CLAIMS

What is claimed is:

1. A bilayer tablet formulation of two antiretroviral drugs useful against HIV which are

a) atazanavir; and

b) cobicistat in the form of cobicistat on silicon dioxide.

2. The formulation of claim 1, wherein said atazanavir is in the form of atazanavir sulfate.

3. The formulation of claim 2, wherein said tablet is not a trilayer tablet, said trilayer tablet having an inert excipient layer as the middle layer.

4. The formulation of claim 3, wherein said bilayer tablet does not show visible cracking.

5. The formulation of claim 4, wherein said bilayer tablet delivers about 300 mg as the free base of atazanavir sulfate, and about 150 mg. of cobicistat.

6. The formulation of claim 5, further comprising at least one excipient selected from the group of stearic acid, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, crospovidone, hydroxypropyl cellulose, and croscarmellose sodium.

7. The formulation of claim 1, wherein said atazanavir and said cobicistat together comprise about 35-85% (w/w) of said formulation.

8. The formulation of claim 1 further comprising a pharmaceutically acceptable carrier, said formulation comprising less than or equal to about 0.2% of degradant BMT-115982 or BMT-089290

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9. A tablet according to claim 1, said tablet having less than about 3% total cobicistat impurities after 8 weeks at 40 ° C and 75% relative humidity or less than about 2% cobicistat impurities at about 12 months when stored at room temperature, when stored at 30°C/75%RH, when stored at 25°C/60%RH or when stored at 25°C/75%RH.

10. The tablet as claimed in claim 9, wherein said tablet does not crack under room temperature conditions within 24 hours of being released from a tablet press.

11. The tablet as claimed in claim 9, wherein said tablet has a hardness value within the range of about 28-39 SCUs.

12. A tablet formulation according to claim 1 to 11 for use in the treatment of HIV infection in a patient.

13. A method of making an atazanavir/cobicistat tablet formulation, which comprises:

a) separately admixing atazanavir together with one or more excipients, wherein at least one of said excipients is microcrystalline cellulose, wherein said atazanavir is first admixed with a first portion of said one or more excipients to produce a first atazanavir admixture, and further wherein said first admixture is then wet granulated with water and then wet milled, sized and dried, and wherein a second portion of said excipients is then admixed with said dried first admixture to produce a second atazanavir admixture;

b) separately admixing cobicistat in the form of cobicistat on silicon dioxide. together with one or more excipients, wherein at least one of said excipients is microcrystalline cellulose, wherein said cobicistat is first admixed with a first portion of said one or more excipients to produce a first cobicistat admixture, wherein said first admixture is then roller compacted and milled into granules, and wherein a second portion of said excipients is then admixed with said granulated first admixture to produce a second cobicistat admixture; and

c) compressing said second atazanavir admixture and said second cobicistat admixture into a bilayer tablet.

14. The method of claim 13, wherein in step a) said first portion of said excipients are intragranular excipients, and said second portion of said excipients are extragranular

excipients; and further wherein in step b) said first portion of said excipients are intragranular excipients, and said second portion of said excipients are extragranular excipients.