

WHAT IS CLAIMED:

1. An osmotic dosage form for once daily administration of deutetrabenazine to a subject in need thereof comprising:
 - a. a tablet core comprising an active layer and a push layer, wherein the active layer comprises an amount of deutetrabenazine microparticles and an active layer control release agent, and wherein the push layer comprises an osmotic agent and a push layer control release agent, and an optional tablet seal coat on the outer surface of the tablet core;
 - b. a semipermeable layer surrounding the tablet core;
 - c. a port extending through the semipermeable layer into the tablet core; and
 - d. an optional immediate release coating external to the semipermeable layer comprising a second amount of deutetrabenazine microparticles.
2. The dosage form of claim 1, wherein the active layer control release agent comprises a polymer having a viscosity of about 50-150 mPa s or about 55-90 mPa s.
3. The dosage form of claim 2, wherein the active layer control release agent polymer comprises a polyethylene oxide having an average molecular weight of 100,000 daltons to 500,000 daltons in an amount of about 60% to about 98% by weight, based on the total weight of the active layer.
4. The dosage form of any one of the preceding claims, wherein the active layer further comprises at least one of:
 - a. an active layer antioxidant present in an amount of about 0.001% to about 1% by weight, based on the total weight of the active layer; and
 - b. an active layer binder present in an amount of about 2% to about 20% by weight, based on the total weight of the active layer.
5. The dosage form of any one of the preceding claims, wherein the osmotic agent comprises an inorganic salt, a carbohydrate or any mixture thereof.
6. The dosage form of claim 5, wherein the osmotic agent comprises an inorganic salt selected from magnesium sulfate, magnesium chloride, potassium sulfate, sodium chloride, sodium sulfate, lithium sulfate, sodium phosphate, potassium phosphate or

any mixture thereof and is present in an amount of about 5% to about 50% by weight, based on the total weight of the dosage form.

7. The dosage form of any one of the preceding claims, wherein the push layer control release agent comprises a polymer having a viscosity of about 5500-7500 mPa s and is present in an amount of about 50% to about 80% by weight, based on the total weight of the push layer.
8. The dosage form of any one of the preceding claims, wherein the weight ratio of the osmotic agent and the push layer control release agent in the push layer is 1:2 – 1:3.5 or 1:2 – 1:2.5.
9. The dosage form of any one of the preceding claims, wherein the push layer further comprises at least one of:
 - a. a push layer binder; and
 - b. a pharmaceutically acceptable excipient
10. The dosage form of any one of the preceding claims, wherein the semipermeable layer comprises a water soluble polymer, a water insoluble polymer or any mixture thereof.
11. The dosage form of claim 10, wherein the semipermeable layer comprises a water insoluble polymer selected from cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose propionate, cellulose acetate butyrate, cellulose ethers like ethyl cellulose, agar acetate, amylose triacetate, betaglucan acetate, poly(vinyl methyl) ether copolymers, poly(orthoesters), poly acetals and selectively permeable poly(glycolic acid), poly(lactic acid) derivatives, cellulose acetate polymer or any mixture thereof in an amount of about 80% to about 99.9% by weight, based on the weight of the semipermeable layer.
12. The dosage form of any one of the preceding claims, wherein the semipermeable layer comprises a pore-forming agent.
13. The dosage form of claim 12, wherein the pore-forming agent comprises a water

soluble sugar, a water soluble salt, a water soluble solvent, a water soluble polymer or any mixture thereof and is present in the semipermeable layer in an amount of about 0.1% to about 20% by weight of the semipermeable layer.

14. The dosage form of any one of the preceding claims, wherein the weight ratio of the semipermeable layer and the tablet core is 1:8-1:10.
15. The dosage form of any one of the preceding claims, wherein the port has a diameter of from about 0.1 mm to about 1 mm.
16. The dosage form of any one of the preceding claims, further comprising a semipermeable layer seal coat on the outer surface of the semipermeable layer.
17. The dosage form of claim 16, wherein each of the tablet core seal coat and the semipermeable layer seal coat independently comprise a binder in an amount up to about 20% by weight, based on the total weight of the dosage form.
18. The dosage form of any one of the preceding claims, comprising the immediate release coating external to the semipermeable membrane, the immediate release coating comprising about 0.1% to about 30% by weight deutetrabenazine microparticles, based on the total weight of the dosage form or about 0.2% to about 5% by weight deutetrabenazine microparticles, based on the total weight of the dosage form or about 0.3% to about 2% by weight deutetrabenazine microparticles, based on the total weight of the dosage form.
19. The dosage form of claim 18, wherein the dosage form comprises:
 - a. a total amount of 6 mg of deutetrabenazine microparticles wherein the immediate release coating comprises about 0.1% to about 0.5% by weight deutetrabenazine microparticles, based on the total weight of the dosage form, or
 - b. a total amount of 12 mg of deutetrabenazine microparticles wherein the immediate release coating comprises about 0.5% to about 1% by weight deutetrabenazine microparticles, based on the total weight of the dosage form, or

- c. a total amount of 24 mg of deutetrabenazine microparticles wherein the immediate release coating comprises about 1% to about 2% by weight deutetrabenazine microparticles, based on the total weight of the dosage form.
- 20. The dosage form of any one of claims 1-18, wherein the dosage comprises from about 6 mg to about 48 mg deutetrabenazine in the form of deutetrabenazine microparticles and wherein about 70%-80% of the total amount of deutetrabenazine microparticles present in the dosage form is present within the active layer and wherein about 20%-30% of the total amount of deutetrabenazine microparticles present in the dosage form, is present within the immediate release coating.
- 21. The dosage form of claim 20, comprising:
 - a) a total amount of 6 mg of deutetrabenazine microparticles, wherein the total amount of deutetrabenazine microparticles is about 0.5% to about 3% by weight, based on the total weight of the dosage form, or
 - b) a total amount of 12 mg of deutetrabenazine microparticles, wherein the total amount of deutetrabenazine microparticles is about 1% to about 5% by weight, based on the total weight of the dosage form, or
 - c) a total amount of 24 mg of deutetrabenazine microparticles, wherein the total amount of deutetrabenazine microparticles is about 5% to about 10% by weight, based on the total weight of the dosage form.
- 22. The dosage form of any one of the preceding claims, wherein the deutetrabenazine microparticles have a particle size of about 1 μm to about 30 μm in diameter, preferably with a D_{90} of 15 μm , a D_{50} 10 μm , and/or a D_{10} of 3 μm .
- 23. A method of treating a hyperkinetic movement disorder in a subject in need thereof comprising orally administering, on a once daily basis to the subject, an osmotic dosage form according to any one of the preceding claims.
- 24. The method of claim 23, wherein the movement disorder is chorea, akathisia, dyskinesia, tremor, tic, chorea associated with Huntington's disease, tardive dyskinesia, a tic associated with Tourette syndrome, Parkinson's disease levodopa-induced dyskinesia or dyskinesia in cerebral palsy.

25. The method of any one of claims 23-24, comprising orally administering to the subject a once daily osmotic dosage form according to any one of claims 1-22 wherein a single dose administration of the osmotic dosage form, which comprises a total amount of 6mg of deutetrabenazine microparticles,
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean AUC_{0-inf} of about 91,250 to 142,750 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean C_{max} of less than about 4,600 pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean AUC_{0-inf} of about 730,000 to 1,142,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean C_{max} of less than about 36,800 pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean AUC₀₋₂₄ of about 102,500 to 200,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean C_{max} of less than about 10,000 pg/mL.
26. The method of any one of claims 23-24, comprising orally administering to the subject a once daily osmotic dosage form according to any one of claims 1-22, wherein a single dose administration of the osmotic dosage form, which comprises a total amount of 12mg of deutetrabenazine microparticles,
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean AUC_{0-inf} of about 182,500 to 285,500 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean C_{max} of less than about 9,200 pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean AUC₀₋₂₄ of about 205,000 to 400,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean C_{max} of less than about 20,000 pg/mL.
27. The method of any one of claims 23-24, comprising orally administering to the subject a once daily osmotic dosage form according to any one of claims 1-22,

wherein a single dose administration of the osmotic dosage form, which comprises a total amount of 24mg of deutetrabenazine microparticles,
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean AUC_{0-inf} of about 365,000 to 571,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean C_{max} of less than about 18,400 pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean AUC₀₋₂₄ of about 410,000 to 800,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean C_{max} of less than about 40,000 pg/mL.

28. The method of any one of claims 23-24, comprising orally administering to the subject a once daily osmotic dosage form according to any one of claims 1-22, wherein a single dose administration of the osmotic dosage form, which comprises a total amount of 36mg of deutetrabenazine microparticles,
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean AUC_{0-inf} of about 547,500 to 856,500 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean C_{max} of less than about 27,600 pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean AUC₀₋₂₄ of about 615,000 to 1,200,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean C_{max} of less than about 60,000 pg/mL.
29. The method of any one of claims 23-24, comprising orally administering to the subject a once daily osmotic dosage form according to any one of claims 1-22, wherein a single dose administration of the osmotic dosage form, which comprises a total amount of 48mg of deutetrabenazine microparticles,
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean AUC_{0-inf} of about 730,000 to 1,142,000 h*pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine that includes a geometric mean C_{max} of less than about 36,800 pg/mL or
provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean AUC₀₋₂₄ of about 820,000 to 1,600,000 h*pg/mL or

provides an *in vivo* plasma profile for total α - and β -dihydrodeutetrabenazine at steady state that includes a mean $C_{\max}$ of less than about 80,000 pg/mL.

30. The method of any one of claims 23-29, comprising administering an osmotic dosage form according to any one of claims 1-22, wherein
not more than 15% of the drug formulation is released after 2 hours when tested in 500 mL acid phosphate buffer at pH 3.0 using a USP II dissolution apparatus; or
not more than 60% of the drug formulation is released after 8 hours when tested in 500 mL acid phosphate buffer at pH 3.0 using a USP II dissolution apparatus.