CLAIMS

1. A self-emulsifying pharmaceutical composition comprising:
    a. an unsaturated free fatty acid;
    b. at least two emulsifiers; and
    c. lopinavir;

    wherein the at least two emulsifiers comprise at least a first emulsifier which has a HLB value greater than about 14 and at least a second emulsifier which has a HLB value less than about 6; and wherein the total emulsifier content is less than 30% by weight of the total composition.

2. The pharmaceutical composition according to claim 1, wherein the unsaturated free fatty acid is oleic acid.

3. The pharmaceutical composition according to any preceding claim, wherein the first emulsifier has a HLB value greater than about 15, such as greater than about 16, greater than about 17, or greater than about 18.

4. The pharmaceutical composition according to any preceding claim, wherein the first emulsifier is a polyol ester, such as a polyol stearate (for example PEG100 stearate), or a polyethoxylated sorbitan ester, such as polysorbate 20.

5. The pharmaceutical composition according to any preceding claim, wherein the second emulsifier has a HLB value less than about 5.5, such as less than about 5, less than about 4.5, or less than about 4.

6. The pharmaceutical composition according to any preceding claim, wherein the second emulsifier is a monoglyceride, such as a glycerol monooleate.

7. The pharmaceutical composition according to any preceding claim, wherein the wt/wt ratio of second emulsifier to first emulsifier present in the composition is between about 1:10 and about 10:1, such as between about 1:5 and about 5:1, between about 1:3 and about 3:1, between about 1:1 and about 5:1, between about 1:1 and about 3:1, between about 1:1 and about 2:1, between about 1:2 and about 2:1, between about 1:1.5 and about 2:1, between about 1:1.3 and about 1:1.1 (such as about 1:1.2), between about 1.1:1 and 1.2:1 (such as about 1.2:1), or between about 1.4:1 and 1.6:1 (such as about 1.5:1).

8. The pharmaceutical composition according to any preceding claim, wherein the at least two emulsifiers is three emulsifiers.

9. The pharmaceutical composition according to claim 8, wherein the first emulsifier has a HLB value greater than 14, the second emulsifier has a HLB value less than 6, the third emulsifier has a HLB value in the range 8 to 15; and the total emulsifier content is less than 30% by weight of the total composition.

10. The pharmaceutical composition according to claim 8 or 9, wherein the third emulsifier is a polyoxyl castor oil derivative (such as PEG 35 castor oil).

11. The pharmaceutical composition according to any preceding claim, wherein the total emulsifier content is less than 25% by weight, less than 20% by weight, less than 15% by weight, 2% to 20% by weight, 2.5% to 15% by weight, 5% to 15% by weight, 8% to 12%, 10% to 20%, 12% to 20%, 10% to 18%, 12% to 18%, 12% to 16%, 13% to 20%, 14% to 20%, 15% to 20%, 13% to 25%, 14% to 25%, 15% to 25%, 20% to 25%, 20% to 26%, 20% to 27%, 20% to 28% or 20% to 29% by weight of the total composition.

12. The pharmaceutical composition according to any preceding claim, wherein the first emulsifier is present in the pharmaceutical composition at about 1% to about 20% by weight of the total pharmaceutical composition, such as about 1% to about 10% by weight, about 10% to about 20% by weight, about 10% to about 15% by weight, about 1% to about 5% by weight, about 3% to about 7% by weight, about 3% to about 6% by weight, about 3% to about 5% by weight (such as about 4% by weight), about 4% to about 5% by weight (such as about 4.3% by weight), or about 5% to about 6% by weight (such as about 5.5% by weight) of the total composition.

13. The pharmaceutical composition according to any preceding claim, wherein the second emulsifier is present in the pharmaceutical composition at about 1% to about 20% by weight of the total pharmaceutical composition, such as about 1% to about 10% by weight, about 2% to about 8% by weight, about 4% to about 7% by weight, about 5% to about 7% by weight (such as about 6% by weight), about 4% to about 6% by weight (such as about 5% by weight), or about 4% to about 5% by weight (such as about 4.5% by weight) of the total composition.

14. The pharmaceutical composition according to any one of claims 8-13, wherein the third emulsifier is present in the pharmaceutical composition at about 1% to about 10% by weight of the total pharmaceutical composition, such as about 2% to about 8% by weight, about 3% to about 7% by weight, about 4% to about 6% by weight, or about 5% by weight of the total composition

15. The pharmaceutical composition according to any preceding claim, wherein the pharmaceutical composition further comprises ritonavir.

16. The pharmaceutical composition according to claim 15, wherein the wt/wt ratio of lopinavir to ritonavir present in the composition is between about 1:10 and about 18:1, such as between about 1:10 and about 15:1, such as between about 1:5 and about 15:1, such as between about 1:1 and about 15:1, such as between about 2:1 and about 15:1, such as between about 4:1 and about 15:1, such as between about 8:1 and about 14:1, such as between about 9:1 and about 14:1, such as between about 10:1 and about 14:1, such as between 10.5:1 and about 18:1, such as between 10.5:1 and 18:1, such as between about 10.5:1 and about 14:1, such as between about 11:1 to about 13:1, such as between about 11.5 and about 17:1, such as between about 11.5:1 and about 16.0:1, such as between about 11.5:1 and about 15:1, such as about 14.5:1, such as 14.5:1, such as about 14:1, such as 14:1, such as about 13.8:1, such as 13.8:1, such as about 13.75:1, such as 13.75:1, such as about 13.5:1, such as 13.5:1, such as about 13:1, such as 13:1, such as about 12.5:1, such as 12.5:1, such as about 12:1, such as 12:1, such as about 11.75:1, such as 11.75:1, such as about 11.5:1, such as 11.5:1, such as about 11.25:1, such as 11.25:1, or such as about 11:1, such as 11:1.

17. A self-emulsifying pharmaceutical composition consisting of:
    a. an unsaturated free fatty acid;
    b. a first emulsifier having a HLB value greater than about 14;
    c. a second emulsifier having a HLB value less than about 6;
    d. a third emulsifier;
    e. an antioxidant;
    f. lopinavir; and
    g. ritonavir;

    wherein the total emulsifier content is less than 30% by weight of the total composition.

18. The pharmaceutical composition according to any preceding claim wherein the pharmaceutical composition is encapsulated within a capsule.

19. The pharmaceutical composition according to any preceding claim for use as a medicament.

20. A method of treating and/or inhibiting the development or progression of cancers and benign proliferative disorders in a subject in need of such treatment or inhibition

comprising administering a therapeutically effective amount of a pharmaceutical composition according to any of claims 1-18 to said subject.

21. A method of treating a patient having an HPV related dysplasia of the cervix comprising administering intra-vaginally or orally to said patient a therapeutically effective dose of a pharmaceutical composition according to any one of claims 1-18.

22. The method of claim 21, wherein the pharmaceutical composition reduces the severity of the HPV related dysplasia.

23. The method of any one of claims 20-22, wherein the composition induces apoptosis of HPV infected cells.

24. The method of any one of claims 20-23, wherein the patient has a cervical cytology of high grade squamous intraepithelial lesion (HSIL), atypical squamous cells of undetermined significance (ASCUS), or low grade squamous intraepithelial lesion (LSIL).

25. A process to manufacture a self-emulsifying pharmaceutical composition of any one of claims 1 to 18, the process comprising the steps of:

a. incorporating (e.g. by mixing) lopinavir in an unsaturated free fatty acid;
b. incorporating (e.g. by mixing) at least two emulsifiers to the mixture from step a) to provide a self-emulsifying composition;

wherein the at least two emulsifiers comprise a first emulsifier having a HLB value greater than about 14 and a second emulsifier having a HLB value less than about 6; and wherein the total emulsifier content is less than 30% by weight of the total composition.