Claims

1. A pharmaceutical composition comprising a eutectic of β-mannitol and Cyclobenzaprine HCl, wherein the eutectic comprises 75%±2% Cyclobenzaprine HCl and 25%±2% β-mannitol by weight.

2. The pharmaceutical composition of claim 1, wherein the Cyclobenzaprine HCl:β-mannitol eutectic molar ratio is 1.76±0.1.

3. The pharmaceutical composition of claim 1 or claim 2, wherein the Cyclobenzaprine HCl is micronized Cyclobenzaprine HCl.

4. The pharmaceutical composition of any one of claims 1 to 3, further comprising a basifying agent.

5. The pharmaceutical composition of claim 4, wherein the basifying agent is K_2HPO_4, Na_2HPO_4 or anhydrous trisodium citrate.

6. The pharmaceutical composition of any one of claims 1 to 5, wherein the eutectic melts at 143.6±3 °C.

7. A method of manufacturing a pharmaceutical composition comprising a eutectic of β-mannitol and Cyclobenzaprine HCl as claimed in any one of claims 1 to 6, said method comprising mixing Cyclobenzaprine HCl and β-mannitol or milling Cyclobenzaprine HCl and β-mannitol.

8. The method of claim 7, comprising milling Cyclobenzaprine HCl and β-mannitol.

9. The method of claim 8, wherein, the Cyclobenzaprine HCl and β-mannitol are milled in a high shear granulator.

10. The method of claim 7, comprising mixing Cyclobenzaprine HCl and β-mannitol.

11. The method of claim 10, wherein the Cyclobenzaprine HCl and β-mannitol are mixed via compression.

12. The method of claim 11, wherein the Cyclobenzaprine HCl and β-mannitol are compressed via roller compaction.

13. The method of any one of claims 7 to 12, wherein the Cyclobenzaprine HCl is micronized Cyclobenzaprine HCl.

14. The method of any one of claims 7 to 13, wherein the pharmaceutical composition further comprises a basifying agent.

15. The method of claim 14, wherein the basifying agent is K_2HPO_4, Na_2HPO_4 or anhydrous trisodium citrate.

16. The method of any one of claims 7 to 15, wherein the eutectic melts at 143.6±3 °C.

17. A eutectic composition of β-mannitol and Cyclobenzaprine HCl, wherein the eutectic comprises 75%±2% Cyclobenzaprine HCl and 25%±2% β-mannitol by weight.

18. The eutectic composition of claim 17, wherein the Cyclobenzaprine HCl:β-mannitol molar ratio is 1.76±0.1.

19. The eutectic composition of claim 17 or claim 18, wherein the Cyclobenzaprine HCl is micronized Cyclobenzaprine HCl.

20. The eutectic composition of any one of claims 17 to 19, wherein the eutectic composition melts at 143.6±3 °C.

21. A method of manufacturing a eutectic composition comprising β-mannitol and Cyclobenzaprine HCl as claimed in any one of claims 17 to 20, said method comprising mixing Cyclobenzaprine HCl and β-mannitol or milling Cyclobenzaprine HCl and β-mannitol.

22. The method of claim 21, comprising milling Cyclobenzaprine HCl and β-mannitol.

23. The method of claim 22, wherein the Cyclobenzaprine HCl and β-mannitol are milled in a high shear granulator.

24. The method of claim 21, comprising mixing Cyclobenzaprine HCl and β-mannitol.

25. The method of claim 24, wherein the Cyclobenzaprine HCl and β-mannitol are mixed via compression.

26. The method of claim 25, wherein the Cyclobenzaprine HCl and β-mannitol are compressed via roller compaction.

27. The method of any one of claims 21 to 26, wherein the Cyclobenzaprine HCl is micronized Cyclobenzaprine HCl.