[0004] Many drug compounds exist in one or more crystalline forms, referred to as polymorphs. These polymorphs of the same molecule exhibit different physical properties, such as melting point, solubility, hardness, etc. In such cases, the danger exists of less soluble polymorphic forms precipitating from a solution made from another more soluble but less stable form. For example, the formation of crystals in an ophthalmic solution can cause serious injury to the eye. In addition, precipitation of the drug substance may cause an apparent reduction in potency and bioavailability of the product.

[0005] Accordingly, there is need for novel crystalline forms of compounds such as the steroid-like compound described herein.

SUMMARY OF THE INVENTION

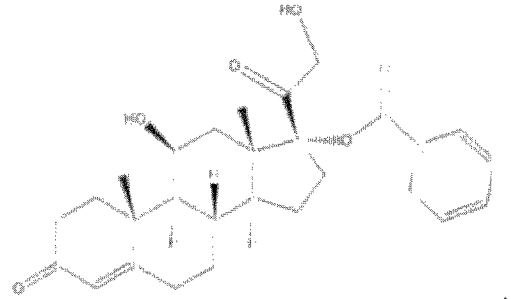
[0006] In accordance with the present invention, there are provided multiple solid forms of a steroid-like compound, and methods for the preparation and use thereof.

[0007] In one aspect of the present invention, there are provided crystalline forms of a steroid-like compound, and methods for the preparation and use thereof. In another aspect, there are provided substantially amorphous forms of a steroid-like compound, and methods for the preparation and use thereof.

[0008] In accordance with yet another aspect of the present invention, there are provided compositions containing said steroid-like compound. In certain aspects, such compositions are suitable for delivery of said steroid-like compound to a subject in need thereof. In certain aspects, there are provided methods for the treatment of a variety of indications, including glaucoma, dry eye disease, ocular hypertension, and the like.

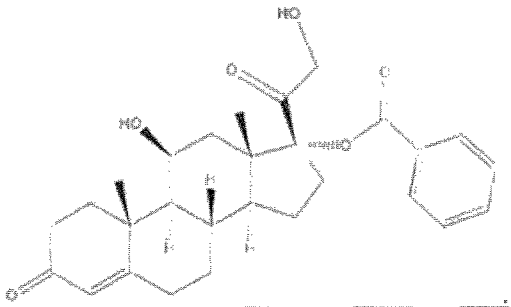
[0009] In accordance with a further aspect of the present invention, there are provided kits containing said steroid-like compound and/or compositions containing same.

[0009a] In accordance with further aspect of the present invention, there is provided a crystalline form of the compound:



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[0009b] In accordance with further aspect of the present invention, there is provided a substantially amorphous form of the compound:



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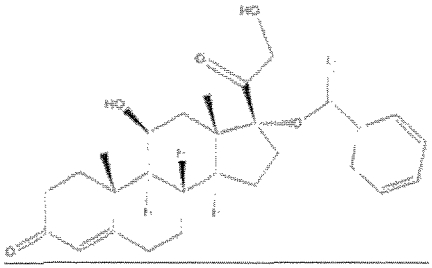
[0009c] In accordance with further aspect of the present invention, there is provided a pharmaceutical composition comprising a therapeutically effective amount of the crystalline form as disclosed herein in an ophthalmically acceptable carrier therefore.

[0009d] In accordance with further aspect of the present invention, there is provided a pharmaceutical composition comprising a therapeutically effective amount of the amorphous form as disclosed herein in an ophthalmically acceptable carrier therefore.

[0009e] In accordance with further aspect of the present invention, there is provided the use of a composition as disclosed herein in the manufacture of a medicament for treating dry eye disease.

[0009f] In accordance with further aspect of the present invention, there is provided the use of a composition as disclosed herein in the manufacture of a medicament for treating glaucoma.

[0009g] In accordance with further aspect of the present invention, there is provided a method for preparing a substantially crystalline form of the compound:



said method comprising subjecting a suspension and/or solution of said compound in a suitable diluent to:

(i) conditions suitable for evaporation of diluent therefrom,

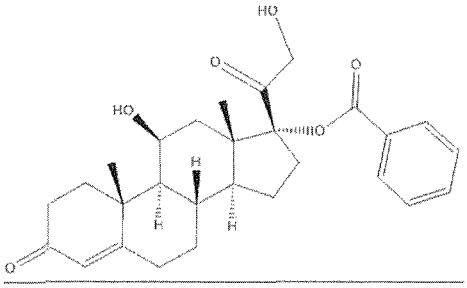
(ii) thermocycling/maturation (between room temperature and 50°C) in nonpolar solvent in the presence of crystalline or amorphous forms of the steroid-like compound, and

(iii) gradually:

reducing the temperature thereof, and/or

adding sufficient non-solvent thereto to promote precipitation of said compound therefrom.

[0009h] In accordance with further aspect of the present invention, there is provided a method for converting amorphous form of the compound:



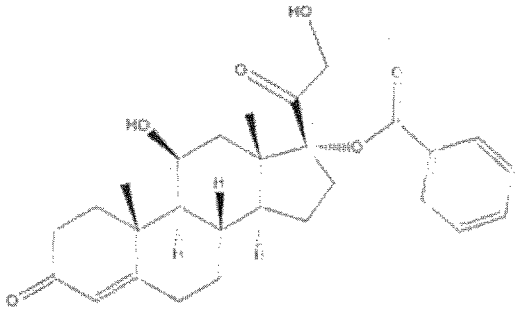
into crystalline form, said method comprising subjecting said compound to elevated humidity and/or temperature for at least 72 hours.

BRIEF DESCRIPTION OF THE FIGURES

[0010] Figure 1 presents an exemplary X-ray powder diffraction (XRPD) pattern for crystalline Form 1 of the steroid-like compound described herein. Major peaks unique to Form 1 include peaks at least at about 7.4, 10.2, 11.4, 12.4, 14.3, 14.7, 17.4, 20.2, 22.4 and 31.6 degrees 2θ. The vertical scale is from 0 to 11300, and the horizontal scale is from 2 to 42.

9. The crystalline form of claim 1 substantially free of other crystalline forms.

10. A substantially amorphous form of the compound:



11. A pharmaceutical composition comprising a therapeutically effective amount of the crystalline form of claim 1 in an ophthalmically acceptable carrier therefore.

12. A pharmaceutical composition comprising a therapeutically effective amount of the amorphous form of claim 10 in an ophthalmically acceptable carrier therefore.

13. ~~A method for treating dry eye disease comprising administering to a subject in need thereof~~ Use of a composition according to claim 11 in the manufacture of a medicament for treating dry eye disease.

14. ~~A method for treating dry eye disease comprising administering to a subject in need thereof~~ Use of a composition according to claim 12 in the manufacture of a medicament for treating dry eye disease.

15. ~~A method for treating glaucoma comprising administering to a subject in need thereof~~ Use of a composition according to claim 11 in the manufacture of a medicament for treating glaucoma.

16. ~~A method for treating glaucoma comprising administering to a subject in need thereof~~ Use of a composition according to claim 12 in the manufacture of a medicament for treating glaucoma.

17. A method for preparing a substantially crystalline form of the compound:

