Summary

In one aspect, the present disclosure refers to composition for reconstituting dried peptides, wherein the composition comprises or consists of 60-80% v/v aqueous solution comprising 0.05 - 0.1M of a weak organic acid having a pK_a of between 1 and 4, 5-10% v/v propylene glycol (CAS no. 57-55-6), 10-20% v/v lower alcohol wherein a lower alcohol is an organic compound having a hydroxyl functional group bound to an alkyl group that has at most 6 carbon atoms, and 5-10% v/v non-ionic hydrophilic surfactant, wherein the non-ionic hydrophilic surfactant is an ethoxylated triglyceride.

In another example, there is provided pharmaceutical composition comprising the reconstitution composition as described herein and further comprising peptides, preferably of between 15 and 100 amino acids in length.

In another example, there is provided pharmaceutical composition as described herein, for use as a medicament, the medicament, preferably being a vaccine.

In another aspect, the present disclosure refers to method for reconstituting dried, preferably lyophilized, peptides, comprising the following subsequent steps:

a) providing a vial comprising dried, preferably lyophilized, peptides, wherein preferably the peptides are peptides of between 15 and 100 amino acids in length,;

b) thawing the peptides, preferably for 5-30 min;

c) adding the reconstitution composition as described herein to the vial comprising the peptides, preferably without swirling the vial;

d) allowing to admix, preferably for 0.5-5 minutes; and

e) swirling until a clear solution is obtained, preferably for 1-3 minutes.

In another aspect, the present disclosure refers to method for preparing a pharmaceutical composition, comprising the subsequent steps of:

(i) collect reconstituted peptides obtainable by the method as described herein in a first syringe;

(ii) connect the first syringe of step (i) to a second syringe comprising an oil-based adjuvant using a connector;

(iii) push the content of the first syringe into the second syringe and backwards; and

(iv) repeat step (iii) 10-50 times in a total in 10-50 seconds.

In another example, there is provided kit of parts comprising a:

1. a first vial containing dried, preferably lyophilized, peptides, wherein preferably the peptides are peptides of between 15 and 100 amino acids in length;
2. a second vial containing a composition as described herein; and optionally,
3. a third vial containing an oil-based adjuvant.

Claims

1. Composition for reconstituting dried peptides, wherein the composition comprises or consists of

60-80% v/v aqueous solution comprising 0.05 - 0.1M of a weak organic acid having a pK_a of between 1 and 4,

5-10% v/v propylene glycol (CAS no. 57-55-6),

10-20% v/v lower alcohol wherein a lower alcohol is an organic compound having a hydroxyl functional group bound to an alkyl group that has at most 6 carbon atoms, and

5-10% v/v non-ionic hydrophilic surfactant, wherein the non-ionic hydrophilic surfactant is an ethoxylated triglyceride.

2. Composition according to claim 1, wherein the organic acid is citric acid.

3. Composition according to claims 1 or 2, wherein the lower alcohol is ethanol.

4. Composition according to any one of claims 1-3, wherein the non-ionic hydrophilic surfactant is ethoxylated castor oil, preferably polyoxyethyleneglyceroltriricinoleate 35 (CAS no. 61791-12-6).

5. Composition according to claim 4, wherein the composition comprises or consists of 75% v/v aqueous solution comprising 0.1M citric acid, 6.25% v/v propylene glycol (CAS no. 57-55-6), 12.5% v/v ethanol and 6.25% v/v polyoxyethyleneglyceroltriricinoleate 35 (CAS no. 61791-12-6).

6. Method for reconstituting dried, preferably lyophilized, peptides, comprising the following subsequent steps:

a) providing a vial comprising dried, preferably lyophilized, peptides, wherein preferably the peptides are peptides of between 15 and 100 amino acids in length,;
b) thawing the peptides, preferably for 5-30 min;
c) adding the reconstitution composition according to any one of claims 1-5 to the vial comprising the peptides, preferably without swirling the vial;

d) allowing to admix, preferably for 0.5-5 minutes; and

e) swirling until a clear solution is obtained, preferably for 1-3 minutes.

7. Method for preparing a pharmaceutical composition, comprising the subsequent steps of:

(i) collect reconstituted peptides obtainable by the method of claim 6 in a first syringe;

(ii) connect the first syringe of step (i) to a second syringe comprising an oil-based adjuvant using a connector;

(iii) push the content of the first syringe into the second syringe and backwards; and

(iv) repeat step (iii) 10-50 times in a total in 10-50 seconds.