

# We achieve therapeutic successes.



# The Burg Pharmacy LAB – Who we are and what we do

When I took charge of the Burg-Apotheke in Königstein im Taunus in 1987, nobody could foresee the drastic health policy changes that pharmacies in Germany would be facing in the following years. Hardly another branch in Germany would be so affected by direct and indirect government regulations as pharmacies. This is due to their special role within healthcare. Day in, day out, time and time again, pharmacies guarantee the supply of one particular commodity to the general public, namely: medication. This really is a great responsibility.



We take this responsibility very seriously. We recognise that every course of medication should be personal. Each customer, every patient is an individual. The task of the prescriber is to recognise this, and to administer treatment in accordance with this understanding.

Our task is then to implement the instructions provided by the prescriber.

In doing this, it is not important whether the drug formulation is personalised to the patient or if it is a pre-manufactured formulation. In each case the quality must be the same. We pride ourselves on ensuring quality standards together with to the necessary know-how.

We are specialists in manufacturing individualised drug formulas. We produce all forms of dosage, in particular injection and infusion solutions, at our sterile laboratory, which is appropriately equipped and has been inspected by the authorities.

Our objective is to make medications available which are tailored to the treatment aims of prescribers and patients alike in the case of illness.

We are sure that you share this goal.

Feel free to use the various options for treatment offered with our products. In addition to the products manufactured in-house as seen on the price lists, we also offer a comprehensive range of homeopathic formulas from Dr Zeeden. Please request the additional price lists for these. We would be delighted to offer you advice.

## Legal requirements control what is feasible

In 2012, the Act on the Operation of Pharmacies (Ap-BetrO) came into effect. Legislators had implemented extensive changes, especially with regards to the manufacture of personalised drugs (formulas). The legislators wanted to transfer the high quality standard of drug manufacture in the industry to the manufacture of personalised formulas in pharmacies. As a result, regulations to guarantee this were put in place. Since drug manufacture is central to a pharmacist's professionalism, and as in times of crisis a pharmacist might have to "fill in" for industry manufacture, this amendment was essential.



As part of the change in the law, the issue of quality standards in the following areas was raised:

- Hygiene
- Analytics
- Documentation

This led to a significant additional expenses for pharmacies. In the area of documentation, in particular, the following criteria for drug manufacture must be observed:

- 1. For each personalised formulation, the formulamust be displayed.
- 2. The formula must be checked for plausibility.
- 3. Manufacturing instructions and protocols must be created.

- 4. A pharmacist must approve the product.
- 5. For batch formulas (=manufacture of up to 100 units per day), the end product must be checked and the formula must be archived.

Burg Pharmacy LAB is the best equipped to achieve this. In both the analytics and logistics departments, we have optimised processes so that we can manufacture and deliver personalised formulas promptly. Throughout Europe. After all, treatments do not tolerate delays. However, to ensure this happens, please request the delivery time with every order.



### Burg Pharmacy LAB is a think tank

### Section 1a (3) 1 Act on the Operation of Pharmacies (ApBetrO):

In the scope of this Act, Pharmaceutical activity is "the development and manufacture of pharmaceutical formulas."



We manufacture drugs. But we also develop them. This allows us to make substances available for treatments, for which there previously was no optimal route because of the properties of the substance.

### For example: Curcumin.

Curcumin has many beneficial effects, but when taken, is not absorbed well by the human body. Due to its low water solubility, it was not possible to create injection solutions until recently. We have solved the problem and developed a concentrate for infusion.

Therefore, we can now prescribe and produce it. Furthermore, this is just one of countless developments we have made.

We specialise in particular in solving problems surrounding oncology treatments and complementary medicine treatments of oncology patients. We are particularly specialised in solving problems which are aimed at therapy in oncology and complementary medicine treatment of oncology patients. In times, in which the "self-diagnosis" of patients often takes priority, you will probably be confronted with requests of this kind yourself.

Responsibility for the course of treatment lies with you – in the hands of the prescriber. We are responsible for the product. Whichever treatments you are considering for your patients – share them with us.

We will rise to the challenge and find a solution. That's a promise.

# The road to becoming a model company

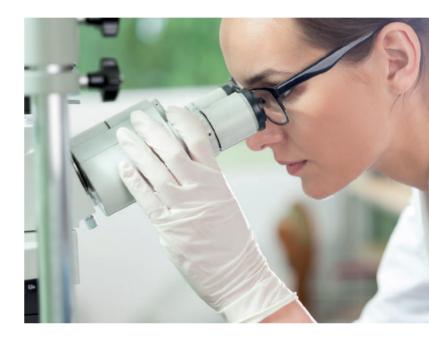
Nowadays, pharmacies must specialise. They have to perform to high standards, be innovative, their benefits have to be measurable for practitioners, customers and patients.

Burg Pharmacy has taken this route. As the pharmacy market liberalised, we changed; from a traditional pharmacy characterised as a "dispensary", still allowed by policy until the 1990s, into a company with many strategic business areas. In this process, manufacturing sterile formulas and producing individual blister packaging were paramount.

In 2013 we also founded EUROZYTO GmbH, a drug manufacture facility authorised for manufacturing according to Section 13 of the Medicinal Products Act (AMG). It also manufactures parenteral nutrition and prepares cytostatic agents according to European GMP guidelines in the context of contract manufacturing.

Burg Pharmacy LAB acts as the interface. Separate teams of specialists in nutrition and cytostatic treatments are available the whole day to offer advice and process orders.

Our logistics and shipping department ensures that your order arrives on time – it makes no difference whether it has come from the manufacturing facility or the pharmacy laboratory.



We also stand for innovation in the area of medicinal products. The development of the NONATUBE®, a nutrition bag designed for the individual compounding of parenteral nutrition, with nine separated, individually fillable chambers, is a major milestone for the complete outpatient care of oncology patients. Furthermore there are, depending on volume and energy requirements as well as the number of medications to be administered, the variations HEPTATUBE® with seven chambers and OCTATUBE® with eight chambers available.

These revolutionary developments facilitate everyday activities for many care providers and patients.

For the therapist this means longer therapeutic intervals and higher therapeutic evidence as well as a stronger patient relationship through the increase of medical expertise.



# We define scientific standards

The new Act on the Operation of Pharmacies (Ap-BetrO) determines the regulations. Quality management strategies are obligatory. The Burg-Apotheke LAB was one of the first pharmacies that volunteered to undergo a TÜV certification according to DIN ISO. This certification that we acquired in 2006 is renewed annually.



The manufacture of personalised formulas should meet industry standards as closely as possible. This includes meeting quality assurance standards in the area of the individual and batch formulas we manufacture.

Legislators have not issued definitive instructions, but leave the testing criteria to the pharmacist's own scientific expertise. Pharmacists must determine the quality controls when testing the final product.

We wish to fulfil this requirement and even go much further with our laboratory equipment and testing methods than which is legally required of us.

This is a good way of doing things. For the safety of treatments. For your patients.

Obviously this doesn't work without dedicated staff. Our production and analytics teams are highly motivated and work hand-in-hand to deliver all orders as quickly as possible.

Regular employee trainings ensure that the high quality standards are maintained.

Scientific standards are good. Complying with them is better.

# The future begins today – our focus, our perspectives

We are in the 21st century. We are globally connected; information is more readily available than ever before. And this is particularly true in the healthcare sector. There are countless forums, self-help groups, and a veritable flood of information on the internet. Sometimes too much information.

Burg Pharmacy wants to support you. Our knowhow and your ideas can be the basis for further developments. We always check feasibility from pharmaceutical, analytical and legal points of view.

Do you wonder about the effectiveness and treatment safety of certain substances? Do you need suggestions for treating certain illnesses? Do you want to use a certain substance which you have read studies about, but you are not sure how? Do you miss formulas which are no longer sold and are looking for alternatives?

These are just some of the issues which are raised time and time again. Every day, our specialist teams answer such and similar questions. We also verify the feasibility of prescription formulas against legal requirements. Thus, we ensure treatment safety in regards to how the product is used.



The future begins today. Please take advantage of the treatment options we offer with our products. Allow us to advise you – and feel free to request further information.

Your pharmacist

Uwe-Bernd Rose

and the team of Burg Pharmacy LAB





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