

# HÄNSELER



SWISS PHARMA  
SOLID SOLUTIONS



Pharmaceutical raw materials and contract manufacturing from Hänseler Swiss Pharma

# AT A GLANCE

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 chain, 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, cosmetic and food environment.

## Finished products & 3,000 raw materials

- Medicinal products, medical devices, dietary supplements and cosmetics
- APIs, excipients, narcotics and ATEX goods
- Flexible batch sizes
- Private label
- Market access to Switzerland

Raw materials  
list 

## GMP-compliant repackaging

We offer repackaging services for large quantities into smaller packages.

Packaging  
list 

## CMO transfer projects

We specialise in handling ATEX-, GMP- and FDA-compliant CMO transfers.

CMO Liquid 

## Documentation

- Active Substance Master File (ASMF) CTD Module 3.2 S
- Common technical and phyto documents
- Serialisation: on request

CMO  
Semi Solid 

# SOLID SOLUTIONS

BY HÄNSELER SWISS PHARMA



## Batch

110 to 2,000 litres

## Packaging

5 g to 25 kg    Container    Plastic  
Sachets and sticks: on request

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

## OTHER GALENIC FORMS

**Liquid Solutions** Extracts, tinctures, syrups, chemical solutions.



## Batch

0.5 to 12,000 litres

## Packaging

10 to 1,000 ml	Bottle	Plastic or glass
5 to 25 litres	Canister	Plastic
25 to 64 litres	Drum	Plastic or stainless steel
220 litres	Tighthead drum	Plastic or steel
1,000 litres	IBC	Plastic

Contract development: Minimum order quantity depends on the product; details on request. Custom manufacturing starts from 20 litres on request.

**Semi Solid Solutions** Ointments, creams, pastes, fats, emulsions.



## Batch

60 to 720 litres

## Packaging

30 to 500 ml	Jar	Plastic
3 to 250 ml	Tubes	Plastic or aluminium

# DEVELOPMENT

YOUR SPECIALISTS FOR RAW MATERIALS  
PROCESSING AND REFINEMENT

We specialise in the development of liquid / thick extracts  
and procedures.

In the field of solids, we can provide support on request for:

- Development of finished mixtures and bulks
- Setting up appropriate validation methods and analytical tests
- Selection of suitable packaging



Refining raw materials  
into active pharmaceutical  
ingredients (APIs), including  
the 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 order quantity varies 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**

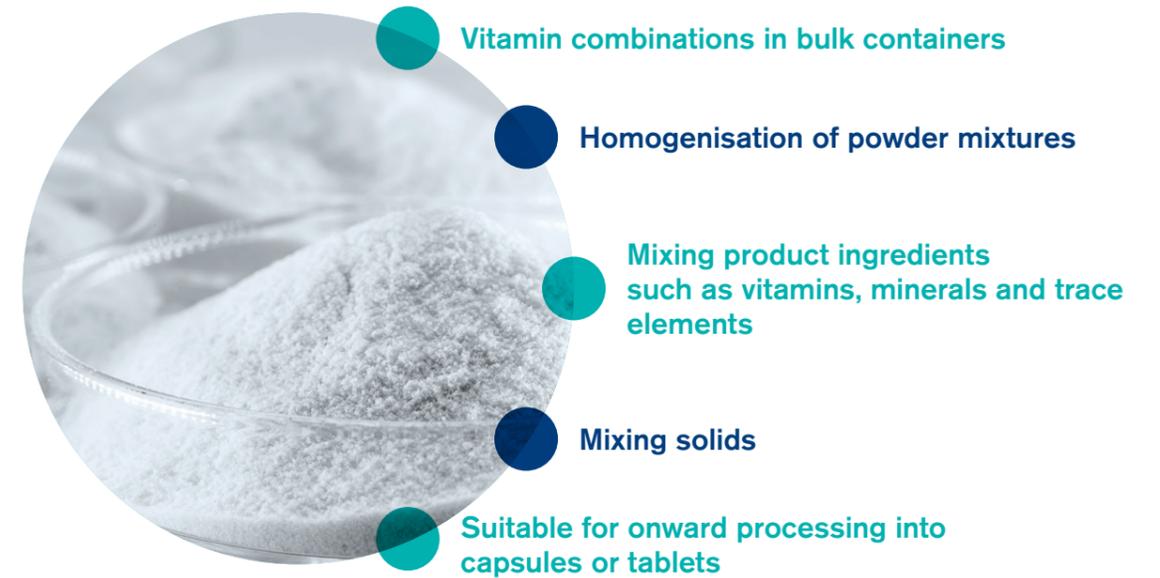
Hänseler Swiss Pharma's core competencies include solid raw materials processing as well as Sourcing. Here Hänseler Swiss Pharma has specialised in the production of **GMP-compliant bulk powder mixtures in the form of premixtures, active pharmaceutical ingredients (APIs) or finished pharmaceuticals**. 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



### Herbal granules



## VERTICAL SINGLE-SHAFT MIXER VM 300 AMIXON AMIXON GMBH



### Technical specification

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

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

### Additional features

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

A photograph of a pharmaceutical manufacturing machine, likely a tablet press, with a teal circular overlay containing text. The machine is made of stainless steel and has several white cylindrical components. The text is in white and reads: "Our Solid Solutions range satisfies customers' most exacting requirements."

**“Our Solid Solutions  
range satisfies  
customers’  
most exacting  
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 the 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 the 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 of 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

<b>Fill volume</b>	20 to 1,000 g
<b>Output</b>	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

<b>Max. counted output</b>	4,000 units per minute
<b>Max. jar diameter</b>	125 mm
<b>Max. jar height</b>	250 mm
<b>Tablet size</b>	4 to 25 mm
<b>Cartoner</b>	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
- 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.





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