

Once-A-Day nutraceutical tablets containing artichoke extract

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Increasingly opportunities are arising for pharmacists to offer assistance in the maintenance of health using a group of food supplement products collectively known as nutraceuticals that include vitamins, minerals, herbs, amino acids, concentrates, metabolites and extracts. The recognition of nutraceuticals as adjuncts and/or preventive treatments for many diseases induced, in the last 5 years, the unprecedented patent activity spearheaded by food and pharmaceutical companies. It is here described the preparation of new controlled release dosage form based on tableted microspheres containing fresh artichoke *Cynara scolymus* extract. The tablets are designed as one-a-day sustained release formulation containing *Cynara scolymus* extract and are proposed as a nutraceutical controlled release dosage form for oral administration.



1. Description of the product

The tablets are prepared by direct compression of microparticles containing the vegetable extract and based on lactose and hypromellose in 50:50 ratio. The fluid extract obtained from the edible part of artichoke is encapsulated by spray-drying. Tablets are designed as once-a-day nutraceutical product such as dietary supplements with potential health benefits, coming from natural food sources and delivered in a medicinal form; controlled release formulation is also able to target the vegetable extract to the intestinal tract.

2. Innovative aspect of the product

Among various pharmacological activities of the constituents of artichoke extract, anti-oxidant capacity, hepatoprotective functions, liver regeneration improvement, inhibition of the cholesterol biosynthesis in hepatocytes and the anti-hyperlipidemic activity and a prebiotic effect have also been reported. Due to its nutritional and therapeutic properties, the artichoke can be a good candidate for the development of nutraceutical formulations. In the market conventional tablets or capsule formulations based on artichoke extract are already present; however, a little work has been done in the controlled release field. As usual controlled release dosage forms improve compliance of the patients due to the reduction of the number of administrations, this becomes particularly useful in the nutraceutical field as this kind of products are administered from 3 to 6 units per day.

Finally the product has a possible general use and broad application for the delivery of nutritional agents once a day.

3. Main advantages of the offer

With the increasing environmental pressures for industry to use "clean technology" and to utilise sustainable sources of materials for manufacturing processes, the use of crude plant extracts, if proved safe and efficacious must be encouraged. Companies that get involved now will become market leaders in a business that is likely to become much more important in the years to come.

Excipients and technologies used for the preparation of the product have several advantages: lactose is the most common carrier material used in food and pharmaceutical product. Hypromellose is a polymer widely used as gel-forming agent in the preparation of controlled release dosage forms. Spray drying, accounts for the majority of commercial encapsulated materials in food products. The spray drying encapsulation process is relatively simple, economical, and easily scaled to large production volumes.

The product is characterised by high versatility as it can be used to vehicle different kinds of extract or other food supplement products. The opportunity to take one a day tablet increases the compliance of the patient especially in this case, where, in opposition to the administration of the medical product, the patient takes the nutraceuticals as own choose.

4. Technology key words

Nutraceutical, vegetal extract, controlled release, spray-dried microspheres, compressed matrices.

5. Current Stage of Development

Development phase – laboratory tested ; Available for demonstration – field tested.

6. Intellectual Property Rights

Product of the research is still not covered by patent

Technical and scientific publications

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