form comprises: (i) large tablet prototype 04 (58% K4M) (DG); (ii) large tablet prototype 28 (58% K100LV); or (iii) large tablet prototype 53 (40% K100LV, 8% Mannitol IG).

In one example, the present disclosure provides a pharmaceutical composition comprising the single-unit dosage form of any one of the preceding claims, and at least one pharmaceutically acceptable carrier or excipient.

In one example, the present disclosure provides a method of treating a disease or condition relating to aberrant function or activity of a T-type calcium channel in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of the single-unit dosage or the pharmaceutical composition described herein.

In one example, the present disclosure provides a method of treating a tremor in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of the single-unit dosage or the pharmaceutical composition described herein.

In one example, the present disclosure provides a method of treating an essential tremor in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of the single-unit dosage or the pharmaceutical composition described herein.

In some examples, the method results in reduction of the essential tremor as assessed by The Essential Tremor Rating Assessment Scale (TETRAS) score. In some examples, the reduction of the essential tremor is assessed by The Essential Tremor Rating Assessment Scale (TETRAS) upper limb score. In some examples, the reduction of the essential tremor is assessed by TETRAS-ADL (activities of daily living). In some examples, the reduction of the essential tremor is assessed by TETRAS performance subscale score or TETRAS performance individual items. In some examples, the method results in reduction of the essential tremor as assessed by accelerometer-based upper limb score. In some examples, the method results in reduction of sigma frequency band. In some examples, the essential tremor is upper limb tremor.

Other objects and advantages will be apparent to those skilled in the art based upon consideration of the ensuing Brief Description of the Drawings, Detailed Description, Examples, and Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts composition and characteristics of active pharmaceutical ingredient, PRAX-944 (also referred to herein as PRAX-944 HCl).

FIG. 2A depicts tablets of various shapes and sizes.

FIG. 2B depicts a comparison between the currently available PRAX-944 dosage form, which is a modified release (MR) formulation available as 5-mg and 20-mg round tablets that are small in size (6 mm in diameter), and an exemplary bioequivalent single-unit dosage form described herein.

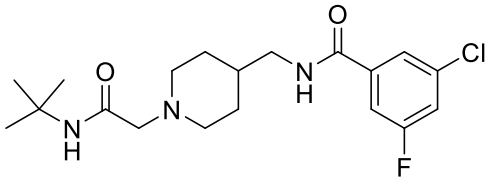
FIG. 3A depicts the PRAX-944-107 study design. N=number of participants planned for the total population; n=number of participants planned per arm. Fasted: Each dose of study drug will be taken with 240 mL of water after an overnight fast. No food or drink, except water, will be allowed for at least 10 hours prior to dosing. Participants are to remain fasted for 4 hours post dose. Participants are not allowed to drink water for 2 hours before and for 1 hour after each dose. Fed: Study drug co-administered with high-fat, high-calorie meal.

FIG. 3B depicts study drugs administered in PRAX-944-107.

FIG. 3C depicts exemplary high dose strength PRAX-944 tablet formulations tested in 944-107 study.

CLAIMS

1. A single-unit dosage form, comprising the compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof, in an amount equivalent to about 15 mg to about 25 mg of freebase form of the compound of Formula (I), wherein:

(a) the single-unit dosage form comprises a length of about 10 to about 20 mm and a width of about 1 mm to about 10 mm; and/or

(b) the single-unit dosage form has a total weight of from about 200 mg to about 600 mg; and/or

(c) the single-unit dosage form comprises from about 1% by weight to about 10% by weight of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

2. The single-unit dosage form of claim 1, wherein the single-unit dosage form further comprises a modified-release polymer.

3. The single-unit dosage form of claim 2, wherein the modified-release polymer is hypromellose.

4. The single-unit dosage form of any one of the preceding claims, wherein the single-unit dosage form further comprises a diluent.

5. The single-unit dosage form of claim 4, wherein the diluent comprises mannitol and/or microcrystalline cellulose.

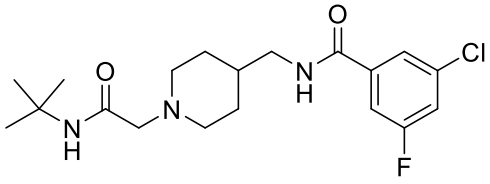
6. The single-unit dosage form of any one of the preceding claims, wherein the single-unit dosage form further comprises a glidant.

7. The single-unit dosage form of claim 6, wherein the glidant comprises silicon dioxide.

8. The single-unit dosage form of any one of the preceding claims, wherein the single-unit dosage form further comprises a lubricant.

9. The single-unit dosage form of claim 8, wherein the lubricant comprises magnesium stearate.

10. A single-unit dosage form, comprising the compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof, in an amount equivalent to about 60 mg to about 70 mg of freebase form of the compound of Formula (I), wherein:

(a) the single-unit dosage form comprises a length of about 10 to about 20 mm and a width of about 1 mm to about 10 mm; and/or

(b) the single-unit dosage form has a total weight of from about 200 mg to about 600 mg; and/or

(c) the single-unit dosage form comprises from about 10% by weight to about 15% by weight of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

11. The single-unit dosage form of claim 10, wherein the single-unit dosage form further comprises a modified-release polymer.

12. The single-unit dosage form of claim 11, wherein the modified-release polymer is hypromellose.

13. The single-unit dosage form of any one of claims 10 to 12, wherein the single-unit dosage form further comprises a diluent.

14. The single-unit dosage form of claim 13, wherein the diluent comprises mannitol and/or microcrystalline cellulose.

15. The single-unit dosage form of any one of claims 10 to 14, wherein the single-unit dosage form further comprises a glidant.

16. The single-unit dosage form of claim 15, wherein the glidant comprises silicon dioxide.

17. The single-unit dosage form of any one of claims 10 to 16, wherein the single-unit dosage form further comprises a lubricant.

18. The single-unit dosage form of claim 17, wherein the lubricant comprises magnesium stearate.