CLAIMS

1. An orally disintegrating film matrix comprising:

a first and second active ingredient, further comprising the second active ingredient impregnated to the orally disintegrating film matrix via 3D printing;

rapidly dissolving binder comprising polyvinyl alcohol (PVA) and polyvinyl alcohol (PVA)–polyethylene glycol (PEG) copolymer; and

film forming polymer comprising hydroxypropyl methyl cellulose (HPMC);

wherein,

the orally disintegrating film matrix has a moisture content of less than 8 wt.%; and

upon contact with the oral cavity, the orally disintegrating film matrix disintegrates within 60 seconds.

2. An orally disintegrating film matrix comprising:

a first and second active ingredient, further comprising the second active ingredient impregnated to the orally disintegrating film matrix via 3D printing;

a moisture deterring polymer;

rapidly dissolving binder comprising polyvinyl alcohol (PVA) and polyvinyl alcohol (PVA)–polyethylene glycol (PEG) copolymer; and

film forming polymer comprising hydroxypropyl methyl cellulose (HPMC);

wherein,

the orally disintegrating film matrix has a moisture content of less than 8 wt.%, and

upon contact with the oral cavity, the orally disintegrating film matrix disintegrates within 60 seconds.

3. A method of forming an orally disintegrating film matrix comprising:

(a) contacting water, a first active ingredient, a rapidly dissolving binder, optionally a first active ingredient, and a film forming polymer, to form a homogeneous mixture;

(b) extruding the homogeneous mixture onto a substrate;

(c) curing the extruded homogeneous mixture to form the orally disintegrating film matrix;

(d) after the curing of the extruded homogeneous mixture to form the orally disintegrating film matrix, impregnating via 3D printing, a second active ingredient to the cured orally disintegrating film matrix; and

(e) sizing the impregnated orally disintegrating film matrix to a desired surface area;

wherein,

the rapidly dissolving binder comprises polyvinyl alcohol (PVA) and polyvinyl alcohol (PVA)–polyethylene glycol (PEG) copolymer; and

the film forming polymer comprises hydroxypropyl methyl cellulose (HPMC).

4. A kit comprising

(a) the orally disintegrating film matrix of any one of claims 1 or 2 or the orally disintegrating film matrix obtained by the method of claim 3;

(b) a sealable and vapor impermeable container closure system;

wherein,

the orally disintegrating film matrix is contained within the sealable and vapor impermeable container closure system.

5. Use of the orally disintegrating film matrix of any one of claims 1 or 2, or the orally disintegrating film matrix obtained by the method of claim 3, in the manufacture of a medicament for delivering a first and second active ingredient to a subject, wherein the medicament is to be orally administered to the subject.

6. The orally disintegrating film matrix of any one of claims 1 or 2, further comprising a moisture deterring polymer comprising aminoalkyl methacrylate copolymers.

7. The orally disintegrating film matrix of claim 6, wherein the moisture deterring polymer comprises aminoalkyl methacrylate copolymers (EUDRAGIT® EPO).

8. The orally disintegrating film matrix of claim 6, wherein the moisture deterring polymer comprises 1-4 wt.% aminoalkyl methacrylate copolymers (EUDRAGIT® EPO).

9. The orally disintegrating film matrix of any one of claims 1 or 2 and 6–8, wherein the rapidly dissolving binder comprises polyvinyl alcohol (PVA) and polyvinyl alcohol (PVA)–polyethylene glycol (PEG) copolymer (Kollicoat® Protect).

10. The orally disintegrating film matrix of any one of claims 1 or 2 and 6–8, wherein the rapidly dissolving binder comprises 40-80 wt.% polyvinyl alcohol (PVA) and polyvinyl alcohol (PVA)–polyethylene glycol (PEG) copolymer (Kollicoat® Protect).

11. The orally disintegrating film matrix of any one of claims 1 or 2 and 6–10, wherein the film forming polymer comprises 5-20 wt.% Hypromellose (hydroxypropyl methyl cellulose (HPMC)).

12. The orally disintegrating film matrix of any one of claims 1 or 2 and 6–11, further comprising at least one of plasticizer, preservative, solvent, coloring agent, flavoring agent, sweetening agent, filler, bulking agent, saliva stimulating agent, stabilizing and thickening agent, gelling agent, taste masking agent, pigment, lubricant, release modifier, adjuvant, solubilizer, emulsifier, fragrance, emulsifier, surfactant, lipid, glidant, stabilizer, antioxidant, anti-tacking agent, acid, base, buffer, and humectant.

13. The orally disintegrating film matrix of any one of claims 1 or 2 and 6-12, wherein upon contact with the oral cavity, the orally disintegrating film matrix disintegrates within 15 seconds.

14. The orally disintegrating film matrix of any one of claims 1 or 2 and 6-13, wherein the orally disintegrating film matrix has a moisture content of less than 4 wt.%.

15. The orally disintegrating film matrix of any one of claims 1 or 2, and 6-14, further comprising citric acid, in an amount sufficient to adjust the pH of the orally disintegrating film matrix to a pH of 4.6 to 5.