





HARKE Pharma HARKE GROUP Life Sciences Division

YOUR DOSAGE FORM EXPERTS





YOUR DOSAGE FORM EXPERTS



Thorsten Harke | President HARKE GROUP

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 qualitydriven product portfolio, we are able to offer a unique and effective partnership.



Mandy Rehländer | Board Member Life Sciences Managing Director HARKE Pharma GmbH

HARKE GROUP

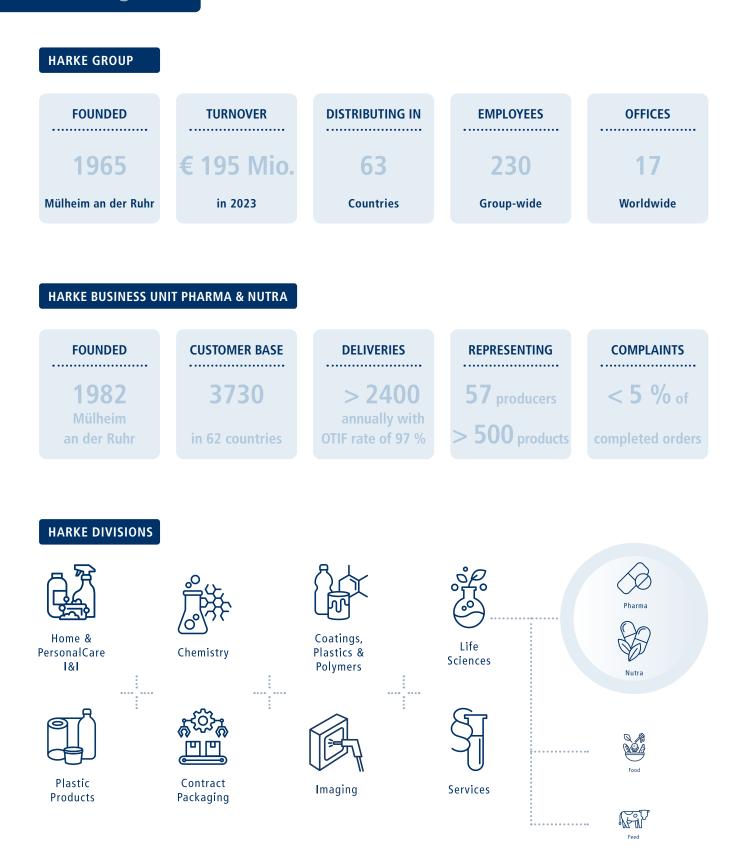
The mother company of HARKE Pharma is a family-owned, international group, offering speciality materials, technical support and customized solutions, including formulating, blending and contract packaging for technical applications.

HARKE GROUP Life Sciences Division

- HARKE Pharma
- HARKE Nutra
- HARKE Food
- HARKE Feed

Facts & Figures

04



WORLDWIDE ASSISTANCE

With offices across many European countries and in India, 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.



05

















Halifax Manchester Dublin Warsaw Brussels 0 0 Paris Budapest 0 0 Lucerne Mohács 0 Lyon Milan Bucharest 0 Istanbul

 Sales Offices Headquarters • Subsidiaries Production/Storage

HARKE Pharma

Our Services

06



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.

Besides that, we can offer a one-stop-shop for nutraceuticals: From the idea to the finished product. We have a close eye on the trends in the Nutraceutical Industry, developing innovative and individual product concepts.

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 CONSULTING

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.

TECHNICAL TRAINING

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

08



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

Polymers

- Acrylates
- Hypromellose, HPMC
- HPMC Acetate Succinate
- HPMC Phthalate
- Isomalt
- Methylcellulose, MC
- Polyvinyl Alcohol, PVA
- Shellac

Cores/Additives

- Globuli Sacchari
- Macrogol
- MCC Starter Cores
- Sugar Spheres
- Tartaric Acid Cores
- Talc

YOUR BENEFITS:

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

YOUR BENEFITS:

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.

Essentials

- Crosslinked PVP
- Hypromellose, HPMC
- Hypromellose SR
- Isomalt
- Low-substituted HPC
- Macrogol
- Methylcellulose, MC
- Microcrystalline Cellulose, MCC

.....

- Natural Calcium Carbonate
- Polyvinylpyrrolidone, PVP
- Sodium Chloride
- Sodium Stearyl Fumarate (SSF)
- Sucrose Ester
- Talc

Premixes/Co-processed Excipients

- Functionalized Calcium Carbonate
- HarkePlus Tab®
- SmartEx[®] Plus

YOUR BENEFITS:

A full basket of excipients, from essentials 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
- Copovidone
- Hypromellose, HPMC
- HPMC Acetate Succinate
- HPMC Phthalate
- Macrogol
- ividerogor
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

YOUR BENEFITS:

Solutions dedicated to tackle solubility problems backed up with state-of-the-art supportive data.



Products by Application

GRANULATION

10



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

Binder

- Copovidone
- Functionalized Calcium Carbonate
- Hypromellose, HPMC
- Isomalt
- Methylcellulose, MC
- Microcrystalline Cellulose, MCC
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

Binder/Disintegrant

Low-substituted HPC (L-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

- Globuli Sacchari
- MCC Starter Cores
- Sugar Spheres
- Tartaric Acid Cores

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.

Essentials

- Copovidone
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP
- PVM/MA

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

- Hypromellose, HPMC
- Macrogol
- Methylcellulose, MC
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

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.

pH Modifiers

- Potassium Hydroxide Pellets
- Sodium Hydroxide Pellets

Thickeners & Gelling Agents

- Hypromellose, HPMC
- Microcrystalline Cellulose, MCC
- Polyvinylpyrrolidone, PVP

Emulsifier

- Hypromellose, HPMC
- Methylcellulose, MC
- Sucrose Ester

Sweetener

• Isomalt

Others

- Macrogol
- Polyvinyl Alcohol, PVA
- Sodium Chloride

YOUR BENEFITS:

A tailored choice of specialities.

CAPSULES



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

Empty Hard Capsules

- HPMC, Gelatine and Pullulan
- BSE & TSE free
- 9 sizes in 2000 colors
- Three different locking systems

YOUR BENEFITS:

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.

Sophisticated Quality

- Manufactured under Clean Room conditions, using specially selected, high-purity PE resin
- Minimum particle counts, extractables and leachables
- Light weight, yet strong physical properties, leakage-proof
- Quality documented by COA

Characteristics

- Monolayer and multilayer bottles
- Wide and narrow mouth size
- Optional UV-light protection, solvent barrier layer, low residue construction
- From 100 ml up to 22.5 Liter, equally 200 Liter drums

YOUR BENEFITS:

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.

Sophisticated Quality

- Compliance to 3 major pharmacopoeias: EP, USP and JP
- Drug Master File Type III (17359) available at FDA
- Processed in Clean Room Environment from carefully selected PE-resin
- Minimum particles, extractables and leachables
- Physical strength, low outgassing

Characteristics

- Long-lasting antistatic properties (optional)
- UV-light shield (optional)
- Various bag sizes and forms or tube roll available

YOUR BENEFITS:

Premium-quality primary packaging for sensitive APIs and intermediates, mostly available in flexible quantities.

Typical Applications			COATINGS					TABLETTING					
ткаде NAME		Instant Release Coating	Modified Release Coating	Protective Coating	Taste Masking	Filler/Diluent	Dry Binder (DC+RC)	Binder Solutions (WG)	Disintegrant	Lubricant/Glidant			
Cellets®	MCC Spheres												
DRUGCOAT®	Acrylates		٠	•	•								
Eka Pellets™	NaOH/KOH												
galenIQ™	Isomalt	•			•	•	٠	•					
GOHSENOL [™] EG	Polyvinylalcohol (PVA)	•		٠	•			•					
HarkePlus [®] Tab	Premix					٠	٠		•				
НРМСР	HPMC Phthalate		•		•								
L-HPC	Low-substituted HPC						•	•	٠				
METOLOSE [®] SH/SR	Hypromellose (HPMC)												
METOLOSE [®] SM	Methylcellulose (MC)	•			•			٠					
Omyapharm®	Functionalized Calcium Carbonate					٠	٠			•			
Omyapure®	Natural Calcium Carbonate					•							
Oxipurity [®] 4000 Series	PEG/Macrogol	•				٠				•			
PEO-NF	Polyethylene Oxide (PEO)						٠						
PHARMACOAT®	Hypromellose (HPMC)	•		٠	•	٠	٠	٠					
pharm-a-spheres®	Sugar Spheres												
Primecel [®] /Chemicel [®]	МСС					•	•		•				
Primesolv®	Silificied MCC					٠	•						
PVP K	Povidone (PVP)	•		•				•					
PVP VA 64	Copovidone	•		•			•	•					
PVPP XL/CL	Crospovidone (XL-PVP)								•				
SANAL® P	Sodium Chloride					•							
Shin-Etsu AQOAT®	HPMC Acetate Succinate		•		•								
SmartEx [®] Plus	Co-processed excipient					٠			٠				
SSB [®] Pharma/AQUAGOLD	Shellac		•	٠	•								
HarkePlus [®] Sucrose Ester	Sucrose Ester									٠			
Talc	Talc	٠	•	•	•	•				•			
TAP®	Tartaric Acid Pellets	•••••											
VEGHA	Sodium Stearyl Fumarate (SSF)									٠			

HARKE Pharma

	SPECIALITIES					S ENF	OLUBILII IANCEM	'Y ENT	SEMI-SOLIDS & LIQUIDS					ENCAPSULATION					
Anti-Capping	Modified Release (DC+WG)	_	a	Extrusion-Spheronization	Orally Disintegrant Tablet	Orally Disintegrant Film	Stabilizing agent	Dissolution enhancer	Mini-Tablets	SD solvent free method	SD solvent method	pH Modification	Thickener	Emulsifier	Eye Drops	Mucoadhesive agent	TDS/Penetration enhancer	Capsule shell	Dispersing Aid (capsules)
		•																	
	•									•	•						•		
												•			•				
		•		•	•				•	•									•
	•					•	•			•			•		•	•	•		
•										•	•								
•				•	•				•	•	•								•
	•			•	•	•			•				•	•	•	•	•		
						•							•	•			•		
												•							
													•						
	•									•			•						
						•	•	•		•	•							•	
		•																	
				•			•						•						
						•		•		•			•		•		•		
						•		•		•									
															•				
					•				•	-	-								
	•									•	•			•	•		•		
	•																		•
		•										•							
	•		•	•		•	•			•	•	•			•		•	•	

Product Categories



• •

ACRYLATES	CE
DRUGCOAT® E	HPI
DRUGCOAT® FS	Нус
DRUGCOAT [®] L	••••••
DRUGCOAT [®] NE	
DRUGCOAT [®] RL	
DRUGCOAT [®] RS	Нур
DRUGCOAT [®] S	L-H
Methacrylic Acid Copolymers	Lov
ACTIVES	Me
Ibuprofen DC 100	ME
Ibuprofen Pellets	ME
	PH
ALKALI	Shi
Eka Pellets™	TYL
Potassium Hydroxide Pellets (KOH)	
Sodium Hydroxide Pellets (NaOH)	FU
CALCIUM MINERALS	Soc
Functionalized Calcium Carbonate	VEC
Natural Calcium Carbonate	16.0
Omyapharm [®]	ISC gal
Omyapure®	yan
CANNABIDIOL	MA
CBD Powder 2%	OX
CBD Powder 6%	Pol
	DEI
CAPSULES	PEI
Gelatine	Cel
HPMC Pullulan	Glo
	lbu
SUNLOC	lbu
CELLULOSE	Sug
Chemicel®	TAF
Microcrystalline Cellulose	Tar
Primecel®	
Primesolv [®] SMCC	PO
Silicified Microcrystalline Cellulose	PEC

LLULOSE DERIVATIVES	POLYETHYLENE OXIDE			
MC P	PEO-NF			
droxypropyl Methylcellulose	POLYVINYL ALCOHOL			
promellose (HPMC)	GOHSENOL [™] EG			
promellose Acetate Succinate				
promellose Phthalate	POLYVINYLPYRROLIDO			
IPC	coportione			
w-substituted HPC				
ethylcellulose	Crosslinked PVP			
ETOLOSE® SH/SR	Povidone			
TOLOSE® SM	PREMIXES/CO-PROCESSED			
ARMACOAT®	HarkePlus Tab [®]			
	SmartEx [®] Plus			
in-Etsu AQOAT [®] (HPMC AS)				
LOPUR®	PRIMARY PACKAGING			
IMARIC ACID ESTER	Aicello Clean Bottles and C Aicello FINE BAG			
dium Stearyl Fumarate (SSF)	Aicello HYPERCLEAN [™] PE-f			
GHA	AICEIIO HYPERCLEAN PE-I			
	SALTS			
	SANAL [®] P			
lenIQ™	Sodium Chloride			
ACROGOL	SHELLAC			
IPURITY® 4000 Series	AQUAGOLD (Aqueous Shella			
lyethylene Glycol (PEG)	Bleached Shellac			
LLETS	SSB [®] AQUAGOLD			
llets [®] (MCC Spheres)	SSB [®] Pharma			
buli Sacchari				
	SUCROSE ESTER			
iprofen DC 100	•••••••••••••••••••••••••••••••••••••••			
Iprofen Pellets				
gar Spheres	Sucrose Stearate			
P® Pellets	TALC			
taric Acid Pellets	Micro ACE			
DLYETHYLENE OXIDE	Talc MS			

O-NF

POLYVINYL ALCOHOL
GOHSENOL [™] EG
POLYVINYLPYRROLIDONE
Copovidone
Crospovidone
Crosslinked PVP
Povidone
PREMIXES/CO-PROCESSED EXCIPIENTS
HarkePlus Tab®
SmartEx [®] Plus
PRIMARY PACKAGING
Aicello Clean Bottles and Containers
Aicello FINE BAG
Aicello HYPERCLEAN™ PE-film
SALTS
SANAL [®] P
Sodium Chloride
SHELLAC
AQUAGOLD (Aqueous Shellac Solution)
Bleached Shellac
SSB® AQUAGOLD
SSB® Pharma
SUCROSE ESTER
Sucrose Laurate
Sucrose Palmitate
Sucrose Stearate
TALC
Micro ACE
Talc MS
Rose Talc

Products A-Z

19

А
Acrylates
Aicello Clean Bottles and Containers
Aicello FINE BAG
Aicello HYPERCLEAN™ PE-film
Alkali
AQUAGOLD (Aqueous Shellac Solution)
В
Bleached Shellac
С
Calcium Minerales
Cannabidiol
Capsules (Gelatine, HPMC, Pullulan)
CBD Powder 2 %
CBD Powder 6 %
Cellets [®] (MCC Spheres)
Cellulose Derivatives
Chemicel®
Co-processed Excipients
Copovidone
Crospovidone
Crosslinked PVP
D
DRUGCOAT [®] E
DRUGCOAT [®] FS
DRUGCOAT® L
DRUGCOAT [®] NE
DRUGCOAT® RL
DRUGCOAT [®] RS
DRUGCOAT [®] S
E
Eka Pellets™
F
Functionalized Calcium Carbonate
G
galenIQ™

Globuli Sacchari

GOHSENOL[™] EG

Н
HarkePlus Tab [®] (Tabletting Premix)
HPMC P
Hydroxypropyl Methylcellulose
Hypromellose (HPMC)
Hypromellose Acetate Succinate
Hypromellose Phthalate
1
Ibuprofen DC 100
Ibuprofen Pellets
Isomalt
K
КОН
L
L-HPC
Low-substituted HPC
Μ
Macrogol
MCC Starter Cores
Methacrylic Acid Copolymers
Methylcellulose (MC)
METOLOSE® SH/SR
METOLOSE [®] SM Micro ACE
Microcrystalline Cellulose (MCC)
,
Ν
NaOH
Natural Calcium Carbonate
0
Omyapharm®
Omyapure®
Oxipurity [®] 4000 Series
Р
PEG
PEO-NF
pharma-a-spheres®
PHARMACOAT®
Polyethylene Glycol (PEG)
Polyethylene Oxide (PEO)
Polyvinyl Alcohol (PVA)

Р
Polyvinylpyrrolidone (PVP)
Potassium Hydroxide Pellets
Povidone
Primary Packaging
Premixes
Primecel®
Primesolv [®] SMCC
PVM/MA
PVP K
PVP VA 64
PVPP XL/CL
D
R
Rose Talc
S
SANAL® P
Shellac
Shin-Etsu AQOAT® (HPMC AS)
Silicified Microcrystalline Cellulose
SmartEx [®] Plus
Sodium Chloride
Sodium Hydroxide Pellets
Sodium Stearyl Fumarate (SSF)
SSB® AQUAGOLD
SSB [®] Pharma
Sucrose Laurate
Sucrose Palmitate
Sucrose Stearate
Sucrose Ester
Sugar Spheres
SUNLOC
-
T
Talc
Talc MS
TAP [®] Pellets
Tartaric Acid Cores
Tartaric Acid Pellets
TYLOPUR®
V
VEGHA

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.



ПКЧ	Nouryon Authorized distributor	<u>OK(A</u>	PEHEL SPECIALITIES		
One of the leading manu- facturers of pharmaceutical Povidones with a high re- sponsibility for environmental compliance.	Since 1905 producer in Bohus (Sweden) for purest alkali pellets of NaOH/KOH.	Leading global producer of advanced mineral products, of- fering a range of next genera- tion excipients providing highly bioavailable sources of calcium.	Family-owned company, emerging Indian excipient house and a leading manufac- turer of the lubricant, sodium stearyl fumarate.		
 KoVidone[®] PolyKoVidone[®] OraRez[®] 	 Highly purified NaOH Highly purified KOH 	 Natural Calcium Carbonate Functionalized Calcium Carbonate 	 Sodium Stearyl Fumarate 		
pharm-a-spheres °	Shir Etsu	STROEVER SCHELLACK BREMEN	Sumitomo Seika		
Family-owned company previ- ously specializing in dragées, now offering a wide range of globuli & neutral starter cores.	Leading supplier of Cellulose derivatives.	Manufacturer of outstanding quality Shellac specialities, based in Northern Germany.	Japanese manufacturer of PEO.		
 Globuli Sacchari Sugar spheres 	 HPMC HPMC-AS HPMC-P L-HPC MC SmartEx[®] Plus 	 Shellac Aqueous Solution Shellac Flakes 	• PEO		
O Sunil Healthcare Limited	THERMO (INDIA) LTD. PHARMA COATING POLYMERS				
Major Indian manufacturer of empty hard capsules.	EXCiPACT certified producer of Acrylate based coating polymers, located in India.	www.ha	rke.com		
• Capsules - HPMC - Gelatine - Pullulan	 Methacrylic Acid Copolymers 				

Why HARKE



countless opportunities for a success



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

ful and future-oriented collaboration





HARKE Pharma GmbH Business Unit Pharma Xantener Straße 1 45479 Mülheim an der Ruhr Germany

- (0) +49 (0) 208 3069-0
- @ pharma@harke.com
- www.harke.com/pharma



0 6 X

in

HARKE GROUP

09 | 2024