CLAIMS

1. A biphasic pharmaceutical formulation comprising:

at least 25 mg/mL of polyethylene glycol (PEG);

at least 100 mg/mL of a protein, wherein less than 50% of the protein is present in a liquid phase with PEG, and the remainder of the protein is present in a solid phase in equilibrium with the liquid phase, wherein the solid phase is excluded from the liquid phase by PEG, and

a semi-permeable membrane, wherein the semi-permeable membrane surrounds the liquid phase and preferentially retains PEG while allowing diffusion of the protein through the membrane,

wherein the protein is stable for at least 30 days at physiological temperature, and the liquid phase has access to an environment with a lower concentration of the protein through the semi-permeable membrane.

2. The biphasic pharmaceutical formulation of claim 1, wherein said protein is between 100 mg/mL and 1400 mg/mL of a protein.

3. The biphasic pharmaceutical formulation of claim 1 or 2, wherein the concentration of PEG is between 25 mg/mL and 150 mg/mL.

4. The biphasic pharmaceutical formulation of claim 1 or 2, wherein the concentration of the protein is between 100 mg/mL and 500 mg/mL.

5. The biphasic pharmaceutical formulation of claim 1 or 2, wherein said solid phase comprises between 0.05 mg/mL and 50 mg/mL of said protein.

6. The biphasic pharmaceutical formulation of claim 1 or 2, wherein said protein has a molecular weight of about 25 kD to about 160 kD.

7. The biphasic pharmaceutical composition of claim 1 or 2, wherein said protein is selected from the group consisting of receptor-Fc-fusion protein, monoclonal antibody, polyclonal antibody, Fab fragment, single-chain variable fragment (scFv), and nanobody.

8. The biphasic pharmaceutical formulation of claim 1 or 2, wherein said protein in the solid phase is stable for at least 60 days at physiological temperature.

9. The biphasic pharmaceutical formulation of claim 1 or 2, wherein at least 85% of said protein in the solid phase has a native molecular weight at 60 days at physiological temperature as determined by size-exclusion chromatography.

10. The biphasic pharmaceutical formulation of claim 1 or 2, wherein said protein in the solid phase is more stable than an equivalent concentration of the solid phase without PEG or in a closed biphasic system.

11. The biphasic pharmaceutical formulation of claim 1, wherein said environment is a physiological environment.

12. A biphasic pharmaceutical formulation, wherein said biphasic pharmaceutical formulation comprises:

a. polyethylene glycol (PEG) at a concentration that limits protein solubility to less than 50 mg/ml and greater than 0.5 mg/ml;

b. at least 100 – 1400 mg/mL of said protein, wherein less than 50% of the protein is present in a liquid phase with PEG, and the remainder of the protein is present in a solid phase in equilibrium with the liquid phase; and,

c. a semi-permeable membrane surrounding the liquid phase,

wherein said protein is stable upon release from said biphasic formulation for at least 30 days at physiological temperature, and said soluble protein can diffuse through the semi-permeable membrane and the PEG is preferentially retained within the membrane.

13. The formulation of claim 12, wherein said PEG is fully soluble, is only in the liquid phase, and is at a lower concentration in said liquid phase than said protein in said solid phase.

14. A biphasic pharmaceutical formulation for use in the treatment of a patient in need of a constituent drug, wherein said biphasic pharmaceutical formulation comprises:

a. at least 25 mg/mL of polyethylene glycol (PEG);

b. at least 100 mg/mL of said constituent drug, wherein less than 50 mg/mL of the constituent drug is present in a liquid phase with PEG, and the remainder of the constituent drug is present in a solid phase in equilibrium with the liquid phase and;

c. a semi-permeable membrane, wherein the semi-permeable membrane surrounds the liquid phase and preferentially retains PEG while allowing diffusion of the constituent drug through the membrane, and

wherein said constituent drug is a protein, said liquid phase is stable for at least 30 days at physiological temperature, and said liquid phase has access through a porous structure to an environment in said patient with a lower concentration of said protein.