CLAIMS

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

   wherein the at least two emulsifiers comprise at least a first emulsifier which has a HLB value greater than 14 and at least a second emulsifier which has a HLB value less than 6; wherein the total emulsifier content is less than 30% by weight of the total composition; and wherein the wt/wt ratio of lopinavir to ritonavir present in the composition is between 10:1 and 14:1.

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

3. The pharmaceutical composition according to any one of claims 1 or 2, wherein the first emulsifier has a HLB value greater than 15, such as greater than 16, greater than 17, or greater than 18.

4. The pharmaceutical composition according to any one of claims 1 to 3, 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 one of claims 1 to 4, 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 one of claims 1 to 5, wherein the second emulsifier is a monoglyceride, such as a glycerol monooleate.

7. The pharmaceutical composition according to any one of claims 1 to 6, wherein the wt/wt ratio of second emulsifier to first emulsifier present in the composition is between 1:10 and 10:1, such as between 1:5 and 5:1, between 1:3 and 3:1, between 1:1 and 5:1, between 1:1 and 3:1, between 1:1 and 2:1, between 1:2 and 2:1, between 1:1.5 and 2:1, between 1:1.3 and 1:1.1 (such as 1:1.2), between 1.1:1 and 1.2:1 (such as 1.2:1), or between 1.4:1 and 1.6:1 (such as 1.5:1).

8. The pharmaceutical composition according to any one of claims 1 to 7, 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 one of claims 1 to 10, 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 one of claims 1 to 11, wherein the first emulsifier is present in the pharmaceutical composition at 1% to 20% by weight of the total pharmaceutical composition, such as 1% to 10% by weight, 10% to 20% by weight, 10% to 15% by weight, 1% to 5% by weight, 3% to 7% by weight, 3% to 6% by weight, 3% to 5% by weight (such as 4% by weight), 4% to 5% by weight (such as 4.3% by weight), or 5% to 6% by weight (such as 5.5% by weight) of the total composition.

13. The pharmaceutical composition according to any one of claims 1 to 12, wherein the second emulsifier is present in the pharmaceutical composition at 1% to 20% by weight of the total pharmaceutical composition, such as 1% to 10% by weight, 2% to 8% by weight, 4% to 7% by weight, 5% to 7% by weight (such as 6% by weight), 4% to 6% by weight (such as 5% by weight), or 4% to 5% by weight (such as 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 1% to 10% by weight of the total pharmaceutical composition, such as 2% to 8% by weight, 3% to 7% by weight, 4% to 6% by weight, or 5% by weight of the total composition.

15. The pharmaceutical composition according to any one of claims 1 to 14, wherein the wt/wt ratio of lopinavir to ritonavir present in the composition is between 10.5:1 and 14:1, such as between 11:1 and 13:1, such as 14:1, such as 13.8:1, such as 13.75:1, such as 13.5:1, such as 13:1, such as 12.5:1, such as 12:1, such as 11.75:1, such as 11.5:1, such as 11.25:1, or such as 11:1.

16. The pharmaceutical composition according to any one of claims 1 to 15 wherein the pharmaceutical composition is encapsulated within a capsule.

17. The pharmaceutical composition according to any one of claims 1 to 16 for use as a medicament.

18. Use of a pharmaceutical composition according to any of claims 1-16 in the manufacture of a medicament for the treatment and/or inhibition of the development or progression of cancers and benign proliferative disorders in a patient in need of such treatment or inhibition.

19. Use of a pharmaceutical composition according to any of claims 1-16 in the manufacture of a medicament for the treatment of a patient having an HPV related dysplasia of the cervix.

20. The use of claim 19, wherein the medicament reduces the severity of the HPV related dysplasia.

21. The use of any one of claims 18-20, wherein the medicament induces apoptosis of HPV infected cells.

22. The use of any one of claims 18-21, 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).

23. A process to manufacture a self-emulsifying pharmaceutical composition of any one of claims 1 to 16, the process comprising the steps of:
    a. incorporating (e.g. by mixing) lopinavir and ritonavir 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 14 and a second emulsifier having a HLB value less than 6; wherein the total emulsifier content is less than 30% by weight of the total composition; and wherein the wt/wt ratio of lopinavir to ritonavir present in the composition is between 10:1 and 14:1.