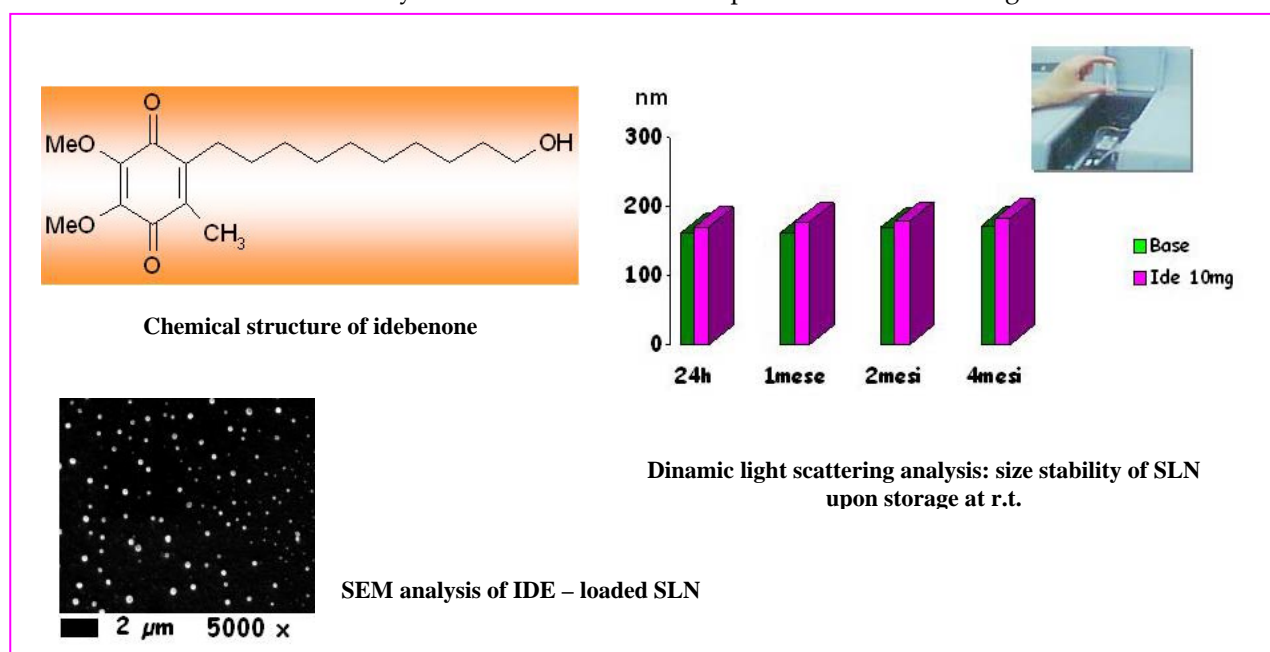


Preparation and physicochemical and technological characterization of SLN prepared by a modified solvent injection technique

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The aim of the research was to evaluate solid lipid nanoparticles (SLN) as drug delivery systems of lipophilic ingredients and to carry out a comparative study on physicochemical and technological characterization of SLN prepared by microemulsion and solvent injection techniques. SLN have been loaded with idebenone (IDE), a synthetic analogue of coenzyme Q10, with antioxidant properties. In vitro biological tests were carried out to evaluate the activity of IDE loaded in SLN compared with the free drug.



1. Description of the product

SLN are normally produced under pressure homogenisation or by a micro-emulsion technique.

Dilution of micro-emulsion is based on two steps:

- the creation of a warm micro-emulsion O/W (70°C);
- the creation of solid lipid nanoparticles by dispersion of warm O/W micro-emulsion in a cold aqueous medium with little stirring.

An alternative method of preparation is the “solvent injection” technique. This consists in dissolving the lipid in an organic solvent which could be pharmacologically acceptable, as ethanol, and inject the lipid solution into an aqueous phase. The excess ethanol present in the dispersion of SLN is left to evaporate with a slow magnetic stirring at room temperature for 24 hours.

2. Innovative aspect of the product

In the last years SLN have been proposed as new drug delivery systems for different ways of administration: topical, pulmonary, oral, ophthalmic and parental.

The product of this research could be destined to pharmaceutical and cosmetic companies.

So, the possibility of realizing an innovative system, able to improve and optimize the bio-pharmaceutical profile and/or efficacy of active molecules is followed by many companies.

The purpose of this research was to prepare, characterize, and evaluate the carrier capacity of SLN as potential delivery system of lipid compounds prepared by solvent injection.

These systems have been characterized by photo-correlation spectroscopy (PCS), with the purpose of evaluating size properties and stability over time. We have also made a morphological study by SEM. The efficiency of encapsulation and the characteristics of drug release from SLN have been studied from a technological and formulative point of view.

3. Main advantages of the offer

The advantages of this approach, compared to existing systems can be resumed as follow:

- Simple and economic preparing procedure
- Fewer quantity of surface-active agents
- Avoiding the utilisation of high temperatures to whom the drug is subjected during the phase of incorporation; this permitS the possibility to use also thermolabile drugs.

4. Technology key words

Solid Lipid Nanoparticles; Idebenone; Microemulsion; Solvent injection; antioxidant activity.

5. Current Stage of Development

Developed phase - Tested in laboratory.

6. Intellectual Property Rights

The product of the research is still uncovered by patent.

Technical and scientific publications

Palumbo, M., Russo, A., Cardile, V., Renis, M., Paolino, D., Puglisi, G., and Fresta, M., Improved antioxidant effect of idebenone-loaded polyethyl-2-cyanoacrylate nanocapsules tested on human fibroblasts., *Pharm. Res.* 19, 71-78 (2002).

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