





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

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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.



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Warsaw

 Headquarters • Subsidiaries

Halifax

Manchester

Dublin

Production/Storage

Bochum

Sales Offices

HARKE Pharma

Our Services

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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

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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

- 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
- Lactose Monohydrate
- Low-substituted HPC
- Macrogol
- Methylcellulose, MC
- Microcrystalline Cellulose, MCC
- Natural Calcium Carbonate
- Polyvinylpyrrolidone, PVP
- Sodium Chloride
- Sodium Stearyl Fumarate (SSF)
- Sugar Ester
- Talc

Premixes/Co-processed Excipients

- Functionalized Calcium Carbonate
- GRANFILLER-DTM
- HarkePlus Tab[®]
- Hisorad[™]
- 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
- 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

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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
- Sugar 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.

Lubricant/Glidant

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	COMMON NAME	Instant Release Coating	Modified Release Coating	Protective Coating	Taste Masking	Filler/Diluent	Dry Binder (DC+RC)	Binder Solutions (WG)	Disintegrant
Cellets®	MCC Spheres								
DRUGCOAT®	Acrylates	•••••	•	•	•				
Eka Pellets™	NaOH/KOH	•••••							
Excipress™ and Lactose	Lactose monohydrate	•••••				•	•		
 Excipure™	Lactose monohydrate	•••••							
galenIQ™	Isomalt	••••			•	•	•	•	
GOHSENOL™ EG	Polyvinylalcohol (PVA)	•••••		•	•			•	
GRANFILLER-D™	Co-processed excipient	•••••				•			•
HarkePlus® Tab	Premix	•••••				•	•		•
HiSORAD™	Co-processed excipient	•••••				•			•
НРМСР	HPMC Phthalate	•••••	•		•				
L-HPC	Low-substituted HPC	•••••					•	•	•
METOLOSE [®] SH/SR	Hypromellose (HPMC)	•••••							
METOLOSE [®] SM	Methylcellulose (MC)	•			•			•	
Omyapharm [®]	Functionalized Calcium Carbonate	•••••				•	•		
Omyapure®	Natural Calcium Carbonate	•••••				•			
Oxipurity [®] 4000 Series	PEG/Macrogol	•				•			
PEO-NF	Polyethylene Oxide (PEO)	•••••					•		
PHARMACOAT®	Hypromellose (HPMC)	•		•	•	•	•	•	
pharm-a-spheres®	Sugar Spheres	•••••							
Primecel [®] /Chemicel [®]	MCC	•••••				•	•		•
Primesolv®	Silificied MCC	•••••				•	•		
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					•			•
SSB [®] Pharma/AQUAGOLD	Shellac		•	•	•				
SURFHOPE® SE	Sugar Ester	•••••							
Talc	Talc	•	•	•	٠	٠			
TAP®	Tartaric Acid Pellets	•••••							
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Sodium Stearyl Fumarate (SSF)

HARKE Pharma

VEGHA

	SPECIALITIES					SOLUBILITY ENHANCEMENT			SEMI-SOLIDS & LIQUIDS					ENCAPSULATION					
Anti-Capping	Modified Release (DC+WG)	Drug Layering	Dry powder inhalation	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)
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HARKE Pharma

Product Categories



ACRYLATES	CE
DRUGCOAT® E	HPI
DRUGCOAT [®] FS	Нус
DRUGCOAT [®] L	Hyr
DRUGCOAT [®] NE	L I
DRUGCOAT® RI	
DRUGCOAT [®] RS	
DRUGCOAT® S	
Methacrylic Acid Copolymers	•••••
	Me
ACTIVES	ME
Ibuprofen DC 100	ME
Ibuprofen Pellets	PH/
ALKALI	Shi
Eka Pellets™	TYL
Potassium Hydroxide Pellets (KOH)	FU
Sodium Hydroxide Pellets (NaOH)	Soc
CALCIUM MINERALS	VEC
Functionalized Calcium Carbonate	ISC
Natural Calcium Carbonate	gal
Omyapharm®	
Omyapure®	LA
CANNABIDIOL	EXC
CBD Powder 2%	EXC
CBD Powder 6%	Lac
	MA
CAPSULES	OX
Gelatine	Pol
НРМС	101
Pullulan	PEI
SUNLOC	Cel
CELLULOSE	Glo
Chemicel®	lbu
Microcrystalline Cellulose	lbu
Primecel®	Sug
Primesolv [®] SMCC	TAF
Silicified Microcrystalline Cellulose	Tar
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CELLULOSE DERIVATIVES
HPMC P
Hydroxypropyl Methylcellulose
Hypromellose (HPMC)
Hypromellose Acetate Succinate
Hypromellose Phthalate
L-HPC
L-HPC Low-substituted HPC
Methylcellulose
METOLOSE [®] SH/SR
METOLOSE® SM
PRANIVIACUAI *
Shin-Etsu AQOAT [®] (HPMC AS)
TYLOPUR®
FUMARIC ACID ESTER
Sodium Stearyl Fumarate (SSF)
VEGHA
VEGNA
ISOMALT
galenIQ™
LACTOSE
EXCIDRESSIM
EXCIPURE™ EXCIPURE™
Lactose Monohydrate
-
MACROGOL
OXIPURITY [®] 4000 Series
Polyethylene Glycol (PEG)
PELLETS
Cellets [®] (MCC Spheres)
Globuli Sacchari
Ibuprofen DC 100
Ibuprofen Pellets
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Sugar Spheres
Sugar Spheres TAP® Pellets

rtaric Acid Pellets

POLYETHYLENE OXIDE
PEO-NF
POLYVINYL ALCOHOL
GOHSENOL™ EG
POLYVINYLPYRROLIDONE
Copovidone
Crospovidone
Crosslinked PVP
Povidone
PREMIXES/CO-PROCESSED EXCIPIENTS
GRANFILLER-D™
HarkePlus Tab®
Hisorad™
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
SUGAR ESTER

> Sucrose Laurate Sucrose Palmitate Sucrose Stearate

TALC Micro ACE Talc MS Rose Talc

Products A-Z

A Acrylates Aicello Clean Bottles and Containers Aicello FINE BAG Aicello HYPERCLEANTM PE-film Alkali AQUAGOLD (Aqueous Shellac Solution) B

Bleached Shellac

C Calcium Minerales Cannabidiol Capsules (Gelatine, HPMC, Pullulan) CBD Powder 2 % CBD Powder 6 % Cellets® (MCC Spheres) Cellulose Derivatives Chemicel® Co-processed Excipients Copovidone Crospovidone Crospovidone Crosslinked PVP

D

DRUGCOAT® E DRUGCOAT® FS DRUGCOAT® L DRUGCOAT® NE DRUGCOAT® RL DRUGCOAT® RS DRUGCOAT® S

Ε

Eka Pellets™ Excipress™ Excipure™

F

Functionalized Calcium Carbonate

G

galenIQ™ Globuli Sacchari GOHSENOL™ EG GRANFILLER-D™ Н HarkePlus Tab[®] (Tabletting Premix) Hisorad™ HPMC P Hydroxypropyl Methylcellulose Hypromellose (HPMC) Hypromellose Acetate Succinate Hypromellose Phthalate Ibuprofen DC 100 **Ibuprofen Pellets** Isomalt Κ KOH L Lactose Monohydrate 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 Ρ PEG **PEO-NF** pharma-a-spheres® **PHARMACOAT®** Polyethylene Glycol (PEG) Polyethylene Oxide (PEO)

Р
Polyvinyl Alcohol (PVA)
Polyvinylpyrrolidone (PVP)
Potassium Hydroxide Pellets
Povidone
Primary Packaging
Premixes
Primecel®
Primesolv [®] SMCC
PVP VA 64 PVPP XL/CL
R
Rose Talc
S
ς ΛΝΙΛΙ ® Ρ
Shellac
Shin-Etsu AQOAT® (HPMC AS)
Silicified Microcrystalline Cellulose SmartEx [®] Plus
Sodium Chloride
Sodium Hydrovido Dollots
Sodium Hydroxide Pellets
Sodium Stearyl Fumarate (SSF)
SSB® AQUAGOLD
SSB® Pharma
Sucrose Laurate
Sucrose Palmitate
Sucrose Stearate
Sugar Ester
Sugar Spheres
SUNLOC
Т
Talc
Talc MS
TAP [®] Pellets
Tartaria Acid Carac
Tartaric Acid Pollate
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.



	NIPPON TALC CO.,LTD.	ПНЧ	Nouryon Authorized distributor
Leading supplier of various food ingredients with a niche in pharma. Long established and major manufacturer of PVA.	The largest Japanese pro- ducer of superior quality Talc products.	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.
 PVASugar Ester	• Talc	 KoVidone[®] PolyKoVidone[®] OraRez[®] 	 Highly purified NaOH Highly purified KOH
	PEHEL SPECIALITIES	pharm-a-spheres®	Shin Etsu
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.	Family-owned company previ- ously specializing in dragées, now offering a wide range of globuli & neutral starter cores.	Leading supplier of Cellulose derivatives.
 Natural Calcium Carbonate Functionalized Calcium Carbonate 	 Sodium Stearyl Fumarate 	 Globuli Sacchari Sugar spheres 	 HPMC HPMC-AS HPMC-P L-HPC MC SmartEx[®] Plus
STROEVER SCHELLACK BREMEN	Sumitomo Seika	© Sunil Healthcare Limited	Vikram THERMO (INDIA) LTD. PHARMA COATING POLYMERS
Manufacturer of outstanding quality Shellac specialities, based in Northern Germany.	Japanese manufacturer of PEO.	Major Indian manufacturer of empty hard capsules.	EXCiPACT certified producer of Acrylate based coating polymers, located in India.
 Shellac Aqueous Solution Shellac Flakes 	• PEO	 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

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HARKE GROUP

10 2023



