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   HARKE GROUP

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**HARKE Pharma**  
HARKE GROUP Life Sciences Division



**YOUR DOSAGE FORM EXPERTS**



## YOUR DOSAGE FORM EXPERTS

### HARKE Pharma

is your technology driven distributor for innovative excipients.

### HARKE Pharma

stands for more than 40 years of supporting our Customers in their development and optimization of innovative dosage forms, by offering extensive technical support, rounded up by a broad range of specialized excipients and selected APIs.

By closely monitoring the ever-changing markets, we identify the latest technological and scientific trends, supporting our Customers to implement them. Our in-house experts are available to efficiently work with our Customers on projects, from concept to commercialization. Utilizing our extensive quality-driven product portfolio, we are able to offer a unique and effective partnership.

### HARKE GROUP

The mother company of HARKE Pharma is a family-owned, international group, offering speciality materials, technical support and customized solutions, including formulating, blending and contract packaging for technical applications.



Thorsten Harke | President HARKE GROUP



Daniel Burchart | Board Member Life Sciences  
Managing Director HARKE Pharma GmbH

### HARKE GROUP Life Sciences Division

- HARKE Pharma
- HARKE Nutraceuticals
- HARKE Food
- HARKE Feed



PHARMA

Facts & Figures

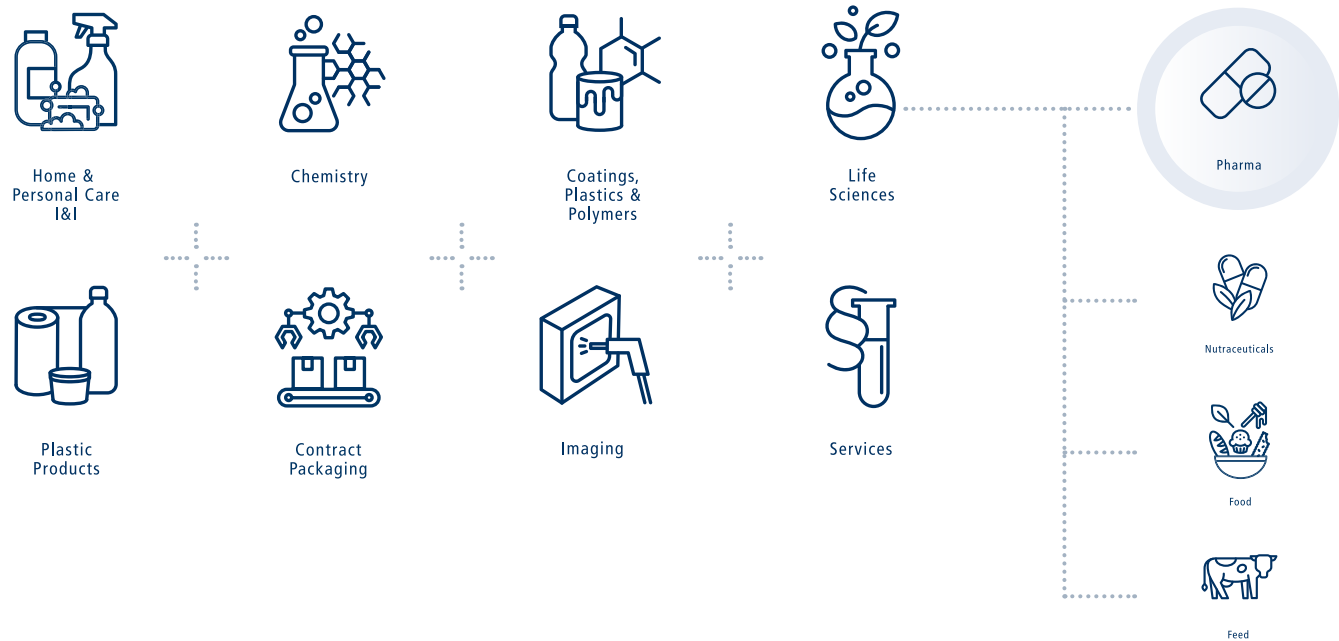
HARKE GROUP



HARKE PHARMA



HARKE DIVISIONS



EUROPE-WIDE ASSISTANCE

With offices across many European countries, we are able to offer our Partners a local presence. Using local languages, our experts are able to provide advice and assistance, anywhere and at any time.



● Headquarters ● Subsidiaries ● Production/Storage ● Sales Offices

## Our Services



### REGULATORY COMPLIANCE

Having over 40 years experience in the distribution of pharmaceutical and nutraceutical raw materials, we put the individual requirements of our Customers at the heart of our activities.

Our teams are well-informed about all legal and regulatory requirements, meaning we are able to support our Customers to be fully compliant.

### SUPPLY CHAIN MANAGEMENT

If your needs are specific logistics solutions, e.g. just-in time deliveries, short lead times, consignment stock – we are your partner of choice.

Our Customers can count on a quality supply chain, using special warehousing and transport partners following the GDP guidelines, whereas state of the art IT (SAP) assures batch traceability.

Transparent communication, minimizing costs and enhancing Customer benefits – this is our contribution to your success.

This way we assure reliable/quick deliveries and best possible availability from our European warehouses and therefore can support you even in cases of "emergency".

### CUSTOMIZED SOLUTIONS

Providing R&D support and researched scientific data, our dedicated team work side-by-side with Customers to achieve development targets, working from idea to implementation.

Our knowledgeable scientists can help to reduce the number of trials, by offering recommendations on the optimal raw materials or formulations for your drug design.

Moreover, we are able to apply our technical and processing know-how, to develop customized formulations, designed to fit the specific needs of our Customers.

### SCIENTIFIC COLLABORATION

Constantly striving to improve our scientific and processing knowledge base, we work together with research institutes and renowned universities.

Every year we support CROs, universities and PhD students with both our technical expertise and excipients, for use in their publications.

### TECHNICAL SUPPORT

Our competent team of experts, from a wide spectrum of pharmaceutical and chemical fields, are at your disposal for formulation advice, problem solving and on-site trials.

### SEMINARS, EXHIBITIONS & CONGRESSES

We organize seminars and practical workshops for our customers to transfer know-how and participate in scientific congresses, such as CRS and APV.

Our team exhibits at major pharmaceutical and nutraceutical trade shows. Across Europe we have an active presence.



# Products by Application

## COATING



Coating protects the API, individualizes the tablet and can modify the release profile.

Polymers
• Acrylates
• Hypromellose, HPMC
• HPMC Acetate Succinate
• HPMC Phthalate
• Isomalt
• Methylcellulose, MC
• Polyvinyl Alcohol, PVA
• Shellac
Cores/Additives
• Macrogol
• MCC Starter Cores
• Sugar Pellets
• Tartaric Acid Cores
• Talc
• Xylitol Pellets
<b>YOUR BENEFITS:</b>
Various high-quality products at competitive prices for your independent coating solutions.

## SUSTAINED RELEASE



The development of controlled release matrix or coating systems requires polymers in good batch to batch reproducibility.

Matrix Agents
• Acrylates
• High-viscous HPMC
• Polyethylene Oxide, PEO
• Polyvinyl Alcohol, PVA
Controlled Release Coating
• Acrylates
Dissolution Retardant
• Talc
<b>YOUR BENEFITS:</b>
A wide range of products suitable for various technologies for your sophisticated formulations.



## TABLETTING



DC excipients and easy-to-use solutions for ODTs and mini-tablets are increasingly required by the industry to grant high production yield.

Commodities
• Crosslinked PVP
• Gelatine
• Hypromellose, HPMC
• Macrogol
• Microcrystalline Cellulose, MCC
• Polyvinylpyrrolidone, PVP
• Talc
Blends/Premixes
• GRANFILLER-D™
• HarkePlus Tab® (Prime)
• HiSORAD™
• SmartEx™
Specialities
• Hypromellose SR
• Isomalt
• Low-substituted HPC
• Methylcellulose, MC
• Sodium Chloride
• Sucrose Ester

**YOUR BENEFITS:**  
A full basket of excipients, from commodities to problem solvers, which adds value to your formulation.

## SOLUBILITY ENHANCEMENT



Many modern drugs show poor solubility and bioavailability. Solubility enhancement consequently becomes more important.

Carriers for Solid Dispersion
• Acrylates
• Hypromellose, HPMC
• HPMC Acetate Succinate
• HPMC Phthalate
• Macrogol
• Polyvinyl Alcohol, PVA
• Polyvinylpyrrolidone, PVP
Specialities
• Isomalt
• Sucrose Ester
• Tartaric Acid Cores
<b>YOUR BENEFITS:</b>
Solutions dedicated to tackle solubility problems backed up with state-of-the-art supportive data.

Products by Application

GRANULATION



In various cases different types of granulation are needed to improve technological properties of the powder.

**Binder**

- Gelatine
- Hypromellose, HPMC
- Methylcellulose, MC
- Microcrystalline Cellulose, MCC
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

**Binder/Disintegrant**

- Isomalt
- Low-substituted HPC

**YOUR BENEFITS:**

Various excipients and grades, to suit either wet or dry granulation processing.

PELLETIZATION



Pellets are produced by e.g. direct pelletization, extrusion-spheronization or using neutral starter cores for layering.

**Extrusion – Spheronization**

- Hypromellose, HPMC
- Isomalt
- Low-substituted HPC
- Microcrystalline Cellulose, MCC
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

**Layering**

- MCC Starter Cores
- Sugar Pellets
- Tartaric Acid Cores
- Xylitol Pellets

**YOUR BENEFITS:**

Time and cost savings, during the production process, increasing production yield.

PATCH SYSTEMS



The demand for topical finished dosage forms is increasing and the use of patch systems is rising continuously.

**Preservatives/Antiseptics**

- Chlorhexidine Salts

**Sticking Agent**

- Polyvinyl Alcohol, PVA

**YOUR BENEFITS:**

Innovative ingredients in different grades at competitive prices.

OPHTHALMICS



Applications for ophthalmic treatment require raw materials with a good bioavailability and microbiological purity.

**pH Modifiers**

- Potassium Hydroxide Pellets
- Sodium Hydroxide Pellets

**Thickeners/Vehicles**

- Macrogol
- Methylcellulose, MC
- Polyvinyl Alcohol, PVA

**Tonicity Agents**

- Sodium Chloride

**YOUR BENEFITS:**

High-quality material at competitive prices with outstanding technical back-up.



Products by Application

SEMI-SOLIDS & LIQUIDS



Semi-solid and liquid dosage forms can be produced in shorter times and higher batch output.

<b>pH Modifiers</b>
<ul style="list-style-type: none"><li>• Potassium Hydroxide Pellets</li><li>• Sodium Hydroxide Pellets</li></ul>
<b>Thickeners &amp; Gelling Agents</b>
<ul style="list-style-type: none"><li>• Hypromellose, HPMC</li><li>• Microcrystalline Cellulose, MCC</li></ul>
<b>Surfactants</b>
<ul style="list-style-type: none"><li>• Polyvinyl Alcohol, PVA</li><li>• Sucrose Ester</li></ul>
<b>Sweetener</b>
<ul style="list-style-type: none"><li>• Isomalt</li></ul>
<b>Others</b>
<ul style="list-style-type: none"><li>• Chlorhexidine Salts</li><li>• Macrogol</li><li>• Sodium Chloride</li><li>• Talc</li></ul>
<b>YOUR BENEFITS:</b>
A tailored choice of specialities.

CAPSULES



Innovative capsule locking systems, prevent additional processing, e.g. no banding for semi-solid encapsulation required.

<b>Empty Hard Capsules</b>
<ul style="list-style-type: none"><li>• HPMC, Gelatine and Pullulan</li><li>• BSE &amp; TSE free</li><li>• 9 sizes in 2000 colors</li><li>• Three different locking systems</li></ul>
<b>Layering</b>
<ul style="list-style-type: none"><li>• GELITA® Gelatine (pig/bovine, Type A/Type B)</li><li>• GELITA® EC</li><li>• GELITA® RXL</li><li>• GELITA® RXL R<sup>2</sup></li></ul>
<b>YOUR BENEFITS:</b>
Competitive capsules to serve individual needs, delivered in even small volumes, within a short time frame.

CLEAN BOTTLES AND CONTAINERS



Primary packaging for high-purity reagents, solvents and any other liquid formulation with the need for highest cleanliness levels.

<b>Sophisticated Quality</b>
<ul style="list-style-type: none"><li>• Manufactured under Clean Room conditions, using specially selected, high-purity PE resin</li><li>• Minimum particle counts, extractables and leachables</li><li>• Light weight, yet strong physical properties, leakage-proof</li><li>• Quality documented by COA</li></ul>
<b>Characteristics</b>
<ul style="list-style-type: none"><li>• Monolayer and multilayer bottles</li><li>• Wide and narrow mouth size</li><li>• Optional UV-light protection, solvent barrier layer, low residue construction</li><li>• From 100 ml up to 22.5 Liter, equally 200 Liter drums</li></ul>
<b>YOUR BENEFITS:</b>
High purity, no pre-cleaning, flexible quantities.

HYPERCLEAN™ PE-FILM/FINE BAG



High-level primary packaging with Aicello HYPER-CLEAN™ PE-Film and antistatic FINE BAG for pharmaceutical use.

<b>Sophisticated Quality</b>
<ul style="list-style-type: none"><li>• Compliance to EP, USP and JP; DMF (FDA) available</li><li>• Processed in Clean Room Environment from carefully selected PE-resin</li><li>• Minimum particles, extractables and leachables</li><li>• Physical strength, low outgassing</li></ul>
<b>Characteristics</b>
<ul style="list-style-type: none"><li>• Long-lasting antistatic properties (optional)</li><li>• UV-light shield (optional)</li><li>• Various bag sizes and forms or tube roll available</li></ul>
<b>YOUR BENEFITS:</b>
Premium-quality primary packaging for sensitive APIs and intermediates, mostly available in flexible quantities.



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Product Categories



ACRYLATES	CELLULOSE DERIVATIVES	POLYETHYLENE OXIDE
DRUGCOAT® E	HPMC-P	PEO-NF
DRUGCOAT® FS	Hydroxypropyl Methylcellulose	
DRUGCOAT® L	Hypromellose	POLYVINYL ALCOHOL
DRUGCOAT® NE	Hypromellose Acetate Succinate	GOHSENL™ EG
DRUGCOAT® RL	Hypromellose Phthalate	
DRUGCOAT® RS	L-HPC	POLYVINYLPIRROLIDONE
DRUGCOAT® S	Low-substituted HPC	Copovidone
Methacrylic Acid Copolymers	Methylcellulose	Crospovidone
	METOLOSE® SH	Crosslinked PVP
ACTIVES/DISINFECTANTS	METOLOSE® SM	Povidone
Chlorhexidine	PHARMACOAT®	
Chlorhexidine Diacetate	Shin-Etsu AQOAT® (HPMC-AS)	PRIMARY PACKAGING
Chlorhexidine Digluconate, 20 %	TYLOPUR®	Aicello Clean Bottles and Containers
Chlorhexidine Dihydrochloride		Aicello FINE BAG
Ibuprofen DC 100	GELATINE	Aicello HYPERCLEAN™ PE-film
Ibuprofen Pellets	GELITA® EC	
	GELITA® Gelatine	SALTS
ALKALI	GELITA® RXL	SANAL® P
Eka Pellets™	GELITA® RXL R²	Sodium Chloride
Potassium Hydroxide Pellets		
Sodium Hydroxide Pellets	ISOMALT	SHELLAC
	galenIQ™	AQUAGOLD (Aqueous Shellac Solution)
BLENDS/PREMIKES		Bleached Shellac
GRANFILLER-D™	MACROGOL	SSB® AQUAGOLD
HarkePlus Tab® (Tabletting Premix)	PEG	SSB® Pharma
HarkePlus Tab® Prime	Polyethylene Glycol (PEG)	
HiSORAD™	Polyglykol	SUCROSE ESTER
SmartEx™		Sucrose Behenate
CAPSULES	PELLETS	Sucrose Laurate
Gelatine	Cellets® (MCC Spheres)	Sucrose Oleate
HPMC	Ibuprofen DC 100	Sucrose Palmitate
Pullulan	Ibuprofen Pellets	Sucrose Stearate
SUNLOC	Neutral Pellets	SURFHOPE® SE
	Sugar Pellets	
	TAP® Pellets	TALC
CELLULOSE	Tartaric Acid Pellets	Micro ACE
Chemical™	Xylitol Pellets	Talc MS
Microcrystalline Cellulose		Rose Talc
Primecel™		

Products A-Z



A	G	P
Acrylates	GELITA® RXL R <sup>2</sup>	PHARMACOAT®
Aicello Clean Bottles and Containers	GOHSENOL™ EG	Polyethylene Glycol (PEG)
Aicello FINE BAG	GRANFILLER-D™	Polyethylene Oxide (PEO)
Aicello HYPERCLEANTM PE-film		Polyglykol
AQUAGOLD (Aqueous Shellac Solution)	H	Polyvinyl Alcohol (PVA)
	HarkePlus Tab® (Tabletting Premix)	Polyvinylpyrrolidone (PVP)
B	HarkePlus Tab® Prime	Potassium Hydroxide Pellets
Bleached Shellac	HiSORAD™	Povidone
	HPMC-P	Primecel™
C	Hydroxypropyl Methylcellulose	
Capsules (Gelatine, HPMC, Pullulan)	Hypromellose	R
Cellets® (MCC Spheres)	Hypromellose Acetate Succinate	Rose Talc
Chemical™	Hypromellose Phthalate	
Chlorhexidine	I	S
Chlorhexidine Diacetate	Ibuprofen DC 100	SANAL® P
Chlorhexidine Digluconate, 20 %	Ibuprofen Pellets	Shellac
Chlorhexidine Dihydrochloride	Isomalt	Shin-Etsu AQOAT® (HPMC-AS)
Copovidone		SmartEx™
Crospovidone	L	Sodium Chloride
Crosslinked PVP	L-HPC	Sodium Hydroxide Pellets
D	Low-substituted HPC	SSB® AQUAGOLD
DRUGCOAT® E		SSB® Pharma
DRUGCOAT® FS	M	Sucrose Behenate
DRUGCOAT® L	Macrogol	Sucrose Laurate
DRUGCOAT® NE	Methacrylic Acid Copolymers	Sucrose Oleate
DRUGCOAT® RL	Methylcellulose	Sucrose Palmitate
DRUGCOAT® RS	METOLOSE® SH	Sucrose Stearate
DRUGCOAT® S	METOLOSE® SM	Sugar Free Pellets (Xylitol)
E	Micro ACE	Sugar Pellets
Eka Pellets™	Microcrystalline Cellulose	SUNLOC
	N	SURFHOPE® SE
G	Neutral Pellets	
galenIQ™		T
Gelatine	P	Talc
GELITA® EC	PEG	Talc MS
GELITA® Gelatine	PEO-NF	TAP® Pellets
GELITA® RXL		Tartaric Acid Pellets
		TYLOPUR®

# Our Partners & Products

## #OnePartnerOneResponsibility

We have a carefully selected raw material portfolio, primarily used for solid and semi-solid dosage forms.

Our experience of marrying the expectations of our Principals, with the needs of our Customers, means that we have a focused list of products, from hand-picked Principals, ideally suited to the possible applications of our Customers.

This helps us to offer the outstanding and well-known HARKE service level.



Japanese Clean Room manufacturing of high-purity primary PE-packaging materials (Joint-venture with HARKE: AICELLO-HARKE GmbH).

- Clean Bottles & Containers
- HYPERCLEAN™ PE-Film
- FINE BAG



Long established and major manufacturer of PVA.

- PVA



Leading supplier of various food ingredients with a niche in pharma.

- Sucrose Ester



Our sourcing agent in China.

- PVP
- Crospovidone
- PVP VA64



The largest Japanese producer of superior quality Talc products.

- Talc



Beneo is part of the Südzucker group. Specialist for naturally derived functional ingredients.

- Isomalt



Fast growing, quality-focused, family-owned cellulose manufacturer.

- MCC



Multinational company, active in various fields in the chemical industry, with a special focus on quality.

- Polyglykol



Leading producer of a diverse range of chemicals, with a special focus on innovative co-processed excipients.

- GRANFILLER-D™
- HiSORAD™



One of the leading manufacturers of pharmaceutical Povidones with a high responsibility for environmental compliance.

- KoVidone®
- PolyKoVidone®
- OraRez®



Since 1905 producer in Bohus (Sweden) for purest alkali pellets of NaOH/KOH and since 1918 for pharmaceutical salt in Mariager Fjord (Denmark).

- Highly purified NaOH, KOH
- SANAL® P, Pharmaceutical NaCl



Family-owned company previously specializing in dragées, now offering a wide range of globuli & neutral starter cores.

- Sugar pellets
- Sugar free pellets (Xylitol)



Leading supplier of Cellulose derivatives.

- HPMC
- HPMC-AS
- HPMC-P
- L-HPC
- MC



Globally active producer of high quality Gelatine, as well as Collagen and Collagen peptides.

- Gelatine



Our own brand, offering solutions to a range of formulation challenges.

- Blends/Premixes
- HarkePlus Tab®
- HarkePlus Tab® Prime



German manufacturer, with knowledge and experience in producing highly spherical particles.

- Neutral MCC Pellets
- Ibuprofen Pellets 100 %
- Tartaric Acid Pellets



Family-owned manufacturer of high quality APIs.

- Chlorhexidine Salts



Manufacturer of outstanding quality Shellac specialties, based in Northern Germany.

- Shellac Aqueous Solution
- Shellac Flakes



Japanese manufacturer of PEO.

- PEO



Major Indian manufacturer of empty hard capsules.

- Capsules
  - HPMC
  - Gelatine
  - Pullulan



EXCiPACT certified producer of Acrylate based coating polymers, located in India.

- Methacrylic Acid Copolymers



## Why HARKE

one group of **16** companies | **15** offices in Europe | **6** divisions  
**25** business units | **15** diverse service functions | **3** laboratories | **2** production sites  
 over **220** employees | working with **30** industries | in more than **63** countries | on **4** continents  
 with over **3,000** customers | and more than **40,000** deliveries per year

## 10 reasons to collaborate with HARKE

relevant portfolio | long-standing business relations | growing company group  
 excellent technical know-how | responsible partner | fast action | sustainable enterprise  
 digitization | stable management | passionate people

**countless opportunities for a successful and future-oriented collaboration**

