



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

into smaller packages.

Privata Jahal

•	Private label		
	Market access to Switzerland	Raw materials	
		list	
G	MP-compliant repackaging		
W	/e offer repackaging services for large quantities		

CMO transfer projects

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

CMO Liquid

Packaging

list



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 Packaging

110 to 2,000 litres 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 customerspecific primary packaging

OTHER GALENIC FORMS

Liquid Solutions Extracts, tinctures, syrups, chemical solutions.



Batch	Packaging
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0.5 to 12,000 litres 10 to 1,000 ml Bottle Plastic or glass

> 5 to 25 litres Canister Plastic

25 to 64 litres Drum Plastic or stainless steel

Tighthead drum Plastic or steel 220 litres

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	Packaging
Jato	i donaging

60 to 720 litres

30 to 500 ml

Plastic

3 to 250 ml Tubes Plastic or aluminium

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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





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.



MANUFACTURING OUR EXPERTISE, YOUR SUCCESS



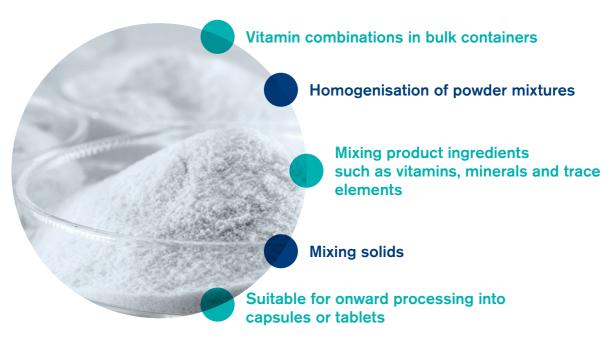
- GMP-compliant powder mixtures for various product categories
- · Modern, qualified production systems
- **Strong manufacturing** competencies in different batch sizes (110 to 2,000 litres)
- Provision of full documentation

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**.

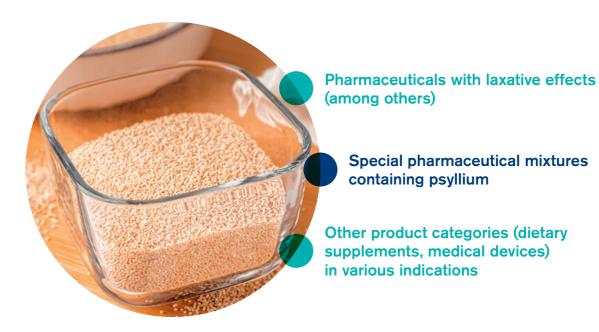
Powder mixtures (premixtures or finished mixtures) are available for the following segments:

- · 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

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

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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

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

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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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