



# **BIOMEDICA** - We have been here for you for over 30 years

Biomedica Ltd. was established in 1991 by its owner, RNDr. Hubert Koukol. The early 1990s in the Czech Republic saw new opportunities on the market for various herbal products. Their development and production became the primary business ambition of the new firm headed by its first director, MVDr. Josef Janíček.

The first products, which were based on the principle of aromatherapy combined with herbal extracts, were developed in 1992. The product portfolio has continued to grow since that time. In 1994, BIOMEDICA registered and produced BIOTUSSIL®, the first phytopharmaceutical product based on an original formula.

By the end of 1995, the company had become successful under the leadership of Ing. Jaroslav Říha, and in 2002 began building its own production facilities in the Hořátev Technological Park near the city of Nymburk.

In 2005, the product portfolio grew rapidly due to several new registered pharmaceuticals – Framykoin powder, Kalium chloratum tablets, and Lactulosa Biomedica syrup.

Cooperation with EU funds contributed to large investments, particularly in its new facilities and state of the art technology. The most recent significant expansion of the company happened in 2021 with the development of new dietary supplement technology and the addition of an extension to its warehouses.







Nowadays, the core of the company consists of three distinct but intertwined pillars:

- Development, registration, and sales of its own products – pharmaceuticals, medical devices, dietary supplements, and cosmetic products,
- Contracted production for pharmaceutical companies; firms operating in the field of medical products, veterinary products, dietary supplements, and cosmetics,
- *Raw material business division* for the food and pharmaceutical industry operating around the world.

BIOMEDICA Ltd. employs a team of experts active in the development, approval, and registration of pharmaceutical products, medical devices, and dietary supplements.

A major contribution to the rapid expansion of BIOMEDICA is its exclusive representation abroad, particularly in Germany, Slovakia and in Vietnam. BIOMEDICA Ltd. currently employs around 300 employees.

### **Production**

## of pharmaceuticals

The first pharmaceutical product made by BIOMEDICA was registered back in 1992. In very beginning, production was located in Prague. The relocation of production to the Hořátev Technological Park in 2005 allowed the firm to fully exploit its sustained experience and know-how, which resulted in the rapid expansion of its product portfolio.

Currently, BIOMEDICA has GMP authorization to produce the following:

- Infusion solutions, filled into plastic bags with a volume of 20-5000 ml,
- Solid-form pharmaceuticals, production of tablets, packing in blisters and packaging, including serialization,
- Liquid-form pharmaceuticals, homogenization and filling into glass bottles with a volume of 50-1000 ml.
- Powders,

homogenization and filling into glass jars and packaging, including serialization.

The production facility consists of three buildings located in the Hořátev Technological Park.







The production of medical devices of **class II b** (**dialysis solutions**), **registered by the MDR at the ITC Zlín notified person**, takes place in a modern building constructed in 2014.

The size of production batches can vary from 300-2000 liters.

The filling device is ideal for plastic bags with volumes ranging from 20-5000 ml.

The package can be vacuum sealed immediately after the bag if filled or in the flow-pack system, after the sterilization of the autoclave.

The sterilization process takes place in modern sterilization equipment operating by automated qualified procedure programs.

Medical devices of **class l** can also be produced in some of our other facilities, depending on the particular type of the product.





BIOMEDICA produces dietary supplements in several production buildings, and since 2023 under the internationally recognized certificate FSSC 22 000.

The production is wide-ranging, from the blending of mixtures (even premixes) with the possibility of granulation, through manufacturing tablets and hard gelatinous capsules and coating them, packing them in blisters, and filling them in glass jars, to packaging the final product.

**The homogenization and granulation** processes can be adjusted, depending on the desired size of the product. Mixtures can be homogenized anywhere from twenty to hundreds of kilograms. Given the non-explosive nature of the manufacturing environment, it is possible to use alcohol in the production process.









**Tablet production** takes place on four tablet presses. Tablets made through the process of moist granulation or direct compression can be coated in the coating machine anywhere from **50 to 300 kg** of tablets at one time.

Diameter	Shape	Weight	Height
5 mm	Lentil with no bisecting line	50-70 mg	2,5-3 mm
9 mm	Lentil with bisecting line	200-350 mg	4-5 mm
9 mm	Lentil with no bisecting line	200-350 mg	4-5 mm
12 mm	Lentil with no bisecting line	500-700 mg	5-6 mm
13 mm	Flat tablet with bisecting line	700-800 mg	4-5 mm
19 mm x 8 mm	Flat tablet with bisecting line - Oblong	700-1000 mg	5-6 mm
21 mm x 8 mm	Flat tablet with bisecting line - Oblong	900-1400 mg	7-7,5 mm

**Hard gelatinous capsules** are filled at three separate automated devices and are made in four different sizes: 3, 1, 0, 00.

The production of **soft gelatinous capsules** has ceased, but in case of need, the order can be subcontracted out to our other external firm in Czech Republic.

All tablets and capsules can be filled in jars on our automated line with an induction closing system or **packed in blisters** of various sizes:



For blister packing	Number of pieces in a blister	Size
Hard gelatinous capsule size 0;1	10	66 x 89 mm
Hard gelatinous capsule size 0;1	20	100 x 130 mm
Hard gelatinous capsule size 0;1	20	72 x 125 mm
Hard gelatinous capsule size 0;1	4	38 x 89 mm
Hard gelatinous capsule size 0;1	10	66 x 89 mm
Hard gelatinous capsule size 0;1	15	80 x 125 mm
Soft gelatinous capsule	15	66 x 89 mm
Tablets – lentils 9 mm	10	38 x 89 mm
Tablets – lentils 12 mm	10	66 x 89 mm
Tablets – lentils 12 mm	10	55 x 80 mm
Tablets – oblong (19x8mm a 21x8 mm)	10	59 x 88 mm
Tablets - oblong (19x8 mm)	20	72 x 125 mm
Tablets – oblong	10	59 x 88 mm

Other formats are possible after prior mutual discussion and agreement.

BIOMEDICA's product portfolio also includes the **production of syrups**, which can be based either on sugar, sorbitol, fructose, or fruit concentrates. For this process, we use big homogenization boilers with a capacity ranging from 250-1000 liters. Current volumes of processed products vary from 50-1000 liters. The production of syrups largely takes place in Luhačovice, near the border with Slovakia.

BIOMEDICA can also manufacture small packages of liquid dietary supplements. Some examples include drops in volumes of **10-50 ml**.



# **Production** of cosmetic products

BIOMEDICA produces a wide range of cosmetic products:

- Gels,
- Creams with an oil/water or water/oil base,
- Emulsions,
- Tensid cosmetics, e.g., shampoos, bath foams and liquid soaps,
- Suspensions.

For the **homogenization** of our production batches, we use a double-walled boiler with a 20-liter volume. In the production plant, there are also four other large homogenization boilers with volumes ranging from 100 to 1000 liters. Another option is manufacturing under vacuum. The heating medium of the boilers is steam.

**Depending on the size of the batch, the final product can be filled** either by a semiautomatic or automatic tube filling machine in volumes ranging from **10-200 ml**. Our filling line is capable of putting cosmetic products into tubes and jars at volumes of up to **1000 liters**.

Our production premises are also designed for the future production of medicinal products. Distilled water is used in the production process.

# **Quality** control system and laboratory

Biomedica has implemented a quality control system, divided according to the type of products it manufactures. This system is reviewed annually, with the quality targets set and evaluated. Our own Quality Control Department is responsible for quality assurance within the company and has the power to control, monitor, evaluate and coordinate the quality control system.

We have established highly advanced laboratories for the quality control of our manufactured products. These laboratories are located in three different buildings, including the laboratory reserved for the quality control of medicinal products subject to strict oversight by state authorities.

Our laboratories contain the following laboratory equipment:

HPLC, AAS/AES, potentiometric titrator, IR spectroscopy, UV/VIS spectroscopy, dissolution apparatus, disintegration device, polarimeter, osmometer, a device for measuring particles below the visibility range in solutions, density meter and rotational viscometer.







# **Development** and product registration

A large portion of our laboratory capacity focuses on the **development of new products**. The BIOMEDICA research team can either develop your formula or help you improve it according to your expectations and needs, for all markets and commodities for sell.

### **Sale** of raw materials

Since 1997, BIOMEDICA Ltd. has been a major importer and supplier of raw material for the cosmetic, food and pharmaceutical industries focusing on raw materials of natural origin.

- ethereal oils for cosmetic products, household chemicals, and the food industry,
- herbal oils and butters for care of the complexion in both regular and organic quality,
- water- and oil-dissoluble extracts broad scale of effective and active herbal-based agents,
- menthol and camphor,
- perfumes, vitamins, and preservatives,
- basic oleo-chemicals vital for the production of emulsions.



For the production of dietary supplements and for the food industry, BIOMEDICA offers a large portfolio of:

- dried herbal extracts,
- seaweed,
- ground herbs,
- vitamins,
- mineral substances,
- pro-biotic cultures,
- nutritional oils (including omega oils),
- amino acids,
- other nutraceutics used for making nutrients for the joints and for sports,
- fruit concentrates of various flavors in liquid and powder forms





BIOMEDICA Ltd. cooperates with major producers and distributors across the European Union, Asia, and America. In the Czech Republic, it represents the following companies on the market:

- Düllberg Konzentra (essential oils),
- CPL Aromas (perfumes),
- Industrial Quimica Lasem (oleo-chemicals),
- Parodi Nutra (herbal oils and butters),
- Kumar (active substances for cosmetics).





These raw materials can be delivered not only in standard packaging, but also in smaller amounts, precisely as requested by the customer. Our customers from all the segments of the industry mentioned above appreciate this option and frequently use it.

Our portfolio offers

### more than 1600 types of raw materials,

all from verified sources. The supply of these raw materials is steadily increasing based on the latest trends and needs of our clients.

In connection with the sale of raw materials, BIOMEDICA provides an expert information service, and its documentation is in compliance with the latest legislation in force.





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