

CLAIMS:

1. An oral delivery system comprising or consisting essentially of a dry homogenous mixture comprising a protein powder and a polysaccharide powder mixture, and an active ingredient dispersed therein, the protein and polysaccharide powder mixture forming a protein/polysaccharide complex coacervate *in situ* upon immersion of the oral delivery system in a gastric fluid, thereby conferring gastric protection and/or modified release to the active ingredient, wherein varying the ratio of protein powder to polysaccharide powder in the oral delivery system varies the level of gastric protection and/or rate of release of the active ingredient.
2. The oral delivery system of claim 1, wherein the polysaccharide powder has, or is conditioned to have, one or more of the following powder flow characteristics:
- (a) an angle of repose (α) greater than about 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, or 65 degrees;
 - (b) a dynamic cohesive index greater than about 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, or 50;
 - (c) a compressibility index (Carr index) greater than about 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, or 38%;
 - (d) a Hausner ratio greater than about 1.18, 1.19, 1.2, 1.21, 1.22, 1.23, 1.24, 1.25, 1.26, 1.27, 1.28, 1.29, 1.3, 1.31, 1.32, 1.33, 1.34, 1.35, 1.36, 1.37, 1.38, 1.39, 1.4, 1.41, 1.42, 1.43, 1.44, 1.45, 1.46, 1.47, 1.48, 1.49, 1.5, 1.51, 1.52, 1.53, 1.54, 1.55, 1.56, 1.57, 1.58, 1.59, or 1.6; or
 - (e) any combination of (a) to (d).
3. The oral delivery system of claim 2, wherein the polysaccharide powder has, or is conditioned to have, all the powder flow characteristics as defined in (a), (b), (c) and (d).
4. The oral delivery system of any one of claims 1 to 3, wherein the protein and polysaccharide powder mixture forms a protein/polysaccharide complex coacervate *in situ* upon immersion of the oral delivery system in a solution of pH below the pKa of the polysaccharide.
5. The oral delivery system of any one of claims 1 to 4, wherein:

- (a) increasing the ratio of polysaccharide powder to protein power in the oral delivery system increases the level of gastric protection and/or decreases the rate of release to the active ingredient;
- (b) the weight ratio of polysaccharide powder to protein power in the oral delivery system is 1:20 to 1:1, 1:15 to 1:1.5, 1:10 to 1:2, 1:9.5 to 1:2.5, 1:9 to 1:3, or 1:8.5 to 1:3.5, 1:8 to 1:4, 1:7.5 to 1:4.5, or 1:7 to 1:5;
- (c) the oral delivery system comprises about 5% to 50%, 10% to 45%, 15% to 40%, or 20% to 35% w/w of the protein and polysaccharide mixture; or
- (d) any combination thereof.
6. The oral delivery system of any one of claims 1 to 5, wherein:
- (a) the protein and polysaccharide powder mixture forms a protein/polysaccharide complex coacervate *in situ* upon immersion of the oral delivery system in a simulated gastric fluid (SGF) consisting of a 37% v/v solution of diluted HCl at pH 1.0, containing 2 g/L of NaCl and 0.1 g/L of pepsin;
- (b) the active ingredient's rate of release is inversely proportional to the strength of the protein/polysaccharide complex coacervate formed *in situ* upon immersion of the oral delivery system in the gastric fluid;
- (c) the protein/polysaccharide complex coacervate formed *in situ* upon immersion of the oral delivery system in the SGF is characterized by the presence of intramolecular beta-sheets, alpha-helices, and/or unordered structures (e.g., as measured by Fourier transform infrared (FTIR) spectroscopy); or
- (d) any combination thereof.
7. The oral delivery system of any one of claims 1 to 6, which is:
- (i) a delayed-release oral delivery system;
- (ii) an extended-release oral delivery system;
- (iii) an oral delivery system providing increased gastric protection to the active ingredient upon oral administration, as compared to administration of an unformulated active ingredient; or
- (iv) any combination thereof.
8. The oral delivery system of claim 7, wherein:

- (i) the delayed release oral delivery system delays the time required for 50% of the active ingredient to be released by at least 30, 60, 90, 120, 150, 180, 210, or 240 minutes, as compared to a corresponding oral delivery system lacking the polysaccharide powder;
- (ii) the extended-release oral delivery system results in release of the active ingredient over a period of at least 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, or 18 hours; and/or
- (ii) the oral delivery system provides increased gastric protection to the active ingredient as compared to administration of an unformulated active ingredient;

upon dissolution testing comprising immersion of the oral delivery system at 37°C in SGF for two hours followed by immersion in simulated intestinal fluid (SIF), wherein the SGF consists of a 37% v/v diluted HCl solution, pH 1.0, containing 2 g/L of NaCl and 0.1 g/L of pepsin, and the SIF consists of a 50 mM NaH₂PO₄ or KH₂PO₄ buffer solution at pH 6.9, containing 0.5 g/L of pancreatin.

9. The oral delivery system of any one of claims 1 to 8, wherein the protein powder comprises or consists of: natural proteins; food-grade and/or pharmaceutical-grade proteins; native proteins; denatured proteins (e.g., thermally denatured proteins); chemically unmodified proteins; chemically modified proteins (e.g., succinylated proteins); plant proteins (e.g., hemp, sacha inchi); animal proteins; dairy proteins (e.g., whey protein); legume proteins (e.g., pea or soy protein); fruit protein (e.g., coconut); cereal proteins (e.g., rice) ; or any mixture thereof.

10. The oral delivery system of any one of claims 1 to 9, wherein the polysaccharide powder comprises or consists of: natural polysaccharides; food-grade and/or pharmaceutical-grade polysaccharides; chemically unmodified polysaccharides; chemically modified polysaccharides; plant polysaccharides; animal polysaccharides; polysaccharides containing negatively charged/acidic groups (anionic polysaccharides); carrageenan (e.g., kappa-carrageenan); xanthan gum; alginate; pectin powder; agar, gellan, guar gum, carboxymethylcellulose, locust bean gum, mannan, glucomannan, hyaluronan, tamarind gum, psyllium seed gum, tara gum, acacia gum, arabic gum, ghatti gum, tragacanth gum, karaya gum, cassia gum, rhamsan gum, welan gum, macrophomopsis gum, curdlan, pullulan, fucoidan, or any mixture thereof.

11. The oral delivery system of any one of claims 1 to 10, wherein the active ingredient is a dietary supplement, a drug, a probiotic, a vitamin, an amino acid, a food extract, or an herbal supplement.

12. The oral delivery system of any one of claims 1 to 11, further comprising one or more nutraceutically or pharmaceutically acceptable excipients and/or additives (e.g., a filler, a binder, a lubricant, and/or a flow agent).
- 5 13. The oral delivery system of claim 12, wherein the additive is or comprises microcrystalline cellulose, magnesium stearate, and/or silicon dioxide.
14. The oral delivery system of any one of claims 1 to 13, which is a tablet or a capsule.
- 10 15. The oral delivery system of any one of claims 1 to 14, wherein the oral delivery system does not comprise an enteric coating.
16. A process for preparing a solid oral dosage form, the process comprising dispersing an active ingredient in a dry homogenous mixture comprising a protein powder and a polysaccharide powder, and
15 formulating the resulting mixture into a solid oral dosage form, the polysaccharide powder having powder flow characteristics enabling interaction with the protein powder such that immersion of the solid oral dosage form in a gastric fluid results in formation of a protein/polysaccharide complex coacervate *in situ*, thereby conferring gastric protection and/or modified-release to the active ingredient.
- 20 17. The process of claim 16, wherein the polysaccharide powder has one or more of the powder flow characteristics as defined in claim 2.
18. The process of claim 16 or 17, wherein solid oral dosage form is the oral delivery system as defined in any one of claims 1 to 15.
- 25 19. The oral delivery system as defined in any one of claims 1 to 15, or the oral dosage form produced by the process of any one of claims 16 to 18, for use in therapy.
20. A method for producing a protein/polysaccharide complex coacervate *in situ* that confers gastric
30 protection and/or modified-release to an active ingredient dispersed therein, the method comprising providing the active ingredient formulated in the oral delivery system as defined in any one of claims 1 to 15, or formulated in the oral dosage form produced by the process of any one of claims 16 to 18, and orally administering the oral delivery system or the oral dosage form to a subject, wherein the protein and

polysaccharide powder mixture forms the protein/polysaccharide complex coacervate *in situ* upon immersion of the oral delivery system in the subject's gastric fluid.

21. A method for treating a disease or condition ameliorated by administration to a subject of an active ingredient which would benefit from gastric protection and/or modified-release, the method comprising providing the active ingredient formulated in the oral delivery system as defined in any one of claims 1 to 15, or formulated in the oral dosage form produced by the process of any one of claims 16 to 18, and orally administering the oral delivery system or the oral dosage form to a subject, wherein the protein and polysaccharide powder mixture forms a protein/polysaccharide complex coacervate *in situ* upon immersion of the oral delivery system in the subject's gastric fluid.