

WE HAVE LOTS TO OFFER.



Pharmaceutical raw materials and contract manufacturing
from Hänseler AG

HÄNSELER 
SWISS PHARMA

OUR HOME IS SWITZERLAND.
OUR WAY OF THINKING IS INTERNATIONAL.



WE PRODUCE QUALITY.
ONLY IF IT SAYS HÄNSELER,
WILL IT BE HÄNSELER!

Hänseler AG is a Swiss GMP / GDP-certified pharmaceutical production and trading company, with its headquarters in Herisau, Switzerland.

The company's three pillars:

- Processing and trading of raw materials
- Production and distribution of private labels and brand names
- Production and packaging on behalf of partner companies

As a modern and expanding company, we focus our attention on distributors, industrial customers, hospital pharmacies as well as the Swiss specialist trade, with a common focus on the end consumer.

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01 PHARMACEUTICAL RAW MATERIALS

As a GMP-certified company, we can claim that all our suppliers fully comply with pharmaceutical guidelines. All our suppliers are qualified in advance by our quality management.

This enables us to guarantee the purity and consistent quality of the products, at every stage of the manufacturing process.

We are offering a wide range of pharmaceutical raw materials with more than 3,000 different articles:

- Essential oils
- Narcotics (Schedules I-IV, such as cannabis)
- Solid chemicals
- Liquid chemicals
- Ethanols
- Resins
- Herbs
- Herbal mixtures
- Solutions
- Solvents
- Oils and fats
- Oleochemical raw materials
- Ointment bases
- Salt mixtures
- Acids and alkaline solutions
- Vitamins
- Water div.

We also **exclusively** represent the following international partners in Switzerland:

- DSM Nutritional Products Europe (vitamins)
- Frey + Lau GmbH (essential oils)
- IOI Oleo GmbH (basic oleochemicals)
- Transo-Pharm Handels-GmbH (Pharma API)
- Heinrich Klenk GmbH & Co. KG (herbs)

02 PRODUCTION

Our modern infrastructure, with qualified facilities, enables the production of various galenic dosage forms and herbal active ingredients under GMP.

02.1 Galenical preparation



Liquid forms	
Categories	Ethanollic solutions (ATEX directive) Aqueous solutions Fresh and dried plant tinctures Liquid and thick extracts PA reduction of liquids (pyrrolizidine alkaloids) Syrups Oils / oily solutions Essential oil blends
Batch sizes	From 500 ml to 3,000 litres



Semi-solid forms	
Categories	Ointments Creams Emulsions
Batch sizes	From 80 to 750 litres



Solid forms	
Categories	Powder mixtures
Batch sizes	From 50 to 2,000 litres

02.2 Packaging

The GMP-compliant packaging of liquid, semi-solid and solid dosage forms / drug substances alongside a wide variety of narcotics is one of our core competencies of our company.

Our flexible filling infrastructure makes it possible to meet different customer needs. Solvents can be filled directly for industrial use in according to GMP guidelines. Thanks to our modern ventilation facilities and filling under lamminar flow, the risk of cross-contamination is eliminated and the highest GMP standard is achieved.

02.2.1 Packaging of liquids

The filling line covers all operations from filling, capping, labelling and batching, up to final packaging. Our GMP quality system ensures consistent filling of the entire batch at all times. Filling under protective gases such as nitrogen or argon is also possible.

Primary packaging

Material	Glass / plastic / stainless steel / steel
Filling volume	From 10 to 1,000 ml (glass and plastic) From 5 to 25 litres (plastic) From 25 litres (plastic and stainless steel) 200 litres (tight head drums made of plastic or steel) 1,000 litres IBC
Closure types	Normal lid Pump spray Dropper / pipette Spatula

Secondary packaging

Types	Folding box / patient information / outer carton
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Number of pieces

Manual	50 to 400 pieces
Semi-automatic	400 to 5,000 pieces
Fully automatic *	From 5,000 pieces

* ATEX-compliant production / packaging possible

02.2.2 Packaging of semi solids

Aluminium, plastic or composite material tubes are filled on our machines. The range of semi-solid forms are are **ointments, creams, emulsions, pastes, and gels**. The range of filling volumes starts with the sample tube and extends up to the bulk.

Primary packaging

Material	Jars / plastic tubes / aluminium tubes
Filling weight	From 3 to 250 ml (plastic and aluminium tubes) From 30 to 500 ml (jar)

Secondary packaging

Types	Folding box / patient information / outer carton
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Number of pieces

Packaging	From 2,000 pieces
Printed tubes	From 10,000 pieces



Herbal medicinal product Kelosoft®, manufactured by Hänseler AG

02.2.3 Packaging of solids

Depending on the product, filling takes place under laminar flow or in the glovebox (equipped for oxygen-sensitive and /or toxic substances). Our infrastructure in this area is suitable for filling **powders, powder blends and tablets/capsules into cans or glass containers**.

Primary packaging

Material	Glass / plastic	
Filling weight / Number of pieces	Manual:	500 mg up to 25 kg
	Semi-automatic:	10 g to 25 kg: from approx. 4,000 pieces
	Fully automatic:	50 g to 1 kg: from approx. 5,000 pieces
	Semi-automatic /	10 to 1,000 tablets / capsules
	Fully automatic:	in cans or glass containers

Secondary packaging

Types	Folding box / patient information / outer carton
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02.3 Distribution / logistics

We implement GDP guidelines and deliver to customers in Switzerland, with our own fleet of vehicles.

Thanks to our GDP-certified logistics partners, we can ensure smooth transport **throughout the globe**.



03 DEVELOPMENT

We support you with our expertise in finding the right solutions. Our aim is to enthusiastically exceed the wishes of our customers.

03.1 Product development

Our product development team can support you in a wide range of areas.

We can find solutions for you, from the development of a herbal active ingredient (extract), or a bulk of finished medicinal products / food supplements (i.e. liquides mixtures, syrups and semi-solid forms such as ointments, creams or gels, and powder mixtures), to filling in suitable primary and secondary packaging.

Focus of development

- Development of suitable extraction methods for herbal raw materials
- Preparation of liquid extracts and thick extracts
- Production of ready-to-use mixtures (liquid aqueous / ethanolic mixtures, syrups, semi-solid forms, powder mixtures)
- Filling

03.2 Analytical methods

With our modern **quality control**, we cover a very wide range of examination methods in routine operations (i.e. IR, UV-vis, polarimeter, DC documentation systems, etc.). Furthermore, we can develop and validate specific content determination methods (HPLC, GC) to suit your needs.

03.3 Stability tests

Our stability department has the following climate chambers for storing samples according to ICH guidelines, for short, and long-term stability studies.

- 25°C/60% relative humidity (climate zone 1)
- 30°C/65% relative humidity (climate zone 4)
- 40°C/75% relative humidity (stress test)



04 DOCUMENTATION

Due to government and customer requirements, documentation is becoming increasingly more significant. We see documentation both as a proof of the quality of our products and as a service for our customers.

Documentation packages

We can support you in the creation of documentation packages for ...

- active ingredients (ASMF / DMF, 3.2. Part-S)
- finished medicinal products (3.2. Part-P)
- cosmetic products (PIF File)
- food supplements
- ... or we can prepare them for you together with our external partners.

We offer documentation packages, that are completely adapted to your requirements.

Basic documentation of raw material / plant raw material

- Certificate of analysis with complete supply chain
- Harvest log
- Proof of origin
- SDS, further technical documents

Basic documentation of plant raw material with residue analysis

- Certificate of analysis
- Harvest log
- Proof of origin
- Testing for pesticides, heavy metals, aflatoxins acc. Ph. Eur.
- Pyrrolizidine alkaloids
- Microbiology

Documentation packages for manufacturing / QA by defined scope

- Manufacturing flow-chart
- Manufacturing specification
- Copy of complete batch documentation
- Process validation report
- Cleaning validation report

05 PRODUCTION AND PACKAGING SYSTEMS

05.1 Distillation systems

Stirring and distillation system / BÜCHI



Equipment

Filling volume	Reaction tank 110 litres
Min./Max. permissible Pressure	-1 / +0.5 bar
Min./Max. permissible Temperature	-60 / +200 °C

Further specifications

- Propeller stirrer with ATEX spur gear motor
- Temperature sensor reactor integrated in baffle
- Temperature sensor glass vapour line
- Pressure measurement probe
- ATEX-compliant

Stirring and distillation system / CROMA TECH



Equipment

Filling volume	Process tank 500 litres (inner tank Ø 1,000 mm, double jacket)
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Further specifications

- Anchor agitator
- Ancillary stirrer

05.2 Systems for liquid products

AB-2100 / VAKUMIX preparation container



- Application**
- Ethanolic solutions
 - Syrups
 - Low viscosity gels

Preparation tank (total tank volume 2,700 litres)

Min. useful volume	Approx. 210 litres
Max. useful volume	2,100 litres
Max. pressure of inner tank	-1/+2 bar
Max. product temperature	132 °C
System	Closed

Preparation tank with heating jacket

Volume	92 litres
Heating jacket pressure	-1/+5 bar
Max. heating temperature	151 °C

Homogenising system

Homogeniser size	G2
Speed range	500 - 4,800 rpm

Energy assembly

Heating	Indirect with plate heat exchanger
Cooling	Directly with water

Further specifications

- Suction device for powder below liquid level
- Pressure and vacuum control
- CIP cleaning device
- SIP device
- ATEX-compliant

Fill and seal packaging line (UDF4020 / KS1020) / BAUSCH UND STRÖBEL
Cartoning machine Vario C5 / WIEDERKEHR VERPACKUNGSMASCHINEN



- Application**
- Fully automatic filling line for liquids such as oils, syrups, and ethanolic solutions

Filling quantities	10 to 1,100 ml
Dosage	By means of 4 valveless rotary piston pumps
Round objects	Ø 16 to 100 mm
Flat objects	Min. 16 × 16 mm Max. 120 × 100 mm
Height	Min. 35 mm Max. 320 mm
Performance	Up to 40 pieces per minute

Further specifications

- Gassing with nitrogen during the filling and sealing process
- Closure with dropper insert, combined with screw caps with tamper evident ring, pilfer-proof caps or dispenser caps
- Labelling front and back



05.3 Systems for semi-solid products

HM 675 / VAKUMIX homogenizing mixer



Application

Production of semi-solid products

Total volume	1,095 litres
Useful volume	675 litres
Max. useful volume	700 litres
Min. useful volume	120 litres
Max. pressure of product	-1/+2 bar
Max. temperature product	132.8 °C
Max. heating pressure	-1/+5 bar
Max. temperature heating	158 °C

Further specifications

- Agitator boiler with heating jacket
- Agitator lid, including sightglass light, vacuum connection, manometer, vacuum valve, ventilation valve, connection piece
- Anchor stirrer with scraper system
- Baffle with Pt100
- Homogenising device
- Circulation line
- Suction device for powder
- Temperature control heating and cooling
- Pressure and vacuum control
- CIP cleaning device

Optima 800 / AXOMATIC tube filling line

Application

Filling of semi-solid forms in aluminium or plastic tubes



Performance	Up to 3,600 pieces per hour
Dosing range	3 to 250 ml
Ø metal tube	13.5 to 42 mm
Ø plastic tube	13.5 to 50 mm
Total length of the tube	70 to 250 mm including cap
Cardboard packaging system	Uhlmann C100 (optional)

05.4 Systems for solid products

HM 2000 Amixon / AMIXON GMBH vertical twin-shaft mixer



Application

Production of powder mixtures

Total volume	2,850 litres
Useful volume	2,000 litres (Max. batch size)
Max. batch weight	1,800 kg
Min. filling level	200 litres (without cutting rotor) 800 litres (with cutting rotor)
Max. operating temperature	+ 40 °C
Max. operating overpressure	- 0.6 bar
Stirrer speed	11 to 38 rpm, adjustable
Cutting rotor speed	1,500 rpm, constant
Timer function	6 sec. to 60 h

Further specifications

- Pharmaceutical version
- Frequency converter
- Cutting rotor with mounting flange
- Electrical control cabinet
- Washing in place
- Working platform

SMC matic 101 / SWISS CAN MACHINERY powder filling line



Filling quantities	20 to 1,000g
Performance	Up to 30 pieces per minute (depending on filling volume)

Further specifications

- Tare scale: empty can
- GTR filler: product filling with dosing screw (vibration during filling possible)
- Gross scale: weigh can filled with product
- Lid feeder: put on lid
- Screwdriver: screw on KS lid
- Capper: fold tin lid onto can
- SF101 inclined conveyor with belt feed to lid feeder

Application

Fully automatic packaging of solids in cans (screw cap or cardboard wrap-around cans)

King TC8 / KING PACKAGING MACHINES tablet filling line



Max. counting performance	4,000 pieces per minute
Max. bottle diameter	125mm
Max. bottle height	250mm
Tablet size	4 to 25mm
Cardboard packaging machine	In one line with Vario C5 cardboard packaging machine (optional)

Application

Fully electronic counting and fully automatic filling of tablets, capsules and dragées into cans / jars

The machine consists of three main components:

1. Mechanical feeding system for the material to be counted (8 lanes)
2. Electronic meter reading system
3. Synchronized conveyor belt and container blocking system

06 SYSTEMS FOR TOXIC HIGH-POTENCY ACTIVE INGREDIENTS

Glovebox

The glovebox meets the highest occupational safety requirements and enables the filling of toxic or highly potent active ingredients (OEB values 4 to 5), along with filling under inert conditions.

Glovebox fillings are possible from a container size of 500mg to 500g (excluding cytostatic drugs). Bag-in-bag packaging is also possible if necessary. The system has been extensively qualified and validated and is used for the filling of active ingredients under GMP conditions (interior ISO 7 at rest).

Highly potent active ingredients are pharmaceutical agents that act at very low concentrations. A maximum of 0.2 milligram per kilogram body weight or 10 milligrams per day are sufficient to produce a significant therapeutic effect. Highly potent active ingredients such as hormones.



07 QUALITY CONTROL INFRASTRUCTURE

As a GMP certified company, quality management is our highest priority. One sixth of our entire staff-qualified and trained professionals, is involved in product process control.

Our goal and promise is to ensure high quality at all levels. This starts with the procurement of raw materials from qualified supply sources, includes quality control of the incoming goods and manufacturing process (including registration dossiers) and ends with the supervision of all project, stability, and validation work connected to contract manufacturing.

Karl Fischer / METROHM AG Titrando 888



Application

Measurement of the water content according to Karl Fischer in accordance with EP 2.5.12 including direct transfer of the weighed-in quantity and the consumption to for Tiamo control and evaluation software

Spectrum Two / PERKIN ELMER infrared spectrophotometer



Application

FT-IR spectrophotometer for identity testing according to EP 2.2.24 with the possibility of measurement by means of KBr-pressing, as well as with the ATR-unit, including transmission to the Spectrum ES control and evaluation software

Autopol Vplus / RUDOLPH RESEARCH polarimeter



Application

Polarimeter for determining the optical or specific rotation according to EP 2.2.7

CAMAG thin-layer chromatography automation



Application

- Automated equipment (sample introduction and evaluation) for qualitative and quantitative determinations in thin-layer chromatography according to EP 2.2.27 and EP 2.3.2
- Control and evaluation via Win Cats software

Lambda 25 / PERKIN ELMER photometer



Application

UV / Vis spectrophotometer for measurements of identity and content according to EP 2.2.25, including transfer to the UV WinLab control and evaluation software

GC 8890 / AGILENT gas chromatograph



Application

- 2 gas chromatographs with autosampler and FID detectors for various validated methods
- 1 gas chromatograph with headspace (including auto-sampler) and FID detector for residual solvent determination according to EP 2.4.24
- 1 gas chromatograph with CTC autosampler, 2 channel, 1 for essential oils according to EP 2.2.28, 1 for fatty acids according to EP 2.4.22
- Control and evaluation via OpenLab server software

HPLC 1260 Infinity II / AGILENT high-performance liquid chromatograph



Application

- 2 HPLC with autosampler, column heater and DAD detectors
- 1 HPLC with autosampler, column heater, DAD and refractive index detector
- Control and evaluation via OpenLab server software

Climate chamber / WEISS-TECHNIK AG



Application

- 2 walk-in climate chambers with approx. 40m³ at 25 °C / 60 % RH
- Automated monitoring of temperature and humidity via radio data logger

HEALTHY GROWTH THROUGH A FRUITFUL BUSINESS PARTNERSHIP.



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