



Pharma

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



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

HARKE GROUP Life Sciences Division

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

Facts & Figures

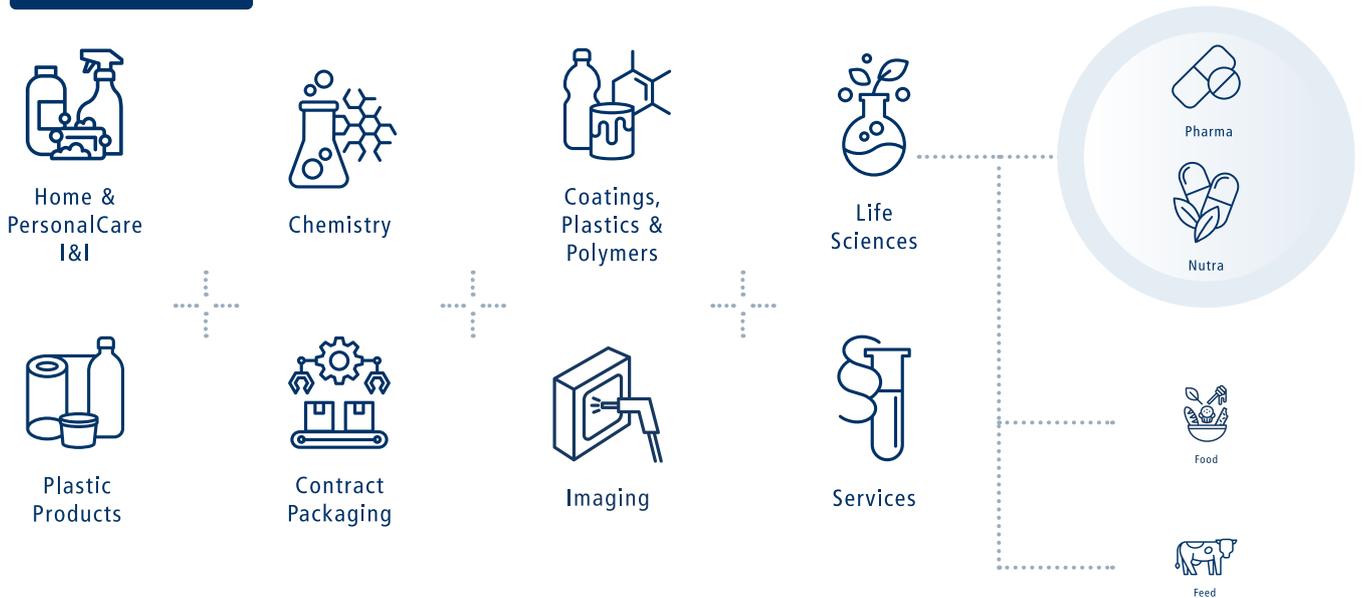
HARKE GROUP



HARKE BUSINESS UNIT PHARMA & NUTRA



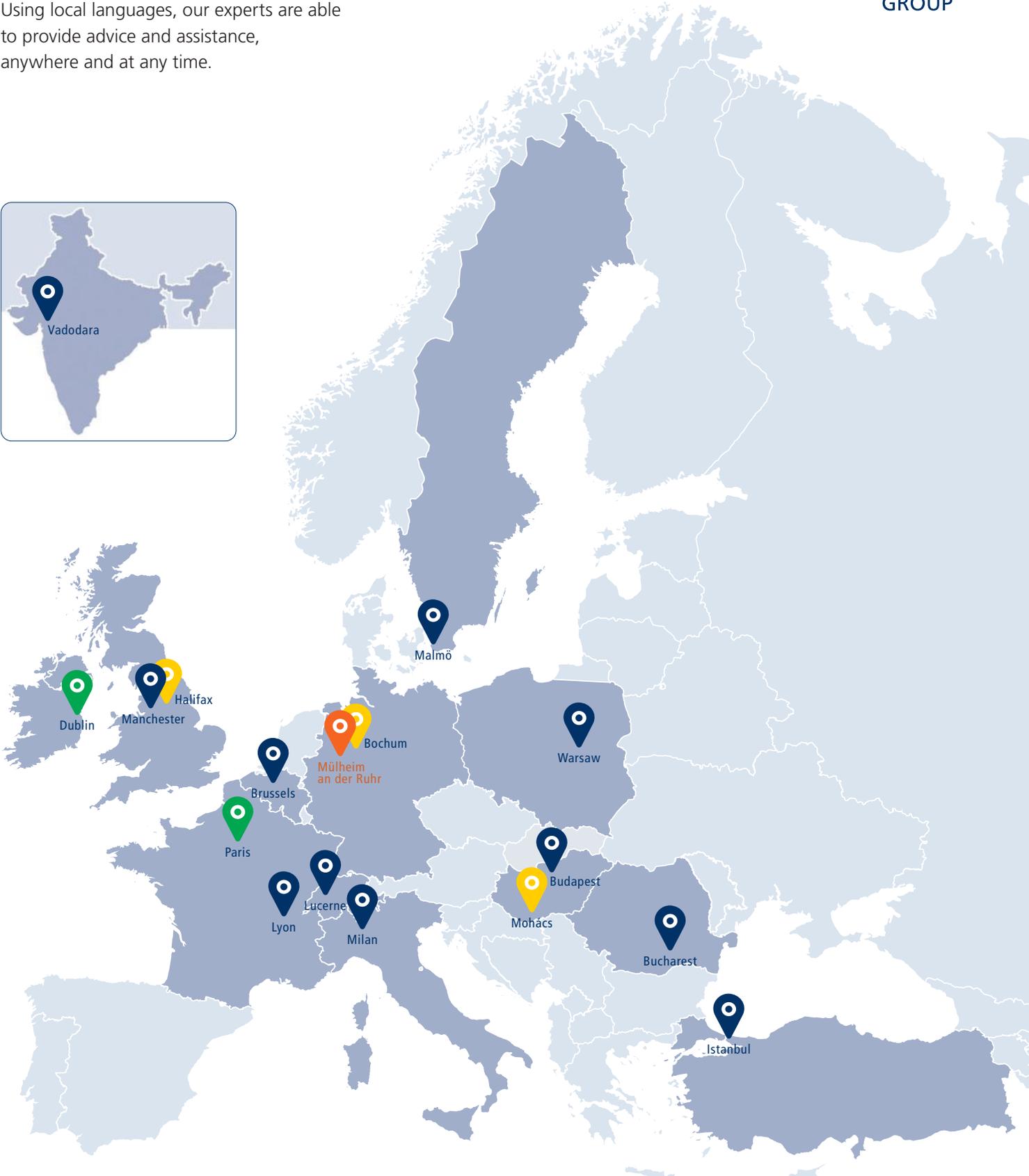
HARKE DIVISIONS



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.



- 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.

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



Glatt Tablet Coater GCC 150

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

Polymers

- Hypromellose (HPMC)
- Hypromellose Acetate Succinate (HPMC AS)
- Hypromellose Phthalate (HPMCP)
- Isomalt
- Methacrylates
- Methylcellulose (MC)
- Polyvinyl Alcohol (PVA)
- Shellac

Cores/Additives

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

YOUR BENEFITS:

Various high-quality products at competitive prices for your independent coating solutions.

MODIFIED RELEASE



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

Matrix Agents

- Hypromellose SR
- Methacrylates
- Polyethylene Oxide (PEO)
- Polyvinyl Alcohol (PVA)

Enteric Coating

- Hypromellose Acetate Succinate (HPMC AS)
- Hypromellose Phthalate (HPMCP)
- Methacrylates

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

- Croscarmellose Sodium (CCS)
- Crosspovidone (cl-PVP)
- Hypromellose (HPMC)
- Hypromellose SR
- Isomalt
- Low-substituted HPC (L-HPC)
- Methylcellulose, MC
- Microcrystalline Cellulose (MCC)
- Natural Calcium Carbonate (NCC)
- Povidone (PVP)
- Silicified MCC
- Sodium Chloride
- Sodium Starch Glycolate (Type A) (SSG)
- Sodium Stearyl Fumarate (SSF)
- Sucrose Ester
- Talc

Premixes / Co-processed Excipients

- Functionalized Calcium Carbonate (FCC)
- HarkePlus® Tab

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

- Copovidone (PVP VA 64)
- Hypromellose (HPMC)
- Hypromellose Acetate Succinate (HPMC AS)
- Hypromellose Phthalate (HPMCP)
- Methacrylates
- Polyvinyl Alcohol (PVA)
- Povidone (PVP)

YOUR BENEFITS:

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

- Copovidone (PVP VA 64)
- Functionalized Calcium Carbonate (FCC)
- Hypromellose (HPMC)
- Isomalt
- Methylcellulose (MC)
- Microcrystalline Cellulose (MCC)
- Polyvinyl Alcohol (PVA)
- Povidone (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 (L-HPC)
- Microcrystalline Cellulose (MCC)
- Polyvinyl Alcohol (PVA)
- Povidone (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 (PVP VA 64)
- Polyvinyl Alcohol (PVA)
- Povidone (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)
- Methylcellulose (MC)
- Polyvinyl Alcohol (PVA)
- Povidone (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)
- Povidone (PVP)

Emulsifier

- Hypromellose (HPMC)
- Methylcellulose (MC)
- Sucrose Ester

Sweetener

- Isomalt

Others

- 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

| TRADE NAME | COMMON NAME | COATINGS | | | | TABLETTING | | | | |
|--------------------------|--|-------------------------|--------------------------|--------------------|---------------|------------------|--------------------|-----------------------|--------------|---------------------|
| | | 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 | | | | | | | | | |
| Chemical®/Primecel® | Microcrystalline Cellulose (MCC) | | | | | ● | ● | | | |
| Dis-In-Cel | Croscarmellose Sodium (CCS) | | | | | | | | ● | |
| DisTab | Sodium Starch Glycolate (Type A), (SSG) | | | | | | | | ● | |
| DRUGCOAT® | Methacrylates | | ● | ● | ● | | | | | |
| Eka Pellets™ | NaOH/KOH | | | | | | | | | |
| galenIQ™ | Isomalt | ● | | | ● | ● | ● | ● | | |
| GOHSENOl™ EG | Polyvinylalcohol (PVA) | ● | | ● | ● | | | ● | | |
| HarkePlus® Sucrose Ester | Sucrose Ester | | | | | | | | | ● |
| HarkePlus® Tab | Premix | | | | | ● | ● | | ● | |
| HPMCP | Hypromellose Phthalate | | ● | | ● | | | | | |
| KoVidone® K | Povidone (PVP) | ● | | ● | | | | ● | | |
| KoVidone® VA 64 | Copovidone (PVP VA 64) | ● | | ● | | | ● | ● | | |
| L-HPC | Low-substituted HPC | | | | | | ● | ● | ● | |
| METOLOSE® SM | Methylcellulose (MC) | ● | | | ● | | | ● | | |
| METOLOSE®/TYLOPUR® SH/SR | Hypromellose (HPMC) | | | | | | | | | |
| Omyapharm® | Functionalized Calcium Carbonate (FCC) | | | | | ● | ● | | | ● |
| Omyapure® | Natural Calcium Carbonate (NCC) | | | | | ● | | | | |
| OraRez® | PVM/MA | | | | | | | | | |
| PEO-NF | Polyethylene Oxide (PEO) | | | | | | ● | | | |
| PHARMACOAT®/TYLOPUR® | Hypromellose (HPMC) | ● | | ● | ● | ● | ● | ● | | |
| pharm-a-spheres® | Sugar Spheres/Globuli Sacchari | | | | | | | | | |
| PolyKoVidone® | Crospovidone (cl-PVP) | | | | | | | | ● | |
| Primesolv® | Silicified MCC (SMCC) | | | | | ● | ● | | | |
| SANAL® P | Sodium Chloride (NaCl) | | | | | ● | | | | |
| Shin-Etsu AQOAT® | Hypromellose Acetate Succinate (HPMC AS) | | ● | | ● | | | | | |
| SSB® Pharma/AQUAGOLD | Shellac | | ● | ● | ● | | | | | |
| Talc | Talc | ● | ● | ● | ● | ● | | | | ● |
| TAP® | Tartaric Acid Cores | | | | | | | | | |
| VEGHA | Sodium Stearyl Fumarate (SSF) | | | | | | | | | ● |

Product Categories



ACTIVES

Ibuprofen DC 100

Ibuprofen Pellets

ALKALI

Eka Pellets™

Potassium Hydroxide Pellets (KOH)

Sodium Hydroxide Pellets (NaOH)

CALCIUM MINERALS

Functionalized Calcium Carbonate (FCC)

Natural Calcium Carbonate (NCC)

Omyapharm®

Omyapure®

CANNABIDIOL

CBD Powder 2%

CBD Powder 6%

CAPSULES

Gelatine

HPMC

Pullulan

SUNLOC

CELLULOSE

Chemical®

MCC LM

MCC LN

Microcrystalline Cellulose (MCC)

Primecel®

Primesolv®

Silicified Microcrystalline Cellulose (SMCC)

CELLULOSE DERIVATIVES

HPMCP

Hydroxypropyl Methylcellulose

Hypromellose (HPMC)

Hypromellose Acetate Succinate

Hypromellose Phthalate

L-HPC

Low-substituted HPC

Methylcellulose (MC)

METOLOSE® SH/SR

METOLOSE® SM

PHARMACOAT®

Shin-Etsu AQQAT® (HPMC AS)

TYLOPUR®

FUMARIC ACID ESTER

Sodium Stearyl Fumarate (SSF)

VEGHA

ISOMALT

galenIQ™

METHACRYLATES

DRUGCOAT® E

DRUGCOAT® FS

DRUGCOAT® L

DRUGCOAT® NE

DRUGCOAT® RL

DRUGCOAT® RS

DRUGCOAT® S

PELLETS

Cellets® (MCC Spheres)

Globuli Sacchari

Ibuprofen DC 100

Ibuprofen Pellets

MCC Starter Cores

Neutral MCC Pellets

pharm-a-spheres®

Sugar Spheres

TAP® Pellets

Tartaric Acid Pellets

PLANT EXTRACTS (API)

Aloes, Cape Tincture (Aloe Ferrox)

Arnica Tincture (Arnica Montana)

Calendula Tincture (Calendula Officinalis)

Hawthorn Tincture (Crataegus)

Horse Chestnut Semen Thick Extract
(Aesculus Hippocastanum)

Motherwort Tincture (Leonurus Cardiaca)

Valerian Root Tincture (Valeriana
Officinalis)**POLYETHYLENE OXIDE**

PEO-NF

POLYVINYL ALCOHOL

GOHSENL™ EG

POLYVINYLPIRROLIDONE

Copovidone

Crosppovidone

Crosslinked PVP

KoVidone® K

KoVidone® VA 64

OraRez®

PolyKoVidone®

Povidone

PVM MA

PVP K

PVP VA 64

PVPP XL/CL

PREMIXES/CO-PROCESSED EXCIPIENTS

HarkePlus® Tab

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

SUPER DISINTEGRANT

Croscarmellose Sodium

Crosslinked CMC Sodium

Sodium Starch Glycolate (Type A) (SSG)

TALC

Talc Micro ACE

Talc MS

Rose Talc

Products A-Z



| | | |
|--------------------------------------|------------------------------------|--|
| A | H | P |
| Aesculus Hippocastanum | HarkePlus® Sucrose Ester | Polyethylene Oxide (PEO) |
| Aicello Clean Bottles and Containers | HarkePlus® Tab (Tabletting Premix) | Polyvinyl Alcohol (PVA) |
| Aicello FINE BAG | Hawthorn Tincture | PolyKoVidone® |
| Aicello HYPERCLEAN™ PE-film | Horse Chestnut Semen Thick Extract | Povidone (PVP) |
| Alkali Salts | HPMCP | Potassium Hydroxide Pellets |
| Aloe Ferrox | Hydroxypropyl Methylcellulose | Povidone |
| Aloes, Cape Tincture | Hypromellose (HPMC) | Primary Packaging |
| AQUAGOLD (Aqueous Shellac Solution) | Hypromellose Acetate Succinate | Premixes |
| Arnica Montana | Hypromellose Phthalate | Primecel® |
| Arnica Tincture | | Primesolv® SMCC |
| B | I | PVM/MA |
| Bleached Shellac | Ibuprofen DC 100 | PVP K |
| | Ibuprofen Pellets | PVP VA 64 |
| | Isomalt | PVPP XL/CL |
| C | K | R |
| Calcium Minerale | KOH | Rose Talc |
| Calendula Officinalis | KoVidone® K | |
| Calendula Tincture | KoVidone® VA 64 | S |
| Cannabidiol | | SANAL® P |
| Capsules (Gelatine, HPMC, Pullulan) | L | Shellac |
| CBD Powder 2% | Leonurus Cardiaca | Shin-Etsu AQOAT® (HPMC AS) |
| CBD Powder 6% | L-HPC | Silicified Microcrystalline Cellulose (SMCC) |
| Cellets® (MCC Spheres) | Low-substituted HPC | Sodium Chloride |
| Cellulose Derivatives | | Sodium Hydroxide Pellets |
| Chemical® | M | Sodium Starch Glycolate (Type A) |
| Copovidone | MCC LM | Sodium Stearyl Fumarate (SSF) |
| Co-processed Excipients | MCC LN | SSB® AQUAGOLD |
| Crataegus | MCC Starter Cores | SSB® Pharma |
| Crospovidone | Methacrylates | Sucrose Laurate |
| Croscarmellose Sodium | Methylcellulose (MC) | Sucrose Palmitate |
| Crosslinked CMC Sodium | METULOSE® SH/SR | Sucrose Stearate |
| Crosslinked PVP | METULOSE® SM | Sucrose Ester |
| D | Microcrystalline Cellulose (MCC) | Sugar Spheres |
| DRUGCOAT® E | Motherwort Tincture | SUNLOC |
| DRUGCOAT® FS | N | T |
| DRUGCOAT® L | NaOH | Talc |
| DRUGCOAT® NE | Natural Calcium Carbonate | Talc Micro ACE |
| DRUGCOAT® RL | Neutral MCC Pellets | Talc MS |
| DRUGCOAT® RS | | TAP® Pellets |
| DRUGCOAT® S | O | Tartaric Acid Cores |
| E | Omyapharm® | Tartaric Acid Pellets |
| Eka Pellets™ | Omyapure® | TYLOPUR® |
| F | OraRez® | V |
| Functionalized Calcium Carbonate | Oxipurty® 4000 Series | Valerian Root Tincture |
| G | P | Valeriana Officinalis |
| galenIQ™ | PEO-NF | VEGHA |
| Globuli Sacchari | pharm-a-spheres® | |
| GOHSENL™ EG | PHARMACOAT® | |

Our Partners & Products

One Partner. One Responsibility.

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



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

- Isomalt



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

- MCC
- MCC LM
- MCC LN
- SMCC



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

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



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

- Neutral MCC Pellets
- Ibuprofen Pellets 100%
- Tartaric Acid Pellets
- CBD Powder 2% and 6%



L.E.V. is a plant extracts and special ingredients manufacturer with 40 years experience.

- Liquid Botanical Extracts
- Tinctures



Since 1918 producer of pharmaceutical salt in Mariager Fjord (Denmark).

- SANAL® P, Pharmaceutical NaCl



Leading supplier of various food ingredients with a niche in pharma. Long established and major manufacturer of PVA.

- PVA



The largest Japanese producer of superior quality Talc products.

- Talc



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

- Copovidone
- Crosspovidone
- Povidone
- PVM/MA



Since 1905 producer in Bohus (Sweden) for purest alkali pellets of NaOH/KOH.

- Highly purified NaOH
- Highly purified KOH



Leading global producer of advanced mineral products, offering a range of next generation excipients providing highly bioavailable sources of calcium.

- Natural Calcium Carbonate
- Functionalized Calcium Carbonate

PEHEL SPECIALITIES

Family-owned company, emerging Indian excipient house and a leading manufacturer of the lubricant, sodium stearyl fumarate.

- Croscarmellose Sodium
- Sodium Starch Glycolate (Type A)
- Sodium Stearyl Fumarate

pharm-a-spheres®

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

- Globuli Sacchari
- Sugar spheres



Leading supplier of Cellulose derivatives.

- HPMC
- HPMC AS
- HPMCP
- L-HPC
- MC



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

- Shellac Aqueous Solution
- Shellac Flakes

Sumitomo Seika

Japanese manufacturer of PEO.

- PEO



Sunil Healthcare Limited

Major Indian manufacturer of empty hard capsules.

- Capsules
 - HPMC
 - Gelatine
 - Pullulan



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

- Methacrylates

www.harke.com

Why HARKE



Countless opportunities for a successful and future-oriented collaboration

one group of **16** companies | **17** offices worldwide | **7** divisions
25 business units | **15** diverse service functions | **4** laboratories | **3** production sites
 over **230** employees | working with **35** 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





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HARKE GROUP

