

# Flexible manufacturing of semi-solid pharmaceuticals

Our solutions for your requirements







### **AZO LIQUIDS – The company**

AZO LIQUIDS GmbH was founded in 2008 by engineers with many years of accumulated experience in the area of liquid and semi-solid processes. We developed a new generation of batch and continuous processing plants with an innovative homogeniser for fully automatic production. Since then, we have been improving our machinery and plants on an ongoing basis and adapting them to meet future market requirements and the needs of our customers. In addition to our products such as batch and continuous processing plants AZO LIQUIDS offers efficient and flexible solutions for a vast array of applications. Thanks to our wide range of experience in the pharmaceutical, cosmetic and food industry, we can help you to realise customised processing plants according to your specific requirements. For the production of these products, parameters such as consistency, homogeneity, smooth handling, process times, stability of the end products and traceability often play a key role. In this regard you can rely on the extensive experience of our engineers to provide a solution to meet or even exceed your requirements.





### Lucas Papaw Remedies – Our customer

Lucas Papaw Remedies, the company that produces Lucas Papaw Ointment is named after the formulator of the ointment Dr Lucas. Dr Lucas, after years of research as a botanist and medical practitioner, stated in his 1906 handbook that he believed the papaw was the finest natural medicine yet discovered. He used the ointment, which he developed for his medical practice in Brisbane, to treat numerous types of illness and disease. People today can derive the same benefits that thousands derived during the lifetime of Dr Lucas.

The company still successfully operates at its Brisbane facility where the Papaw ointment continues to be produced. You may be amazed to hear that the formula for the famous ointment is still the same proven remedy today as when it was created over 100 years ago. The Papaw fruit is received fresh to the factory in Brisbane where it is fermented under strict quality control conditions. Every piece of fruit to be used is hand selected. Once the fruit has been fermented to just the correct level, it is used to make the ointment.

The base used in Lucas Papaw Ointment meets the purity and safety standards of the United States FDA and the European Pharmacopeia. The manufacturing process is in complete compliance with the Code of Good Manufacturing Practice as administered by the Therapeutic Goods Administration (TGA). All Lucas Papaw Ointment produced is stringently tested to ensure it is of the highest quality. The ointment is prepared in an extremely clean environment to ensure it is free from any impurities.





## From handmade production to industrial production

For more than a decade Lucas Papaw Remedies and AZO LIQUIDS have been in a strong business partnership. Both companies are collaborating to meet projected future demands both in terms of capacity and quality.

As little as 10 years ago the production at our customer's site was still mainly manual. The customer relied on one small 200 litre processing vessel, which was used for all their manufacturing steps. Both intermediate as well as the final product were produced with this processing vessel, resulting in numerous manual operations and product transfers.

The first project was simply a capacity increase by installing a second processing vessel with an 800 litre capacity and a control update of the old 200 litre processing vessel. This new processing vessel was used for the manufacture of the final product only. Due to great success in the market shortly afterwards the next capacity increase became necessary. Two more processing vessels were purchased and installed by AZO LIQUIDS. The customer now had one 400 litre processing vessel to manufacture the intermediate product and two 800 litre processing vessels for the manufacture of the final product.

From the beginning the Lucas Papaw Remedies ointment is a product, that has been licensed for pharmaceutical use – more precisely a TGA (Therapeutic Goods Administration) license. This was an important feature for today's chief executive, Mr. Kevin Talbot as one of his great achievements was obtaining TGA certification in 1992 after many years and many challenges along the way. Today's requirements for pharmaceutical production are stringent, regarding traceability, documentation and hygiene. The existing plant set-up could not satisfy these requirements anymore. Consequently, the process steps had to be modified in order to further meet the requirements of the TGA and to keep the pharmaceutical license.





The latest project as described in this brochure lead to the installation and implementation of a fully automated plant design and subsequently all manual operations and transfers were eliminated. With this last step a significant increase in capacity was achieved as well as a reduction in manufacturing costs. Product losses were also reduced to a minimum by means of highly sophisticated technical solutions like a pigging unit to minimise waste levels as well as a cleaning system (CIP) for quick and efficient cleaning. Although this is a very sophisticated and fully automatic plant maximum flexibility has also been built in, e.g. individual parts of the plant can be operated separately. Finally, it has to be mentioned that the product can now be fully traced from the start of the manufacturing process through to final packing. This last point had become increasingly necessary to maintain the pharmaceutical license for the product. The SCADA system furthermore ensures compliance with

pharmaceutical regulations and assures process control by complying with the ISA S88.01 standard. Moreover, AZO LIQUIDS used a skid design for this project, optimising disassembly, transportation and local assembly thereby reducing installation times and associated costs.

In conclusion, the new plant assures tracking and tracing from start to the end. 10 years of development have reached a preliminary peak. The intensive cooperation between Lucas Papaw Remedies and AZO LIQUIDS over this long period of time has advanced the production to the next level. Both customer and AZO LIQUIDS can proudly look back on a very successful project in all aspects. AZO LIQUIDS is incredibly grateful for the trust and good cooperation with Lucas Papaw Remedies and looks forward to further successful cooperation in the future.





KIESEL Steriltechnik GmbH Engelsberg 3 75015 Bretten

Fon +49 7252 9637-10 Fax +49 7252 9637-20 www.kiesel-steriltechnik.com info@kiesel-steriltechnik.com



### Special features of the system components

#### 800 litre processing unit for concentrate production

- Conversion of the existing 800 litre unit with a customised designed agitator and a lifting device for the lid for easier addition of the ferment.
- Possibility of transferring concentrate from the 800 litre unit to three storage tanks.

#### 3 x 3,000 litre concentrate storage tanks

- Storage tanks with dished tank heads and an agitator setup designed for optimal homogeneous mixing of the individual concentrate batches of the 800 litre unit
- Possibility of transferring concentrate to two further 800 litre units.

#### 2 x 800 litre processing unit for ointment production

 Standard units with scraper-agitator assemblies, two baffles, double jackets for temperature control, the possibility to add concentrate via load cells, the possibility to add further raw materials via dosing mechanisms.

#### 6 x 12,000 litre ointment storage tanks

 Storage tanks with dished tank heads and an agitator setup designed for optimal homogeneous mixing of the individual ointment batches of the two 800 litre units. Possibility of feeding ointment from the storage tanks into packing lines of the customer.

#### **CIP** system

- A system with 2 x 3,000 litre tanks for cleaning the complete plant
- System components are connected to each other via mixproof valves technology in such a way that the individual parts of the plant can be cleaned separately without affecting the functionality of other parts of the plant.

#### Automation

- The SCADA system is based on the AZO LIQUIDS professional controller and can be upgraded at any time. A clear visualisation and intuitive operation are provided by a touch panel.
- Batch-oriented documentation according to FDA regulations
- A full audit trail
- Batch protocol with all events and curves of the key process parameters
- Storage of an almost unlimited number of recipes
- Manual and automatic operation



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awellservice Hans Schaub · Steinbuck 9 79379 Müllheim · Tel. +49 (0)7631 13507 j.schaub@awell.de www.gebaeudereinigung-schaub.de Weighing Components for Production and Automation



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Urban & Lorenzen GmbH · Altholzkrug 41 · D-24976 Handewitt · Tel. +49 (0)461 910 21 lorenzen@urban-lorenzen.de · **www.urban-lorenzen.de** 





## Comment from Mr. Jake Swinglehurst:

"We have a great relationship with AZO LIQUIDS and it makes the projects we undertake run efficiently. This project was by far one of our biggest projects in all aspects but the project ran seamlessly from start to finish and it's a credit to AZO LIQUIDS, their Australian agent Fallsdell Machinery and everyone involved to have achieved this in the short time-frame that was allowed."



AZO LIQUIDS GmbH Otto-Lilienthal-Str. 8 D- 79379 Neuenburg am Rhein Tel.: +49 7631 9739-0 www.liquids.azo.com azo-liquids@azo.com