

HÄNSELER



SWISS PHARMA
SOLID SOLUTIONS



Pharmaceutical raw materials and contract manufacturing from Hänseler Swiss Pharma

SOLID SOLUTIONS

BY HÄNSELER SWISS PHARMA

**GMP is in our DNA –
we take your products from idea to market success.**



We support our partners with enthusiasm and Swiss quality throughout the entire value creation process, offering you tailor made solutions for your market success. Starting with product development and continuing through sourcing, manufacturing and packaging through to successful market development, we offer fluid processes for solid confidence in the pharmaceutical environment.

Our core competencies in the solid solutions segment:

- **Sourcing of solid raw materials**
- **Powder mixtures as premixtures,
active pharmaceutical ingredients (APIs)
or finished pharmaceuticals**
- **Filling all possible powder types in customer-
specific primary packaging**


DEVELOPMENT

YOUR SPECIALISTS FOR RAW MATERIALS
PROCESSING AND REFINEMENT

Hänseler Swiss Pharma will be happy to support you in developing your product idea in three galenical areas – Liquid Solutions, Semi-Solid Solutions and Solid Solutions.

In these three areas, we will support you in the development of ...

- plant-based active ingredients (extracts)
- bulk finished pharmaceuticals / dietary supplements through to defining filling in suitable packaging
- appropriate extraction methods for plant-based starting materials
- liquid and thick extracts
- finished mixtures
- ointment basic components / creams / lotions / gels / pastes / suspensions
- formulas for pharmaceuticals, cosmetics or dietary supplements and selection of suitable packaging
- and setting up appropriate validation methods and analytical tests



Refining raw materials into active pharmaceutical ingredients (APIs), including associated documentation, is one of our core competencies.



SOURCING OF RAW MATERIALS

OUR EXPERTISE, YOUR SUCCESS



- Sourcing of solid raw materials at source: **high quality and advantageous prices**
- Raw materials supplied in different **customer-specific qualities**
- Access to **high-quality narcotics** for onward processing into solutions
- **In-depth understanding of raw materials** for different customer requirements
- We also specialise in solid raw materials subject to **high safety requirements / hazardous substances**

Our wide range of pharmaceutical raw materials, which we either supply as commercial products or produce ourselves, comprises more than 3,000 different products. These include solid raw materials in the following classes:

- **Solid chemicals**
- **Herbs**
- **Herbal blends**
- **Salt mixtures**
- **Vitamins**
- **Narcotics**

Minimum purchase volumes vary by raw material. We will be happy to advise you in person and provide an overview of the available solid raw materials.

« Sourcing raw materials to customer-specific requirements is one of Hänseler Swiss Pharma's core competencies. We can also bring our profound understanding of customers and raw materials to products with high safety requirements. Since Hänseler Swiss Pharma has access to exclusive trade channels, we are able to procure hard-to-obtain raw materials for our discerning customers. »

Dr. Dominik Hauser, Managing Director CEO

MANUFACTURING

OUR EXPERTISE, YOUR SUCCESS



- **GMP-compliant powder mixtures** for various product categories
- **Modern, qualified production systems**
- **Strong manufacturing** competencies in different batch sizes (110 to 2,000 litres)
- **Provision of full documentation**

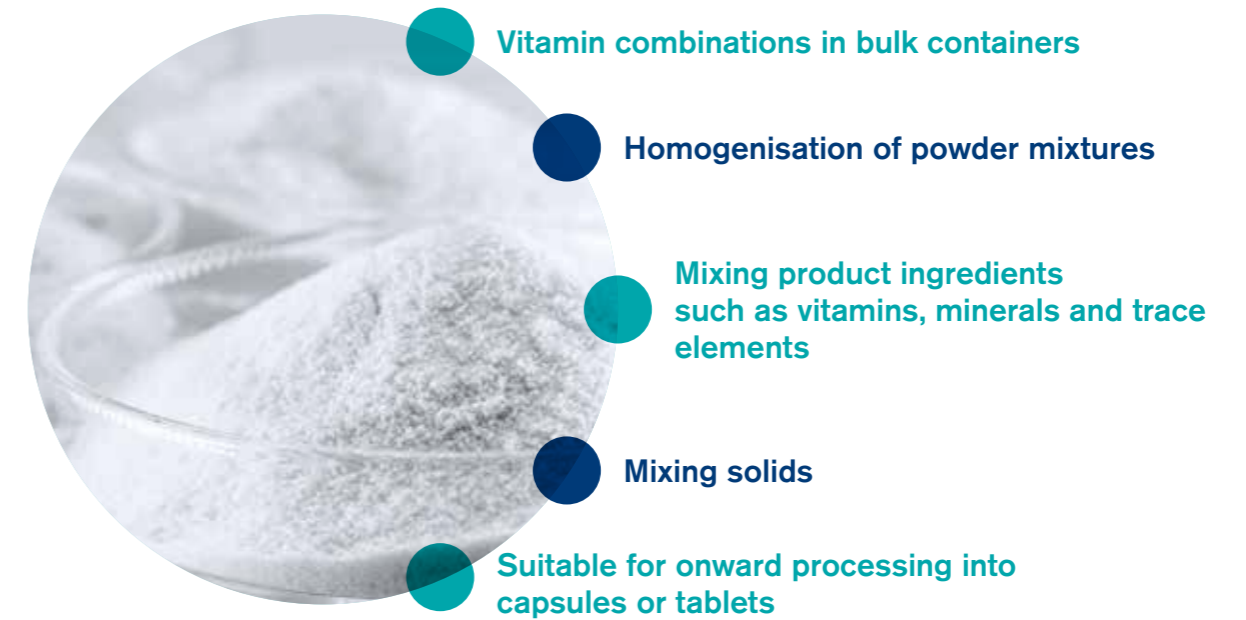
Hänseler Swiss Pharma's core competencies include solid raw materials processing as well as Sourcing. Here Hänseler Swiss Pharma has specialised in the production of **GMP-compliant bulk powder mixtures in the form of premixtures, active pharmaceutical ingredients (APIs) or finished pharmaceuticals.** We can supply powder mixtures in a range of container sizes **in batches from 110 to 2,000 litres.**

Powder mixtures (premixtures or finished mixtures) are available for the following segments:

- **Pharmaceuticals, vitamins or active ingredients**
- **Dietary supplements**
- **Cosmetics**
- **Herbal blends**
- **Chemical and metallic mixtures**



Dietary supplement premixtures



Vitamin combinations in bulk containers

Homogenisation of powder mixtures

Mixing product ingredients such as vitamins, minerals and trace elements

Mixing solids

Suitable for onward processing into capsules or tablets

Herbal granules



Pharmaceuticals with laxative effects (among others)

Special pharmaceutical mixtures containing psyllium

Other product categories (dietary supplements, medical devices) in various indications

VERTICAL SINGLE-SHAFT MIXER VM 300 AMIXON AMIXON GMBH



Technical specification

Total capacity	435 litres
Max. usable capacity	300 litres
Min. fill	110 litres (with cutting rotor)
Operating temperature	40 °C (designed for max. 120 °C)
Working overpressure	+/-0 bar
Agitator speed	8.8 to 62 rpm
Cutting rotor speed	300 to 2,100 rpm
Controller	SPS (Siemens S7) formula management automatic operation

Additional features

- Pharma standard
- Automatic cleaning (Cleaning in Place)
- Ergonomically optimised feed-in
- Extremely gentle mixing technology
- Mixing log
- Scale-up to HM 2000 possible

VERTICAL TWIN-SHAFT MIXER HM 2000 AMIXON AMIXON GMBH



Technical specification

Total capacity	2,850 litres
Max. usable capacity	2,000 litres
Max. batch weight	1,800 kg
Min. fill	800 litres (with cutting rotor)
Max. operating temperature	40 °C
Max. working overpressure	-0.6 bar
Agitator speed	11 to 38 rpm, regulatable
Cutting rotor speed	1,500 rpm constant
Mixing technology	Ribbon mixing

Additional features

- Pharma standard
- Automatic cleaning (Cleaning in Place)
- Extremely gentle mixing technology
- Work platform for ergonomic working



**«Our Solid Solutions
range satisfies
customers'
most discerning
requirements.»**

PACKAGING

OUR EXPERTISE, YOUR SUCCESS



- Filling under **GMP-compliant conditions** (laminar flow)
- **To suit customers' individual needs:** Manual, semi-automatic or automatic filling
- **Primary packaging as requested by customer** (glass or plastic)
- Highly potent active ingredient filling under **modified atmosphere** available

Hänseler Swiss Pharma specialises not only in the sourcing and manufacturing of solid raw materials, but also in **filling and packaging them in a range of container types and sizes**. Our GMP-compliant infrastructure (filling under laminar flow conditions) is suitable for **filling powders, powder mixtures and tablets or capsules**. We are able to provide manual, semi-automatic or fully automatic filling, depending on order volume, in glass or plastic containers.

Packaging solutions

Primary packaging



Secondary packaging

If required, primary packs can be packaged in customer-specific folding cartons, incl. patient information, and in export cartons for onward marketing.

GLOVE BOX

Oxygen-sensitive and / or toxic substances and highly potent active ingredients* (OEB Levels 4 to 5) are filled in a glove box. This satisfies maximum occupational exposure requirements and enables us to provide modified-atmosphere filling.

Glove box filling is available for container sizes from 500 mg to 500 g (excluding cytostatics). Bag-in-bag packaging is also available where required. The system has been fully qualified and validated and is used for filling active ingredients under GMP conditions (cleanroom ISO 7 at rest).



* Highly potent active ingredients are APIs that are effective in very small concentrations. A maximum of 0.2 milligrams per kilogram body weight or 10 milligrams a day is sufficient to provoke a significant therapeutic effect. Hormones are an example of a highly potent active ingredient.



SMC MATIC 101 POWDER FILLING SYSTEM SWISS CAN MACHINERY



This machine is used to package solids fully automatically in screw-top or cardboard jars.

Technical specification

Fill volume	20 to 1,000 g
Output	up to 30 units per minute (depending on fill volume)

KING TC8 TABLET FILLING SYSTEM KING VERPACKUNGSMASCHINEN



This machine is used to package tablets, capsules and dragées fully automatically in jars.

Technical specification

Max. counted output	4,000 units per minute
Max. jar diameter	125 mm
Max. jar height	250 mm
Tablet size	4 to 25 mm
Cartoner	attached for secondary packaging



DOCUMENTATION

OUR EXPERTISE, YOUR SUCCESS

Regulatory and customer requirements are increasing the significance of documentation. We regard documentation both as a quality certificate for our products and as a service to our customers. We therefore provide a range of documentation packages.

Documentation packages for active pharmaceutical ingredients

ASMF (Active Substance Master File) package

CTD Module 3 – Part 3.2 S

Technical package

Documentation for CTD Module 3 – Part 3.2 S:

- General information such as nomenclature and structure
- Flow chart preparation
- Stability data
- Sterility testing
- Documentation for starting substances (SDS, other technical documents)

Phyto package

Statement for CTD Module 3 – Part 3.2 S:

- Analytical certificate with full supply chain
- Harvest protocol
- Certificate of origin
- Documentation for starting substances (SDS, other technical documents)
- Testing for pesticides, heavy metals and aflatoxins
- Pyrrolizidine alkaloids
- Microbiology
- Flow chart preparation
- Stability testing to customer specifications

Documentation packages for finished pharmaceuticals

CTD Module 3 – Part 3.2 P

Compiling the necessary documentation in accordance with customer instructions.

Documentation packages for cosmetic products

The package contains all the documents needed to create a PIF.

On request, we can also commission safety reports.

Documentation package for excipients

The package covers excipient requirements to ICH Q9.





Hänseler Swiss Pharma
Industriestrasse 35
9100 Herisau, Switzerland
T +41 71 353 58 58
www.haenseler.ch
info@haenseler.ch

Hänseler Pharma GmbH
Fischerstraße 11
DE-67655 Kaiserslautern
T +49 631 6277 9955
www.haenseler-pharma.de
info@haenseler-pharma.de

Follow us on social media



HÄNSELER 
SWISS PHARMA