SOFTPEARLS®

CONTRACT MANUFACTURING SERVICE

IBSA

Caring Innovation

ABOUT
SOFT CAPSULES (SOFTGELS)

Soft capsules were invented in the 1930s to conceal the unpleasant taste and smell of medicines. Since then, production techniques have greatly improved.

It has been estimated that over 40% of active pharmaceutical ingredients (APIs) have poor biopharmaceutical properties, such as poor water-solubility and/or permeability.

These characteristics are somewhat problematic for the oral bioavailability of compounds that need to be formulated as medicines that are bioavailable when taken by the oral route.

The oral administration of certain medicinal products as solid pharmaceutical forms (e.g. tablets) is a technologically arduous challenge, because certain active ingredients can be oily or poorly soluble in water.

PEARLtec technology is a process for obtaining softgel (soft capsules) that makes it possible for a liquid matrix, in a suspension or a gel, to be incorporated into a continuous soft gelatine shell, thereby improving both the oral intake of the medicinal product and patient compliance.

The first step consists in weighing the capsule ingredients, before they are processed using dedicated machines known as turbo emulsifiers. During this part of the process, the optimally balanced excipients are blended together and prepared for the next step.

The heart of the process is the encapsulation step (PEARLtec).

The mass that will form the capsule shell is hot-extruded into two ribbons that pass through two roller moulds positioned opposite one another, and that give the capsule its shape.

A high-precision syringe pump then injects the previously formulated active substance, inside a mass known as filler, into the capsule being moulded.

This makes it possible to obtain tiny transparent beads consisting of two heat-moulded shells.

During the formation of the capsule, all the essential and critical parameters are monitored by means of in-process controls.

This makes it possible to keep the quality of the finished product under control.

Before packaging, the dried capsules are inspected one by one in order to eliminate any flaws.

The quality and stability of the finished product are further guaranteed by special primary and secondary packaging.

In short, this technology makes it possible to take a liquid solution in a solid pharmaceutical form, which is highly advantageous for very low concentration formulations, as it ensures dose uniformity.

The advantages:

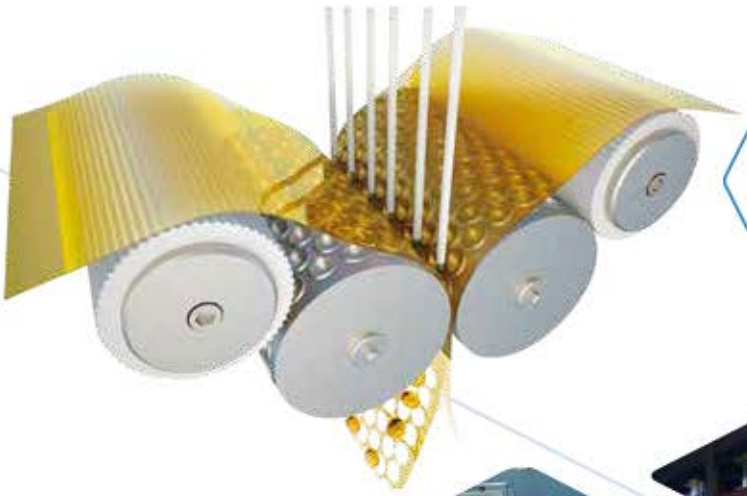
- High dosing precision and better oral bioavailability than other oral solid forms;
- Excellent dissolution profile, regardless of the pH;
- Ease of oral administration;
- Neutral or flavourless taste.

ADVANTAGES

- THE RELEASE OF THE ACTIVE INGREDIENT IS FASTER AS IT IS ALREADY IN SOLUTION
- HIGHER STABILITY
- HIGH DOSAGE PRECISION
- HIGHER BIO-AVAILABILITY

- EASY AND PRACTICAL TO BE ASSUMED
- TASTELESS
- HIGHER EFFECTIVENESS AND GREATER COMPLIANCE

Softgel technology allows both **drugs** and **nutraceuticals** to be formulated and made: the wide range of formats and colours **satisfies all client needs.**



Produced trought the exclusive Softgel technology, soft capsules are created from the fusion of two fluid gelatine films in a rotating mould machine.

IBSA

IBSA'S PRODUCTION SITE LODI

Year	2001
Surface	12.000 mq
Staff	153
Therapeutic dose	300 mio/year

Over the years, the Lodi plant, which was purchased by the Swiss Group Institute Biochimique SA in 2001, has seen a complete and radical revamping of the existing production areas and the construction of a new state-of-the-art manufacturing facility equipped with cutting-edge production lines for the development of novel delivery systems for medicinal products, medical devices and food supplements.

The plant covers a total surface area of 12,000 m², housing 12 production departments, the warehouse and starting material sampling areas, the dispensing department for the preparation of work orders, the Research & Development labs, the chemistry and microbiology Quality Control labs, and the Regulatory Affairs, Quality Assurance, Production, Engineering and Maintenance offi ces.
The pharmaceutical production area and the starting materials warehouse occupy 5,500 m², whereas the food supplement manufacturing area and its dedicated warehouse occupy a surface area of 1,000 m².

The plant is staffed by a workforce of 185 resources.

The nearby Lodi 2 area is home to the Management Offi ces and the packaging materials and fi nished product warehouse. This warehouse is currently being extended and once the construction work is complete it will occupy an area of over 2,500 m².

The plant manufactures products for injection, both in sterile conditions and terminally sterilised, in **conventional ampoules and pre-fi lled syringes, preparations for topical use** (creams, gels and solutions) **in BoV** (Bags on valves) **and soft capsules** (soft gel).
The plant's production lines, which in 2019 manufactured approximately 24.5 million pieces, boast **state-of-the-art technology** Insert and are **environmentally sustainable**.
The hefty investments made for the modernisation of the industrial plant and processing lines have made it possible to achieve production plants with high effi ciency standards.

The annual production capacity of the various product ranges is as follows:

- Conventional ampoules 12 million units
- Pressurised cans (BOV) 7.5 million units
- Aluminium tubes 2 million units
- Pre-fi lled syringes 19 million units
- Soft capsules - pharma line 160 million units
- Soft capsules - nutraceutical line 130 million units

The pharmaceutical products manufactured at the Lodi 1 plant serve the IBSA group and supply a number of markets including, in addition to Italy, Switzerland, Great Britain, Hungary, Slovakia, Czech Republic, Poland, Greece, Spain, Scandinavian countries, Russia, Egypt, Turkey, United Arab Emirates, USA, Brazil and Korea.

AUTHORISATIONS

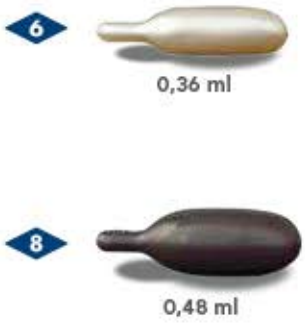
- Italian Medicines Agency (AIFA) (for the pharmaceutical products mentioned - two-yearly inspections)
- GMP Certifi cate
- FDA Certifi cate (for certain specifi c products)
- Quality System: Certifi ed in accordance with ISO 9001: 2015 and ISO 13485 2016 (IMQ)
- Manufacture of Medical Devices: subject to regular inspections by the various European Notifi ed Bodies
- Manufacture of nutraceuticals: authorised by the Ministry of Health and supervised by the Local Health Service.

SOFTPEARLS®
NUTRITIONAL DIVISION
CAPSULES SIZE AND SHAPES

OVAL

OBLONG

TUBE



ROUND

UNIT OF MEASURE

MINIM/MINIMS (USA O UK) = 0,06
MILLILITERS - ML

IBSA

TECHNOLOGIES
THERAPEUTIC SOLUTIONS FOR MORE EVOLVED CARE

At IBSA, innovating is our daily challenge, the focal point of all our operations, and whose origin lies in a brilliant insight: to transform existing therapeutic solutions with known properties into simpler, more evolved instruments of care.

We are committed to breathing new life into sectors that are often overlooked, by using state-of-the-art technologies to improve the bioavailability of the active substances of commonly-used medicinal products, and developing delivery systems that are more compatible with the real needs of individuals, in order to improve their Quality of life.

To this end, over the years, our Researchers have developed innovative technologies, novel formulations and delivery systems better suited to care.

PHARMACEUTICAL FORMS	PRODUCT CATEGORY			
	Drug	Medical Device	Nutraceutical	Cosmetic
Gonadotropins purification process				
Orodispersible film (ODF)				
Softgel capsules				
Pre-filled syringes				
Progesterone & βciclodestrine				
Single dose strips				
Patches: medicated, with natural ingredients and for basic medication				
BoV (Bag-on-Valve)				
Nahyco® Hybrid Technology				
Device for intravesical infusion (GAG)				

CONTACT US

Business.Development@ibsa.it

www.ibsa.it

businessdevelopment.ibsagroup.com

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