CLAIMS

What is claimed is:

1. An immediate or modified release solid oral dosage form comprising a dosage form core, wherein the dosage form core comprises:

tebipenem pivoxil or a pharmaceutically acceptable salt thereof and excipients including a binder, a lubricant, an optionally a diluent.

2. The dosage form core of claim 1, wherein weight to weight ratio of tebipenem pivoxil to the excipients in the core is from 30:60 to 60:30.

3. The dosage form core of claim 1, wherein weight to weight ratio of tebipenem pivoxil to the excipients in the core is from 30:45 to 45:30.

4. The dosage form of claim 1, wherein the dosage form is an immediate release dosage form and releases more than 85 % of the tebipenem pivoxil or tebipenem pivoxil salt in 15 minutes when measured by the USP Paddle method at 50 rpm in 900 mL of 50 mM acetate buffer, pH 5.0 at 37 °C.

5. The immediate release dosage form of claim 4, wherein the excipients additionally comprise a disintegrant.

6. The immediate release dosage form of claim 5, wherein the disintegrant is croscarmellose sodium, crospovidone, sodium starch glycolate, or any combination of any two or more of the foregoing.

7. The dosage form of claim 1, wherein the dosage form is a modified release dosage form and provides an in vitro release of NMT 50 % of the tebipenem pivoxil or tebipenem pivoxil salt after 30 minutes when measured by the USP Paddle method at 50 rpm in 900 mL of 50 mM acetate buffer, pH 5.0 at 37 °C.

8. The modified release dosage form of claim 7, wherein NLT 85% of the total amount of tebipenem pivoxil or tebipenem pivoxil salt is released after 4 hours, when measured by the USP Paddle method at 50 rpm in 900 mL of 50 mM acetate buffer, pH 5.0 at 37 °C.

9. The modified release dosage form claim 7, wherein NLT 85% of the total amount of tebipenem pivoxil or tebipenem pivoxil salt is released after 2 hours, when measured by the USP Paddle method at 50 rpm in 900 mL of 50 mM acetate buffer, pH 5.0 at 37 °C.

10. The modified release dosage form of claim 7, 8, or 9, wherein the excipients additionally comprise a release control agent.

11. The modified release dosage form of claim 10, wherein the release control agent is hydroxypropyl methylcellulose, hydroxypropyl cellulose, hypromellose acetate succinate, polyvinyl pyrrolidone, copovidone, or any combination of any two or more of the foregoing.

12. The dosage form of any one of claims 1 to 11, wherein

the binder is microcrystalline cellulose, silicified microcrystalline cellulose, ethyl cellulose, lactose, or any combination of any two or more of the foregoing.

13. The dosage form of claim 12, wherein the binder is microcrystalline cellulose.

14. The dosage form of any one of claims 1 to 13, wherein the dosage form comprises a diluent and the diluent is starch, sucrose, monohydrate lactose, mannitol, sorbitol, or any combination of any two or more of the foregoing.

15. The dosage form of any one of claims 1 to 14, wherein the dosage form comprises a lubricant and the lubricant is a fatty acid ester, stearic acid, magnesium stearate, glyceryl behenate, calcium stearate, sodium stearyl fumarate, sodium lauryl sulfate, magnesium lauryl sulfate, sodium benzoate, talc, hydrogenated oil, Carnauba wax, or any combination of any two or more of the foregoing.

16. The modified release dosage form of claim 7, 8, or 9, wherein the dosage form core comprises 30% to 60% (w%/ w) of tebipenem pivoxil, 10% to 40% hydroxypropyl methylcellulose or polyvinylpyrrolidone, 5% to 20% mannitol, 5% to 20 % microcrystalline cellulose, and 0.1% to 5% magnesium stearate.

17. The immediate release dosage form of claim 4, wherein the dosage form core comprises 30 % to 60 % (w%/w) tebipenem pivoxil, 1% to 10 % crospovidone, 115% to 25% monohydrate lactose or mannitol, 15 % to 25% microcrystalline cellulose, and 0.1% to 5% magnesium stearate.

18. The immediate release dosage form of claim 6 or 17, wherein the weight to weight ratio of tebipenem pivoxil to crospovidone is 20:1 to 5:1.

19. The immediate release dosage form of any one of claims 4 to 6 or 17 wherein the dosage form core does not include hydroxypropyl methylcellulose

20. The dosage form of any one of claims 1 to 19, wherein the tebipenem pivoxil is in the form of tebipenem pivoxil free base.

21. The dosage form of any one of claims 1 to 19, wherein the tebipnenem pivoxil is in the form of tebipenem pivoxil HBr.

22. The dosage form of any one of claim 1 to 21, wherein the dosages form core compries 100, 300, 500, 600, 900, or 1000 milligrams of tebipenem pivoxil.

23. The dosage form core of any one of claims 1 to 22, wherein the dosage form core is a tablet core.

24. The dosage form core of any one of claims 1 to 22, wherein the dosage form core is a granule.

25. The dosage form of claim 24 wherein the granules are in a capsule.

26. The dosage form core of any one of claims 1 to 23, wherein the core further comprises a coating.

27. The tablet core of claim 23, wherein the tablet core is coated to form a coated tablet, and the coated tablet has a thickness of 6.00 to 7.00 millimeters.

28. The dosage form of claim 27, wherein the tablet core is coated with a coating that comprises from 2% to 5% (w%/w) of the total weight of the coated tablet.

29. The dosage form of any of claims 1 to 28, wherein the dosage is formulated for twice a day or three times a day administration.

30. A method of treating a urinary tract infection in a patient comprising administering the dosage form of any one of claims 1 to 29 to the patient.