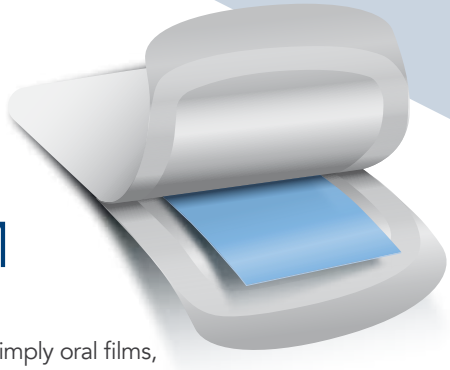
ORODISPERSIBLE FILM

A NEW CONCEPT IN DRUG DELIVERY

IBSA

Caring Innovation



ABOUT
ORODISPERSIBLE FILM

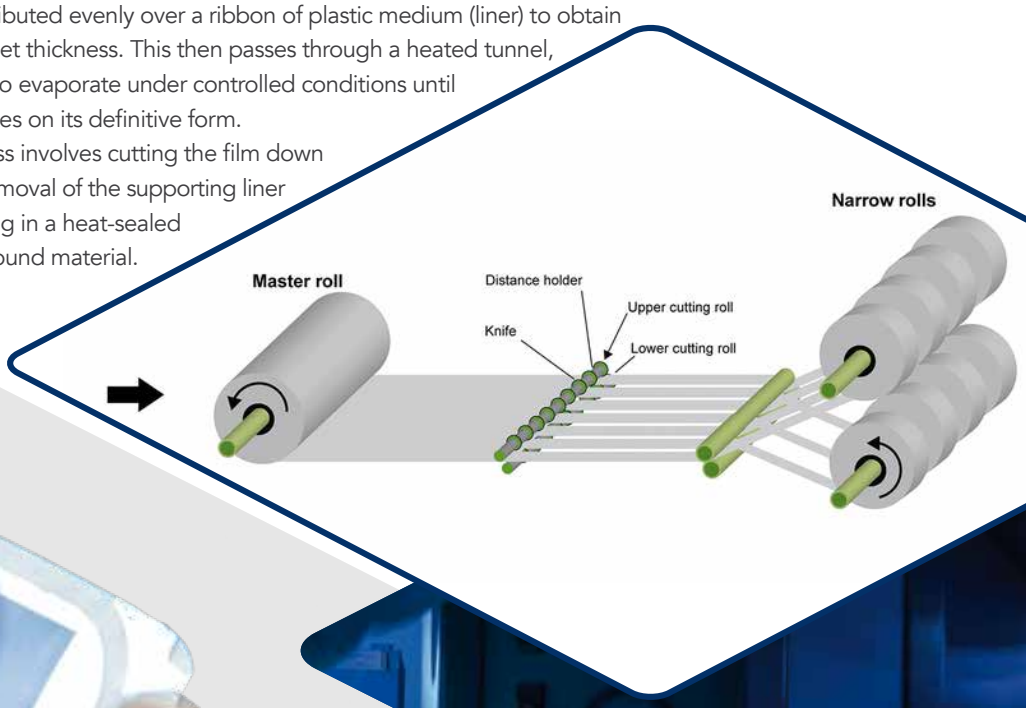
Orodispersible films (ODF), also known as orosoluble films or simply oral films, are a new oral pharmaceutical form, whose characteristics are able to improve the treatment compliance of certain groups of subjects whose needs are not met by capsules and tablets. They take the form of small, thin, flexible sheets, similar to postage stamps that, when placed inside the mouth, dissolve rapidly in contact with saliva. The dissolution time is usually a few dozen seconds and in any case no more than one minute.

The weight of a single film is usually a few hundred mg, meaning that very little saliva is required for dissolution. ODFs are normally individually-packaged in heat-sealed sachets, in order to preserve their mechanical properties, avoid contact with atmospheric humidity and guarantee adequate stability. Individual packaging, combined with a limited size and weight make the individual dose unit convenient and discrete, even for use outside the home, in all situations, because it does not need to be taken with water. The use of ODFs is still limited to just a few applications, due to their complex manufacturing process (very limited number of companies are able to master this technology on an industrial scale).

The main production technique for ODFs is based on the coating process. In this case, the first step of production is the preparation of a homogeneous coating mass in which all the ingredients are dissolved in a suitable solvent, usually it's water – it's possible to incorporate other poorly-soluble active substances or functional ingredients into this mass, provided they are homogeneously dispersed. In order to achieve this aim, it is necessary to act both on the particle size of these insoluble ingredients, which must be suitably fine and poorly dispersed, and on the dissolver tank stirring system in which the mass is prepared, which can be also fitted with a turbo emulsifier.

The coating mass is then used to feed a continuous coating machine inside which, using a calibrated blade, it is distributed evenly over a ribbon of plastic medium (liner) to obtain a layer with an even, pre-set thickness. This then passes through a heated tunnel, where the water is made to evaporate under controlled conditions until the orodispersible film takes on its definitive form.

The last step of the process involves cutting the film down to single dose unit size, removal of the supporting liner and individual packaging in a heat-sealed sachet of compound material.



ADVANTAGES OF FAST DISSOLVING ORAL FILMS

- PRECISE AND ACCURATE DOSING
- WATER IS NOT REQUIRED
- SWALLOWING IS AVOIDED

- RAPID DISSOLUTION AND ONSEST
- MAY IMPROVE BIOAVAILABILITY
- LOCAL OR SYSTEMIC EFFECT

- MAY BE PREFERRED OVER CONVENTIONAL ORAL DOSAGE FORMS
- CONSUME AT ANYPLACE ANYTIME
- IMPROVED PATIENTS COMPLIANCE (pediatrics, geriatric, mental illness, dysphagic)

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The ODFs obtained by coating are usually square or rectangular, with a thickness of a few hundred microns and sides with lengths that can vary from 1 to 4 cm. A correct coating process makes it possible to guarantee a uniform content in line with the pharmaceutical requirements, ensuring that the concentration of active ingredients is constant over the entire area of the film. Thanks to the water-soluble film-forming polymer that constitutes the main structure of the film, the ODF has good tensile strength, elasticity and flexibility. These properties give the ODF good manageability, which is extremely important for the user, and appropriate processability, which is essential for large-scale production.

A film-forming polymer and a plasticiser alone could be sufficient to obtain an ODF; however, these two ingredients are usually combined with a flavouring, to improve palatability, and a colouring, to improve its appearance. As mentioned previously, the main ingredient of an ODF is the film-forming polymer, which can also be a blend of two or more polymers.

There are a number of water-soluble polymers that can serve this purpose, including pullulans, alginates, modified cellulose and maltodextrins. It is important for the polymer to have not just the right solubility, processability, manageability and stability characteristics, but also that is has a neutral or pleasant flavour and does not leave residues in the mouth.

For the production of its orodispersible films, IBSA chose maltodextrins as the main polymer, taking to industrial scale a patented formulation platform that forms the basis of the IBSA FilmTech technology.

Maltodextrins have the advantage of being a common, affordable food ingredient with good palatability and rapid dissolution times inside the mouth, where they dissolve completely without leaving an aftertaste.

Orodispersible films always permit immediate release: ODFs release their ingredients very rapidly and can therefore make their absorption easier and quicker than with a tablet or capsule. In certain specific cases, depending on the nature of the active substance, ODFs can also improve the absorption of active substances and functional ingredients. Orosoluble preparations such as ODFs are the preferred oral form for most people. For certain user categories, such as dysphagic, bed-ridden and elderly subjects, those who have problems taking water and children, the use of ODFs instead of conventional oral forms becomes a necessity rather than a mere preference.

As a matter of fact, when compared to tablets, capsules, powders and syrups, orodispersible films allow a precise and accurate dose even for those who have problems swallowing or cannot use water to aid administration.

A LEADING EUROPEAN MANUFACTURER OF ORODISPERSIBLE FILM

WATER-SOLUBLE EXCIPIENTS

IBSA'S PRODUCTION SITE CASSINA DE' PECCHI

Year	2010
Surface	10.500 mq
Staff	71
Therapeutic dose	76 mio/year

In 2017, it started manufacturing **sildenafil in orodispersible film** (ODF) and in 2019 it commenced the production of **food supplements**, again in orodispersible film form. The productions with a higher technological and innovative content manufactured at the plant include orodispersible fi lm (ODF). A patented technology has allowed IBSA to become one of the few companies in Europe to manufacture both pharmaceutical and nutraceutical products.

A second fi eld of production with a **higher technological and innovative content** are the medicated transdermal patches based on drug-in-adhesive technology that allows controlled release of the medicinal product.

The plant covers a total surface area of 10,520 m², including research and development laboratories, a dedicated quality control department and offi ces.

The production areas and warehouse occupy an area of 5,450 m2 and utilities 3,404 m2. More than 70 people work there.

Production focuses on the following technologies and pharmaceutical forms:

- Medicated patches for topical and transdermal administration
- Patches with natural active ingredients for cosmetic applications and medical devices
- Basic plasters and special wound dressings
- Orodispersible fi lm (ODF)

Annual productive capacity for the various pharmaceutical forms is:

- Topical patches:
  - transdermal patches 20 million units
  - orodispersible fi lm 16 million units
- Dressings 25 million units
- Nutraceuticals in ODF 15 million units

The products manufactured at the Cassina plant serve both the IBSA Group and directly supply a number of markets, including, in addition to Italy, France, England, Hungary, Slovakia, Czech Republic, Spain, the Baltic Republics, Scandinavian countries, the EMEA area and South America.

AUTHORISATIONS

- The Quality System is certifi ed in accordance with ISO 9001: 2015 and ISO 13485 2016 (IMQ)
- AIFA authorisation and GMP compliance certifi cate (Directive 2001/83/EC and Legislative Decree 219/2006) for:
  - production, primary and secondary packaging, control of non-sterile medicinal products ("impregnated matrices", transdermal patches, orodispersible film)
  - manufacturing of non-sterile investigational medicinal products ("impregnated matrices", transdermal patches, orodispersible film)
- Authorisation for psychoactive and psychotropic substances (Italian Presidential Decree 309 of 09/10/1990)

ORODISPERSIBLE FILM (ODF)
FILM SIZE AND SHAPES

STD Standard
D/FS Drug/Food supplement

STD Standard
D/FS Drug/Food supplement

STD Standard
D/FS Drug/Food supplement

P Possible
D/FS Drug/Food supplement

STD Standard
D/FS Drug/Food supplement

STD Standard
D/FS Drug/Food supplement

STD Standard
D/FS Drug/Food supplement

STD Standard
D/FS Drug/Food supplement

STD Standard
D Drug

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)				

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