

CLAIMS:

1. An injectable depot formulation comprising, cariprazine free base particles and a pharmaceutically acceptable carrier, wherein the cariprazine free base particles have a median particle size by volume (Dv50) ranging from 2 μm to 40 μm .
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2. The injectable depot formulation as claimed in Claim 1, wherein the cariprazine free base particles are present in an amount ranging from 4 wt% to 65 wt%, based on a total weight of the injectable depot formulation.
3. The injectable depot formulation as claimed in Claim 1, wherein the
10 pharmaceutically acceptable carrier comprises at least one of a suspending agent, a buffering agent, and a tonicity agent.
4. The injectable depot formulation as claimed in Claim 3, wherein the suspending agent is present in an amount ranging from 0.2 wt% to 10 wt%, based on the total weight of the injectable depot formulation.
- 15 5. The injectable depot formulation as claimed in Claim 3, wherein the suspending agent comprises a cellulose derivative, povidone, polyethylene glycol, or combinations thereof.
6. The injectable depot formulation as claimed in Claim 5, wherein the cellulose

derivative comprises carboxymethyl cellulose, sodium carboxymethyl cellulose, and methyl cellulose.

7. The injectable depot formulation as claimed in Claim 3, wherein the buffering agent is present in an amount ranging from 0.01 wt% to 2 wt%, based on the total weight of the injectable depot formulation.

8. The injectable depot formulation as claimed in Claim 3, wherein the buffering agent comprises sodium phosphate monobasic, disodium hydrogen phosphate, citric acid, sodium citrate, or combinations thereof.

9. The injectable depot formulation as claimed in Claim 3, wherein the tonicity agent is present in an amount ranging from 0.01 wt% to 6.5 wt%, based on the total weight of the injectable depot formulation.

10. The injectable depot formulation as claimed in Claim 3, wherein the tonicity agent comprises mannitol, glucose, sucrose, trehalose, and sodium chloride.

11. The injectable depot formulation as claimed in Claim 3, wherein the pharmaceutically acceptable carrier further comprises a wetting agent.

12. The injectable depot formulation as claimed in Claim 11, wherein the wetting agent is present in an amount ranging from 0.01 wt% to 3 wt%, based on the total weight of the injectable depot formulation.

13. The injectable depot formulation as claimed in Claim 11, wherein the wetting agent comprises polysorbate, poloxamer, lecithin, sorbitan monolaurate, and polyoxyethylene fatty acid esters.
14. The injectable depot formulation as claimed in Claim 3, wherein the pharmaceutically acceptable carrier further comprises a pH-adjusting agent.
15. The injectable depot formulation as claimed in Claim 14, wherein the pH-adjusting agent is present in an amount ranging from 0.01 wt% to 1 wt%, based on the total weight of the injectable depot formulation.
16. The injectable depot formulation as claimed in Claim 14, wherein the pH-adjusting agent comprises sodium hydroxide and hydrogen chloride.
17. Use of an injectable depot formulation in the manufacture of a medicament for treating psychosis, cognitive impairment accompanying schizophrenia, bipolar disorder, acute mania, mild-to-moderate cognitive deficits, dementia, psychotic states associated with dementia, psychotic depression, mania, paranoid and delusional disorders, dyskinetic disorders, neuroleptics-induced parkinsonism, tardive dyskinesia, eating disorders, attention deficit disorder, hyperactivity disorders in children, depression, anxiety, sexual dysfunction, sleep disorders, emesis, aggression, autism, major depressive disorder or drug abuse,

the injectable depot formulation comprising cariprazine free base particles and a pharmaceutically acceptable carrier, wherein the cariprazine free base particles have a median particle size by volume (Dv50) ranging from 2 μm to 40 μm .

18. An injectable depot formulation comprising cariprazine free base particles and a pharmaceutically acceptable carrier, wherein the cariprazine free base particles have a median particle size by volume (Dv50) ranging from 2 μm to 40 μm , wherein the pharmaceutically acceptable carrier comprises at least one of a suspending agent, a buffering agent, a tonicity agent, and combinations thereof, wherein the suspending agent comprises cellulose derivative, povidone, and polyethylene glycol, the buffering agent comprises sodium phosphate monobasic, disodium hydrogen phosphate, citric acid, and sodium citrate, and the tonicity agent comprises mannitol, glucose, sucrose, trehalose, and sodium chloride.

19. The injectable depot formulation as claimed in Claim 18, wherein the cariprazine free base particles have a median particle size by volume (Dv50) ranging from 8 μm to 40 μm .

20. The injectable depot formulation as claimed in any one of Claims 1 to 16 for use as a medicament.