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Quality - Brief History (pt. II)

LiqFillCaps SELFCaps

Green Propolis

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Due to the richness of the Brazilian florae, the local propolis – Green Propolis – has unique properties and has been the subject of constant scientific research.

Revolutionary Pharmaceutical Technology
LiqFillCaps SELFCaps

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The LiqFillCaps SELFCaps formulation displays an incomparable potential in improving rate and extent of the absorption of poorly water-soluble drugs.

Immediately after oral administration, a LiqFillCaps SELFCaps formulation rapidly disperse in gastrointestinal fluids, yielding fine emulsions, micro- or nanoemulsions, designated as SEDDS (Self-Emulsifying Drug delivery System), SMEDDS (Self-Microemulsifying Drug delivery System) or SNEDDS (Self Nanoemulsifying Drug delivery System), respectively, all containing the solubilized drug.

A remarkable advantage of LiqFillCaps SELFCaps formulation is the direct result of its miniscule globule size and composition, thus the micro/nanoemulsified drug can easily be absorbed through lymphatic pathways, bypassing the hepatic first-pass effect.

Recent developments in various methodologies employed to characterize resulting LiqFillCaps SELFCaps formulation system, such as globule size and shape, ability to encapsulate the drug, gastrointestinal and thermodynamic stability, rheological characteristics, and so forth, are vastly and comprehensively presented in the scientific literature and assist as a guide to LiqFillCaps in formulating an effective and robust LiqFillCaps SELFCaps formulation ready to be filled into a hard gelatin/hypromellose capsule or a soft gelatin capsule.

In simplistic way, a LiqFillCaps SELFCaps formulation comprises the drug solubilized in a mixture of oil, surfactant(s) and/or co-solvents.

The LiqFillCaps SELFCaps formulation results in faster drug release from emulsions, micro- or nanoemulsions in a reproducible manner, which can be designed further to make the release characteristics independent of the gastrointestinal physiology and the fed/fasted state of the patient.

What are food supplements?

These are foods that are intended to complement and/or supplement a normal diet and work as concentrated sources of nutrients or other substances with nutritional or physiological effect, alone or in combination, marketed in dose form such as capsules, tablets, pills and other similar forms, sachets of powder, ampoules of liquid, drop dispensing bottles, and other similar forms of liquids or powders that are intended to be taken in small quantities dosages.

Law Decree No. 136/2003 of 28 June

Did you know that...

EFSA (European Food Safety Authority) was established in January 2002 after a series of incidents related to food in the late '90s, as an independent source of scientific advice and communication of risks associated with the food chain.

In the long history of quality there are two milestones to consider. The first milestone corresponds to the advent of mass production (1914) associated with the Industrial Revolution and the second, more recent, concerns the growing importance assumed by the service sector.

Until mid-twentieth century, the concept of quality was based on the physical characteristics of the product in accordance with the specifications for the production and product design according to their functionality. So it was up to producers to design the quality and ensure that this was effectively achieved, initially focusing on the inspection and, later, in Quality Control and the establishment of Quality Systems.

If until the rising of mass production products were designed according to the specific needs of customers, there was a direct producer (artisan) / client, and it was the producer who performed all activities of the value chain (design, production, inspection, repair and sale the product), and since then, thanks to demographic change, technological development and the simultaneous intensification and sophistication of trade, it became necessary to increase production to levels to which the craft organization could no longer respond.

In line manufacture. Later, the Taylorist model collapsed with the failure of the dichotomy management/execution and recognition of the need to use all the skills to satisfy customers and improve continuously.

Thus, it was necessary to create a model of production and market relations, based on the progressive increase of production units and the consequent division of labor. So, by that date all activities were performed by the same person since then, with this new way of working, which reached its zenith with continuously. Taylorism, each worker has to perform a single task, according to the with practices such as the above, coupled with the efficiency of production processes and supply and knowledge of the needs and expectations of people, quality has become more customer-oriented. Thus, companies have a long-term aim on getting the full satisfaction of customers, contributing to a sustainable development of the society where they operate and to improve the citizen’s quality of life. New management philosophies were development that pointed towards Total Quality regarded as a broad and qualitative concept covering the whole company.

As a result, production costs, as well as non-conformities identified in the final product, would see their values reduced with the introduction of Quality Control and the approach involving workers in small improvements in the production process, based on the use of simple tools of Quality Control and teamwork to solve problems.

Total Quality is understood as a management philosophy that promotes an organizational culture focused on customer satisfaction through continuous improvement based on preventive action, achieved at the expenses of active and responsible participation of all, aiming at long-term success and benefit for all members of the organization and society in general. It is considered the engine of a changing process, the type of culture that promotes, together with the requirement, training, motivation and disciplinary action, obtains better results and leads organizations to success and excellence.
The Green Propolis is a resinous substance that results from mixing the collection of the bee species Apis mellifera, with their own saliva. Phenolic compounds such as flavonoids, aromatic acids and diterpenes are the main components of green propolis responsible for its numerous biological activities. These biological activities include antioxidant effects, antifungal, antiviral, antimutagenic and immunomodulator.

Green Propolis has been used in traditional medicine and therapeutic and prophylactic properties have been reported against inflammation, cardiovascular disease, liver toxicity and cancer.

The antiviral activity of Green Propolis was demonstrated against a range of viruses, and there are several studies demonstrating the anti-viral activity against influenza virus.
The VIGIA System has been the target of great interest, search and query. Dr Inês Gonçalves, Head of the VIGIA System, enlightens us, by answering some frequent questions:

1. What is the VIGIA System and when was it released?
The VIGIA System, Monitoring of Food Supplements, is used for the detection, assessment, management and prevention of events not related to the function of products, into the system. We are operating since 2008.

2. How was the VIGIA System created and what are its advantages for the users?
VIGIA System was created due to:

a) The need to develop strategies to strengthen the safety of food supplements
b) The need for continuous improvement of quality and safety, raising the level of protection of the consumers’ health
c) Growing trend of legal requirements - Due to the increasing need for improved knowledge in the area of food supplements, we believe that, in the future, it will be required to implement a surveillance system for food supplements, as it happens currently to the medical drugs.

The users of VIGIA have a team consists of specialized physicians and pharmacists who can answer questions related to the rational use of food supplements, analyze possible drug interactions, determine the causal link between an event unrelated to the function of product and the intake of that product and do the necessary follow-up of every situation.

3. How many laboratories are associated to this system?
The laboratories have noticed the safety and confidence that a VIGIA product transmits to consumers, so we have currently more than 30 laboratories that have placed their products on the VIGIA System and we have an increase number of additional requests, including those from the international market. As a result of our participation in international events, foreign companies have already integrated their products in the VIGIA System.

4. What has been the feedback from users over the years of the VIGIA System?
We have had an excellent feedback; people recognize our work, are truly grateful to our advice and follow up of each case. Often we notice that we receive contacts resulting from the advice received by previous VIGIA users.

5. How does it work?
Preferably, it should be the consumer who will take or has taken the product, to contact VIGIA, in the shortest period of time possible (via phone, email or online notification on the Vigia site). After exposing the existing doubts, we assess the situation and report the final conclusions to the consumer. Later, we returned to its contact to do the follow up.

6. How important, in your opinion, is it to create a vigilance system for food supplements in Portugal?
The VIGIA is a revolutionary system, in Portugal and in the remaining countries. VIGIA has products from the domestic and international market. The VIGIA System is a service designed to promote health and well-being of consumers. Reduces the occurrence of events not related to the function of the product and has a proactive view of the occurrence of unwanted events. Basically we are promoting the health of consumers, which becomes a competitive advantage for laboratories that have integrated their products.
8. Has the VIGIA System got projects for the future?

The VIGIA System continues to walk towards the future. We want to increase the safety and confidence of consumers, allowing them to easily access information about the VIGIA products. We are developing a new application - VIGIA version 2.0 - for smartphones, capable of providing all the information on a VIGIA product, simply by reading the QR code on the packaging or search by product name, brand, or active ingredient statement.

The application provides other important information for the consumer, how to find the nearest sales point, and even show the street from the selected sales point. In addition, you can also read news about health and get the reference values of blood glucose, blood pressure, cholesterol, etc.

9. What are the useful contacts of the VIGIA System?

E-mail: vigia@labialfarma.com
www.vigia.labialfarma.com