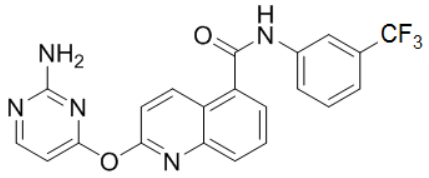
CLAIMS

WHAT IS CLAIMED IS:

1. A pharmaceutical composition, comprising:

(i) a compound of Formula (I):



(I),

or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof; and

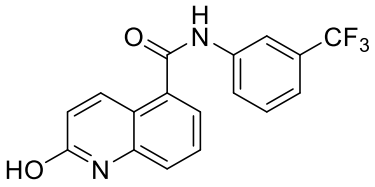
(ii) at least one pharmaceutically acceptable excipient,

wherein the pharmaceutical composition is in a dosage form for ophthalmic dosing or administration.

2. The composition of claim 1, wherein the dosage form is a suspension comprising fine particles of a compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof.
3. The composition of claim 2, wherein the particles are micronized.
4. The composition of claim 2 or 3, wherein the particles of the compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof have a diameter of from about 0.1 μm to about 40 μm, from about 0.1 μm to about 10 μm, or from about 0.3 μm to about 5 μm.
5. The composition of claim 3 or 4, wherein at least about 10%, about 20%, about 30%, or about 40%, about 50%, about 60%, about 70% , about 80%, about 90%, or about 95% of the particles have a diameter of from about 0.1 μm to about 40 μm.
6. The composition of any one of claims 2-5, wherein the particles have a D50 value of less than about 5 μm.
7. The composition of any one of claims 1-6 wherein the dosage form is a modified-release dosage form.
8. The composition of any one of claims 1-7, wherein the composition comprises from about 0.025% to about 2.0% w/v, about 0.05% to about 0.5% w/v, or about 0.05% to about 0.15% w/v of a compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof.

9. The composition of any one of claims 1-8, wherein the at least one pharmaceutically acceptable excipient is a diluent, buffering agent, suspending agent, a wetting agent, solubilizer, emulsifier, antioxidant, pH adjuster, an anti-oxidant, an osmotic pressure regulator, preservative, detackifier, anti-foaming agent, chelating agent, thickening agent, viscomodulator, tonicifier, colorant, opacifier, binder, filler, plasticizer, or any combination thereof.
10. The composition of claim 9, wherein the suspending agent is a carbomer homopolymer, carbomer copolymer, carbomer interpolymer, polycarbophil, a cellulose derivative, a polyvinyl alcohol, a povidone, a hyaluronic acid or a salt thereof, chondroitin sulfate, a natural gum, or any combination thereof.
11. The composition of claim 10, wherein the concentration of the suspending agent in the compositions is up to about 1% w/w or about 0.5% w/w.
12. The composition of any one of claims 9-11, wherein the wetting agent is polyoxyl 15-hydroxystearate.
13. The composition of claim 9 or 10, wherein the pH adjuster is a buffer.
14. The composition claim 13, wherein the buffer is a phosphate buffer selected from potassium phosphate, sodium dihydrogen phosphate dihydrate ($NaH_2PO_4 \cdot 2H_2O$), di-sodium hydrogen phosphate dodecahydrate ($Na_2HPO_4 \cdot 12H_2O$), or a combination thereof, or a hydrate thereof.
15. The composition ofclaim 9, wherein the osmotic pressure regulator is sodium chloride.
16. The composition of any one of claims 9-15, wherein the anti-oxidant is a thiosulfate.
17. The composition of claim 16, wherein the thiosulfate is sodium thiosulfate.
18. The composition of claim 16 or 17, wherein the concentration of the anti-oxidant in the composition is up to about 0.2% w/w.
19. The composition of any one of claims 1-18, wherein the composition is stable for up to 24 months at a temperature of from about 20 ℃ to about 25 ℃.
20. The composition of any one of claims 1-19, wherein the composition is at least about 90%, about 95%, about 96%, about 97%, about 98%, about 99%, about 99.1%, about 99.2%, about 99.3%, about 99.4%, about 99.5%, about 99.6%, about 99.7%, about 99.8%, about 99.9%, or about 100% pure.
21. The composition of any one of claims 1-19, wherein the composition comprises up to about 2% w/w of total impurities.

22. The composition of any one of claims 1-19, wherein the composition comprises less than about 0.9% w/w, about 0.8% w/w, about 0.7% w/w, about 0.6% w/w, about 0.5% w/w, about 0.4% w/w, about 0.3% w/w, about 0.2% w/w, or about 0.1% w/w of total impurities.
23. The composition of claim 21 or 22, wherein the impurity is a degradant.
24. The composition of any one of claims 21-23, wherein the impurity comprises the compound of Formula (II):



(II).

25. The composition of any one of claims 1-24, wherein the composition has a pH of from about 4.0 to about 9.0, or about 5.0 to about 8.0, or about 6.5 to about 8.0, or about 7.0 to about 8.0.
26. A method of preparing the composition of any one of claims 1-25, comprising:

(i) micronizing the compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof;

(ii) sterilizing the micronized compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof; and

(iii) admixing a therapeutically effective amount of the compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof with the least one pharmaceutically acceptable excipients.

27. The method of claim 26, wherein a suspension comprising particles of the compound of Formula (I), or an isotopic variant, tautomer, pharmaceutically acceptable salt, solvate, or hydrate thereof is formed.
28. The method of claim 26 or 27, wherein the sterilization is performed at a temperature of about 121 °C.
29. The method of any one of claims 26-28, wherein the sterilization is performed for a period of from about 20 to about 30 minutes.