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 HBr and excipients,

wherein the weight to weight ratio of tebipenem pivoxil (as a free base) to the excipients in the core is from 1:2 to 2:1,

and the excipients include a binder, a lubricant, an optionally a diluent.

2. 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 HBr 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.

3. The immediate release dosage form of claim 2, wherein the excipients additionally comprise a disintegrant.

4. The immediate release dosage form of claim 3, wherein the disintegrant is croscarmellose sodium, crospovidone, sodium starch glycolate, or any combination of any two or more of the foregoing.

5. The dosage form of claim 1, wherein the dosage form is a modified release dosage form and provides an in vitro release of not more than (NMT) 50 % of the tebipenem pivoxil HBr 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 and wherein the excipients additionally comprise a release control agent.

6. The modified release dosage form of claim 5, wherein not less than (NLT) 85% of the total amount of tebipenem pivoxil HBr 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.

7. The modified release dosage form of claim 5, wherein not less than (NLT) 85% of the total amount of tebipenem pivoxil HBr 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.

8. The modified release dosage form of claim 5, 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.

9. The dosage form of any one of claims 1 to 8, wherein

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

10. The dosage form of claim 9, wherein the binder is microcrystalline cellulose.

11. The dosage form of any one of claims 1 to 10, 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.

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

13. The modified release dosage form of claim 5, 6, or 7, 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.

14. The immediate release dosage form of claim 2, wherein the dosage form core comprises 30 % to 60 % (w%/w) tebipenem pivoxil, 1% to 10 % crospovidone, 15% to 25% monohydrate lactose or mannitol, 15 % to 25% microcrystalline cellulose, and 0.1% to 5% magnesium stearate.

15. The immediate release dosage form of claim 4 or 14, wherein the disintegrant is crospovidone and the weight to weight ratio of tebipenem pivoxil HBr to crospovidone is 20:1 to 5:1.

16. The immediate release dosage form of any one of claims 2 to 4 or 14 wherein the dosage form core does not include hydroxypropyl methylcellulose

17. The dosage form of any one of claim 1 to 16, wherein the dosages form core comprises 300, 500, 600, 900, or 1000 milligrams of tebipenem pivoxil.

18. The dosage form core of any one of claims 1 to 17, wherein the dosage form core is a tablet core.

19. The dosage form core of any one of claims 1 to 17, wherein the dosage form core is a granule.

20. The dosage form of claim 20 wherein the granules are in a capsule.

21. The dosage form core of any one of claims 1 to 19, wherein the core further comprises a coating.

22. The tablet core of claim 18, 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.

23. The dosage form of claim 22, 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.

24. The dosage form of any of claims 1 to 23, wherein the dosage is formulated for twice a day or three times a day administration.

25. The use of an oral dosage form of any one of claims 1 to 24 in the manufacture of a medicament for the treatment of a urinary tract infection in a patient.

26. The use of an oral dosage form of any one of claims 1 to 24 in the manufacture of a medicament for the treatment of a bacterial infection in a patient.

27. The use of an oral dosage form of any one of claims 1 to 24 in the manufacture of a medicament for the treatment of a *Mycobacterial tuberculosis* infection in a patient.

28. A tablet core comprising tebipenem pivoxil HBr and excipients, wherein tebipenem pivoxil (as a free base) comprises at least 55% by weight of the tablet core.

29. The tablet core of claim 28, wherein tebipenem pivoxil (as a free base) comprises at least 60% by weight of the tablet core.