Preparation basics for a development protocol of Liposome product

We have tried to assemble as follows some of the points and questions that any scientist could have before starting the development of a liposome product. Obviously, all the questions will not have the same relevance as it will depend on the active principle used and the objective desired. Also depending on the development and the evolution, new questions will araise to which we will have to answer and even we will probably be obliged to reconsider some previously answered. We should not forget that these points are interrelated. Althoug some of them could be unknown, kindly answer to those you know. We could maybe help you to answer to other. A study of the bibliography published in this respect could also be helpful. Although they seem complicated, our own experience says that the most part of questions and problems have finally an answer and a solution.

Form for developing an active principle in Liopsomes

1. Description of the environment, functions and objective desired.
1. Why an active principle should be encapsulated in liposomes?
2. Which is the objective and function desired?
3. In which environment, alive organism or other (ex. Industrial application) will be applied?

4. Which will be the best route of administration or application way?
5. Which active principle will be the most suitable and in which of its possible forms (salt or base)?
6. Which dose or concentration is used in its current form and which will be used in its liposomed form?
7. Which type of liposome and lipidic composition will be the most appropiate?
8. How and in which conditions (ex. Sterile) will be the product stored or preserved?
9. Which would or will be a reasonable price for the future product in the market?

10. Once specified this first group of questions, it is necessary to know the maximum characteristics of the active principle.
1. Characteristics of the active principle:
1. Chemical structure
2. Molecular weight
3. PKa, isoelectric point
4. Purity

5. Solubility in mg/ml of solvent:
1. Water
2. Methanol.

3. Ethanol.
4. Chloroform
5. Dimethylsulphoxide
6. Isopropanol.
7. Glycols.
8. Oils (types of oils).
9. Phospholipids

10. pH influence
11. Viscosity of different solutions and different concentrations.
12. Conditions from which one should be protected:

1. From the contact with oxygen .
2. From the light, specially from the UVA rays
3. From the temperature.
4. From watery salt concentrations (high or low)

5. Stability (in the long term) :

1. As dry or liofilized (freeze-dried) substance.
2. If there is any degradation, which is the result of it.
3. Possible groups that in time can be sterified or hydrogenated.
4. Polymerization of the molecule under special conditions or formation of cyclical derivatives.
5. Formation of dimers.
6. Whether the molecule needs any special stabilizer to be stabilized.
7. If the molecule is hydrolized, under which conditions make it and with which type of dissolvents.

8. Sterility
9. Content of heavy metal traces
10. Whether the molecule can catalyse any chemical reaction and which.
11. Toxicity
12. Whether the molecule may provoke irritation to the skin or cause allergenic effects
13. Analytical method to make a quantitative determination of the active product.

Do it yourself. TT-somas (spanish version)