



Innovation
through
formulation

Azelis India

Pharma brochure



2023



Innovation
through
formulation

Azelis India

Pharmaceuticals & Healthcare

Your partner for innovative solutions.

With more than 70 years in the Indian pharmaceutical industry, Azelis is a market-leader in supplying manufacturers with high quality specialty ingredients for Pharmaceuticals & Healthcare.

Constant development, changing regulation and evolving healthcare demands. All are challenges our partners in the pharmaceutical market face day in day out. From specialty ingredients and API, to complex formulations and new technologies, we can support you at each step of your product development, from product concept to development and manufacture with excellent regulatory expertise. We can also support you in the sourcing of your packagings.

Azelis' sales experts and dedicated lab experts can help you achieve the performance for standard and advanced dosage forms in full compliance with the local and global regulation. We can introduce to you tailored-made innovative solution to fit with your product properties, process, quality, format, and cost to maximize your value.






















Azelis' Lab Experts in our new Pharmaceutical & Healthcare Regional Center of Excellence can support you in solving technical and process challenges, customize a formulation, or create a new one.

We're here to help with formulation experience you can rely on.

Together, let's create innovative solutions for your needs!

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Pharm
Lab



USA

Dober is a leading supplier for science based cleaning solutions.

Chematic® - formulated detergents - Jointly developed by Evonik and Dober to support fast, safe, easy, and cost effective cleaning post Eudragit® based formulation productions.

Scientifically developed based on chemistry of Eudragit® polymers.

Grades -

Chematic® LS Plus, RL/RS, NE/NM, FL - Developed different cleaning grades suited per Eudragit® grade.

Detergents for Eudragit® polymers:

Application	Enteric	Taste Masking & Moisture Protection	SR Cationic	SR Neutral
EUDRAGIT® Type	L/S/FS/FL30D -55	E/ReadyMix®	RL/RS	NE/NM
Chematic® cleaning recommendations*	Chematic® L/S Plus Cleaner, FL Cleaner T=20-60 Deg C C=4-8% v/v	Chematic® RL/RS Cleaner T=25-80 Deg C C >_ 2-6% v/v	Chematic® RL/RS Cleaner T=25-80 Deg C C >_ 4-8% v/v	Chematic® NE/NM Cleaner T=40-60 Deg C C =3-8% v/v



USA

Chematic® targeted cleaning for Eudragit® polymers:

- Removes haze & pigments
- Saves downtime & costs
- Easy to use, water based cleaners
- Fast cleaning, Increase asset utilization
- Regulatory compliant
- Suited for manual & CIP/WIP cleaning
- Manufactured in cGMP plant

Advantages over conventional cleaning agents:

- Non-corrosive and compatible with all equipment MOC like SS-304, SS-316, silicone, plastic etc.
- Safe for handling, can be safely used for manual cleaning
- ETP can be avoided with optimized cleaning process
- Also cleans insoluble residues, talc, Tio₂ & pigments



USA

Founded in 1897, Dow is a materials science leader committed to delivering innovative and sustainable solutions for customers in packaging, infrastructure and consumer care.

Dow is a leading choice for pharmaceutical, personal care and food products.

CARBOWAX™ SENTRY™ PEGs and MPEG

Standard polyethylene glycol (PEG) and methoxypolyethylene glycol (MPEG) are highly versatile excipients and active pharmaceutical ingredients (API) produced to meet the exacting requirements of the pharmaceutical industry.

CARBOWAX™ SENTRY™ PEGs and MPEGs do more than meet requirements – they establish industry standards for innovation, performance, flexibility and compliance.

Applications:

- Used as a base in ointments and suppositories
- Binders and coatings in tableting
- Drug solubiliser/carriers in liquid preparations and gelatin capsules
- Esterification

Certifications:

- Manufacturing, handling, and storage are conducted with cGMP
- In accordance with the most current IPEC guide



USA

CARBOWAX™ SENTRY™ Polyethylene Glycol (PEG)

Product	CTFA (a)/INCI (b)nomenclature	Packaging	Available Form	Applications
300 (NF / Ph.Eur.)	PEG-6	Bulk, drum, IBC	Liquid	<ul style="list-style-type: none"> • Liquid oral dose • Solid oral dose • Softgels
400 (NF / Ph.Eur.)	PEG-8	Bulk, drum, IBC	Liquid	<ul style="list-style-type: none"> • Liquid oral dose • Ointment/lotion • Solid oral dose • Softgels
540 blend (PEG 300/PEG 1450)	PEG-6 (and) PEG-32	Bulk, drum	Fused solid	<ul style="list-style-type: none"> • Solid oral dose
600 (NF / Ph.Eur.)	PEG-12	Bulk, drum, IBC	Liquid	<ul style="list-style-type: none"> • Liquid oral dose • Solid oral dose • Softgels
1000 (NF)	PEG-20	Bulk, drum	Fused solid	<ul style="list-style-type: none"> • Solid oral dose
1450 (NF)	PEG-32	Bulk (molten), bag, drum	Molten, flake	<ul style="list-style-type: none"> • Ointment/lotion
3350 (USP/ Ph.Eur.)	PEG-75	Bag, FIBC	Granular, powder, flake	<ul style="list-style-type: none"> • Liquid oral dose • Solid oral dose • Softgels



USA

CARBOWAX™ SENTRY™ Polyethylene Glycol (PEG)

Product	CTFA (a)/INCI (b)nomenclature	Packaging	Available Form	Applications
4000 (NF/Ph.Eur.)	PEG-90	Bag, FIBC	Molten, powder, flake	<ul style="list-style-type: none"> Ointment/lotion Softgels
4600 (NF)	PEG-100	Bag	Flake	<ul style="list-style-type: none"> Ointment/lotion
8000 (NF / Ph.Eur.)	PEG-180	Bag, FIBC	Granular, powder, flake	<ul style="list-style-type: none"> Solid oral dose

CARBOWAX™ SENTRY™ Methoxypolyethylene Glycol (MPEG)

Product	CTFA (a)/INCI (b)nomenclature	Packaging	Available Form	Applications
350 (NF)	PEG-6 Methyl Ether	Bulk, drum	Liquid	<ul style="list-style-type: none"> Ointment/lotion
550 (NF)	Methoxy PEG-10	Bulk, drum	Liquid	<ul style="list-style-type: none"> Ointment/lotion



DSM has been a global leader in vitamin development and manufacturing for more than 70 years. Being the first & only company in the world that can provide access to US and Japanese Drug Master File (DMFs) & the COS for all 13 essential vitamins, DSM has the most extensive portfolio of fat-soluble and water-soluble vitamins in the industry.

Vitamins are essential organic nutrients that aid metabolism, growth and physical well-being. Like all DSM solutions, their vitamins are of the highest quality with a high level of regulatory support, impurities management, both globally and market-specifically.

With unique innovation & expertise, DSM can provide potential solutions to minimize the risk of nitrosamine formation in your formulations such as blocking nitrosamine formation with commonly used antioxidants as an excipient- ascorbic acid (Vitamin C) and alpha-tocopherol (Vitamin E).

DSM nutritional products:

- Patent-protected vitamins
- Pharmaceutical grade quality
- GMP certified
- Sustainable, secure supply



Vitamin A

Product Code	Products
04 2187 1	Dry Vitamin A Palmitate, Type 250 CWS/F (tocopherol)
50 1754 5	Retinyl Palmitate 250 CWS/F PH
04 2401 3	Vitamin A Palmitate 1.7 MIU/g (BHA/BHT)
04 2400 5	Vitamin A Palmitate 1.7 MIU/g
50 1626 2	Retinyl Palmitate 1.7 MIU/g Ph
50 1227 9	Dry Vitamin A Acetate 500 B

Vitamin E

Product Code	Products
50 1657 7	Dry Vitamin E 50% CWS/S Ph
04 2008 5	DL-alpha-Tocopheryl Acetate
50 1626 0	dl-a-Tocopheryl Acetate Ph
04 1027 6	DL-alpha-Tocopherol
50 1674 1	all-rac-alpha-Tocopherol Ph



Vitamin D

Product Code	Products
50 1621 2	Dry Vitamin D3 100 SD/S Ph
50 1647 3	Dry Vitamin D3 100 CWS Ph
50 1752 4	Vitamin D3 1.0 MIU/g* Ph
50 1157 4	Vitamin D3 1.0 MIU/g
50 1626 3	Vitamin D3 Crystalline Ph

Vitamin K1

Product Code	Products
04 3492 2	Dry Vitamin K1 5% SD
04 3501 5	Vitamin K1
50 1322 4	Vitamin K1 API (US DMF only)



Vitamin B1

Product Code	Products
04 2947 3	ROCOAT Thiamine Mononitrate 33 1/3%
50 1625 7	Thiamine Hydrochloride Ph
04 1894 3	Thiamine Mononitrate

Vitamin B2

Product Code	Products
TBD	Riboflavin Universal PH
50 1626 1	Riboflavin 5'-Phosphate Ph
04 7040 6	Riboflavin Universal

Vitamin B3

Product Code	Products
04 8784 8	Niacinamide
50 1629 1	Niacinamide Ph (US DMF only)



Vitamin B5

Product Code	Products
TBD	Calcium D-Pantothenate Ph
04 1267 8	Calcium D-Pantothenate
50 1625 8	D-Panthenol Ph

Vitamin B6

Product Code	Products
04 2945 7	ROCOAT Pyridoxine Hydrochloride 33 1/3%
50 1626 5	Pyridoxine Hydrochloride Ph (origin: China)
50 1646 0	Pyridoxine Hydrochloride Ph (origin: Germany)

Vitamin B7

Product Code	Products
50 1165 5	D-Biotin
50 1629 1	D-Biotin Ph



Vitamin B9

Product Code	Products
50 1625 9	Folic Acid Ph

Vitamin B12

Product Code	Products
50 1251 1	Vitamin B12 1% SD
04 2909 0	Vitamin B12 0.1% WS
04 2915 5	Vitamin B12 Crystalline
50 1630 0	Vitamin B12 Crystalline Ph (US DMF)

Beta-Carotene

Product Code	Products
50 1434 4	β -Carotene Crystalline Ph
50 1438 7	β -Carotene 30% FS Ph
50 1435 2	BetaTab® 20% S Ph



Vitamin C

Product Code	Products
04 0809 3	Ascorbic Acid Fine Granular
04 2246 0	Ascorbic Acid Fine Powder
50 1645 0	Ascorbic Acid Fine Powder Ph
50 1625 5	Ascorbic Acid Ph
TBD	Calcium Ascorbate Ph
04 1944 3	Calcium Ascorbate
50 1625 6	Sodium Ascorbate Ph
50 0976 6	Ascorbic Acid Ultra Fine Powder
04 2511 7	Coated Ascorbic Acid, Type EC
50 0774 7	Ascorbic Acid 95% Granulation
TBD	Ascorbic Acid 95% Granulation Ph



Germany

Evonik is a leading provider of functional pharmaceutical excipients and advanced formulation solutions under the brand name Eudragit®.

Eudragit® is a one-stop solution to all drug delivery needs. The main functionalities are delayed release, extended release, moisture protection, taste masking and solubility enhancement.

Product range:

Enteric Release Polymers & Additives

Grade	Available Form	Applications	Dissolution Property
EUDRAGIT® L 100-55	Powder	<ul style="list-style-type: none">• For drug targeting in duodenum	
EUDRAGIT® L 30 D-55	Aqueous dispersion	<ul style="list-style-type: none">• Solubility enhancement	
EUDRAGIT® FL 30 D-55	Aqueous dispersion of combination polymer of L & NM grade	<ul style="list-style-type: none">• Flexible coatings without addition of plasticizer• Suitable for MUPS tablets• Variety of release profiles can be achieved	Dissolution above pH 5.5



Germany

Enteric Release Polymers & Additives

Grade	Available form	Applications	Dissolution property
PlasACRYL® HTP 20	Thixotropic liquid easy-to-use glidant and plasticizer premix, specifically designed for EUDRAGIT® L 30 D-55 formulations	<ul style="list-style-type: none"> High performance coating additive Optimize and achieve coating efficiency, reduces processing times Significant cost saving with no loss in quality 	NA
EUDRAGIT® L 100	Powder	<ul style="list-style-type: none"> For drug targeting in jejunum 	Dissolution above pH 6.0
EUDRAGIT® L 12.5	Organic solution		
EUDRAGIT® S 100	Powder	<ul style="list-style-type: none"> For drug targeting in ileum/colon Solubility enhancement 	Dissolution above pH 7.0
EUDRAGIT® S 12.5	Organic solution		
EUDRAGIT® FS 100	Powder	<ul style="list-style-type: none"> For drug targeting in ileum/colon Solubility enhancement 	Dissolution above pH 7.0
EUDRAGIT® FS 30 D	Aqueous dispersion		
PlasACRYL® T20	Thixotropic liquid easy-to-use glidant and plasticizer premix, specifically designed for EUDRAGIT® FS 30 D formulations	<ul style="list-style-type: none"> Excellent anti-tacking agent, works at very low level Excellent in preventing gun choking during longer processing time 	NA



Germany

Sustained Release Polymers

Grade	Available Form	Applications	Dissolution Property
EUDRAGIT RL 100	Granules	<ul style="list-style-type: none"> Developing sustained release dosage form by both matrix and reservoir technique 	<ul style="list-style-type: none"> Insoluble High permeability pH-independent swelling
EUDRAGIT® RL PO	Powder		
EUDRAGIT® RL 30 D	Aqueous dispersion		
EUDRAGIT® RL 12.5	Organic solution		
EUDRAGIT® RS 100	Granules		<ul style="list-style-type: none"> Insoluble Low permeability pH-independent swelling
EUDRAGIT® RS PO	Powder		
EUDRAGIT® RS 30 D	Aqueous dispersion		
EUDRAGIT® RS 12.5	Organic solution		
EUDRAGIT® NM 30 D	Aqueous dispersion	<ul style="list-style-type: none"> Developing sustained release dosage form by both matrix and reservoir technique Possible to process at very low temperature – suitable for thermolabile compounds Neutral polymer 	<ul style="list-style-type: none"> Insoluble Low permeability pH-independent swelling No plasticizer required Highly flexible



Germany

Immediate Release Polymers

Grade	Available Form	Applications	Dissolution Property
EUDRAGIT E 100	Granules		
EUDRAGIT® E 12.5	Organic solution		<ul style="list-style-type: none"> • Soluble below pH 5.0 • Permeable above pH 5.0
EUDRAGIT® E PO	Powder	<ul style="list-style-type: none"> • Immediate release coating • Taste masking • Odour masking • Better swallowability • Superior optical appearance • Solubility enhancement 	
EUDRAGIT® E PO Readymix	Ready-to-use powder blend		
EUDRAGIT® IR Readymix White	Ready-to-use powder blend		<ul style="list-style-type: none"> • Soluble below pH 5.0 • Slowly dissolving above pH 5.0



Europe

- High quality herbal extracts made with patented technologies
- Used in dietary supplements, functional food & beverages, pharmaceutical & cosmetics

Extracts	Description	Applications
Echinacea®	Dry pressed juice from echinacea purpurea	<ul style="list-style-type: none"> • Immune health • Cough, cold & flu treatment
Fenulife®	Deodorized fenugreek galactomannan	<ul style="list-style-type: none"> • Blood sugar control • Weight control, gut
Linumlife®	Flax ingredient, rich in lignans	<ul style="list-style-type: none"> • Men's health • Positive effect on hair loss
Neuravena®	Wild green oat powder extract	<ul style="list-style-type: none"> • Cognitive health • Improves overall mental health
Pumpkin®	Pumpkin seed extract	<ul style="list-style-type: none"> • Healthy bladder function • Helps maintain healthy prostate
Soylife®	Soy germ ingredient, rich in isoflavones	<ul style="list-style-type: none"> • Bone & joint health • Women's health

Additional extracts:

BroccoRaphanin, chamomile, cranberry, devil's claw, green tea, ginseng, horse tail, ivy leaf, lemon bar, pelargonium, portusana, red vine leaf, saw palmetto, schisandra chinensis.



USA

Extracts	Description	Application
Acacia Gum	Spray dried white powder NF/FCC	Used as a binder, emulsifying agent, suspending or viscosity increasing agent in pharma and cosmetics
Arabic Gum		
Karaya Gum	Off white fine powder	Used as a thickener, binder and stabilizer

- ISO 9001:2008
- Manufactured under GMP
- Certified HACCP based food safety plans



Germany

Gelatin:

Multifunctional natural product, TSE/BSE free, EDQM certified

Applications:

Hard & soft gelatin capsules, tablets, vitamin coatings, blood plasma expander, injectable, wound healing devices, hemostatic sponges, vaccines, gummies.

GELITA® Gelatin Products	Applications
80 to 300 Bloom Bovine Bone/Hide/Pigskin Gelatin	<ul style="list-style-type: none"> • Tablets, capsules
RXL and RXL Advance Gelatin - Special Patented Process	<ul style="list-style-type: none"> • Soft gelatin capsules • Helps to resolve crosslinking & shelf life issues
GELITA® RXL R2 Gelatin	<ul style="list-style-type: none"> • Immediate release of active in softgel
GELITA® EC Gelatin Product	<ul style="list-style-type: none"> • Soft gelatin capsules • Enteric fill release, enabling enteric capsules in one production step.
GELITA® Low Endotoxin Gelatin	<ul style="list-style-type: none"> • Plasma expander, injectable
VACCIPRO® Gelatin	<ul style="list-style-type: none"> • Vaccination grade • For vaccine stabilizer
MEDELLAPRO® Gelatin	<ul style="list-style-type: none"> • Used in wound healing devices, bone pastes and surgical adhesives, injectable (very low endotoxin level less than 600EU/g)



Japan

SAMIC J-BASE (Hydrocarbon Gel)

A high performance Ointment manufacturing base.

Make: Sanwa Kasei Kogyo Co. Ltd, Japan

Hydrocarbon Gel consisting of paraffin as a main ingredient and polyethylene as gelling agents. Gelled liquid paraffin using 5-10% of synthetic chemical resin.

Advantages of Hydrocarbon Gel vs. white petroleum jelly

- Less change in consistency (hardness) at varying temperatures. While white petroleum jelly melts at 40C, Hydrocarbon Gel maintains stable shape. It shows little change in consistency at temperature from -15 ° C to +70 ° C and is liquefied at 100 ° C.
- Being made of liquid paraffin, Hydrocarbon Gel repels water and is applicable in oral medicine.
- It can be used as an ophthalmic ointment base causing lesser degree of irritation.
- It can be used as a dental stomatitis ointment base for its excellent hydrophobic property.
- Causing lesser irritation on the inflammation affected parts for its no use of emulsifier, good elongation property.
- Excellent long term stability.

Application:

- Used for ointments for inflammations, stomatitis, hemorrhoids and so on.
- As an alternative to petroleum jelly, this product also helps to overcome the weakness of petroleum jelly.
- General external medicine, dental external medicine and oral medicine as pharmaceutical additives.
- Used widely globally including in USA, as ethical pharmaceuticals and OTC drugs.



USA

- Mining and manufacturing on 4 continents
- Micronization process, maintains highest available aspect ratio of talc particles
- High degree of brightness & additional grades available on request
- Certification: ISO 9001:2015, ISO 14001:2015, OHSAS 18001:2007, China registration
- Used as carrier, glidant, lubricant in pharmaceuticals
- Used as matting agent, opacifier in cosmetics

Talc Grade	Description	Compliance
Talc 140	Median diameter D50 : 3.5 µm Thru 325 mesh (44 µm) sieve : 99.9%	USP-EP
Talc LoMicron5	Median diameter D50 : 0.65 µm Top Cut D98 : 4.5 µm	
Talc 114	Median diameter D50 : 5.5 µm Thru 325 mesh (44 µm) sieve : 99.9%	USP-EP-JP
Talc 1656	Median diameter D50 : 3.5 µm Thru 325 mesh (44 µm) sieve : 99.9%	
Talc 3355 Dense	Median diameter D50 : 12.00 µm Thru 200 mesh (74 µm) sieve : 95%	USP-EP-JP
Talc 3355	Median diameter D50 : 8.00 µm Thru 200 mesh (74 µm) sieve : 99%	
Talc 5259	Median diameter D50 : 8.0 µm Thru 200 mesh (74 µm) sieve : 99%	USP-EP-JP-FCC



Japan

TASTE SENSING SYSTEM TS-5000Z

Make: Insent - Intelligent Sensor Technology Inc., Japan

TS-5000Z employs the same mechanism as that of the human tongue, converts the taste of various substances such as drugs, food & beverages into numerical data.

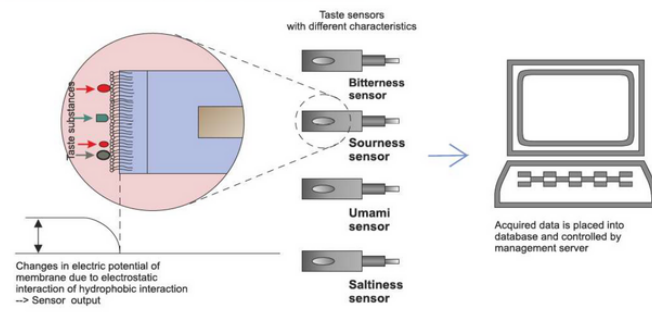
It's unique after-taste measurement technology, even express richness and sharpness.

TS-5000Z is a powerful tool for use in a variety of fields such as quality control, product development, marketing, and sales, where objective evaluation of taste required.

Features:

- Use of multi-channel type lipid membrane sensors imitating living organisms.
- Tasteless reference solution used as a substitute to human saliva.
- Quantification of taste via original algorithms.
- Measurement operations done via touch panel. Wizard format makes operation easy, even by novices.
- Global management of measurement data in database.

Reaction principle of taste sensors





OLEOCHEMICALS
TECHNICAL APPLICATIONS

Germany

Lipid-based excipients and active pharmaceutical Ingredients.

IOI Oleo is the leading European supplier of oleochemical specialties.

With two production sites in Witten and Wittengerge, IOI Oleo GmbH produces active ingredients and excipients for the pharmaceutical industry.

The Witten plant under EU GMP guidelines, is regularly monitored by the German Health Authority. Also follow other regulations and standards: ISO 9001, ISO 45001, EMAS, RSPO SCCS, EU GMP, US FDA, HACCP, Halal / Kosher, Cosmos / Ecocert.

Decades of experience and expertise of specialties, our brands are considered all over the globe as the benchmark in parenteral nutrition as well as topical, oral, rectal applications and animal health.

- DYNASAN® - Monoacid triglycerides for various applications
- IMWITOR® - Functionalized lipids for drug delivery systems
- MIGLYOL® - MCT oil and related C8-C10 fatty esters
- SOFTIGEN® - Liquid solubilizer for lipophilic substances
- SOFTISAN® - Specialties for topical and oral application forms
- WITEPSOL® - Hard fats for suppositories and ovules



OLEOCHEMICALS
TECHNICAL APPLICATIONS

Germany

Products	Description	Applications
DYNASAN 118 Glyceryl Tristearate	Triglyceride ester of the selected saturated single Fatty Acid C18	<ul style="list-style-type: none"> • Effective lubricant • In suppositories, as crystallisation accelerators to improve congealing processes • A high melting point lipid for use in sustained /modified release in oral dosage matrices • Hot melt extrusion/coatings
IMWITOR 491/742/900/948/960/988 Glycerol Monostearate	Ester of chiefly Palmitic and Stearic Acid and Glycerol	<ul style="list-style-type: none"> • Co-emulsifier, lubricant, plasticizer, dispersing adjuvant, embedding agent, binder or consistency regulator
MIGLYOL 810/812/840 Medium-Chain Triglycerides	Triglyceride ester of saturated Caprylic and Capric Fatty Acids and Glycerol	<ul style="list-style-type: none"> • Emulsifying agent, suspending agent, oily base for emulsion, drug carrier & penetration enhancer
SOFTIGEN 767 Macrogol 6 Glycerol Caprylocaprate	Ethoxylation product of medium chain partial Glycerides with Glycerol	<ul style="list-style-type: none"> • Refatting, solubilizing and wetting agent
SOFTISAN 378 Hard Fat	Specialty blend of Triglycerides based on saturated C8 - C18 Fatty Acids and Glycerol	<ul style="list-style-type: none"> • Fat base for ointments, lotions & creams • Carrier of active ingredients in hard and soft gelatine capsules
WITEPSOL H/ S/ W Hard Fat	Hard fats comprise of Fatty Acids and Glycerol	<ul style="list-style-type: none"> • Suppository & ovule base



Germany

Magnesium, calcium & additional mineral compounds for pharma/food/cosmetics.
Offer several grades concerning bulk density, particle structure & origin.

MagGran®

Granulated magnesium and calcium compounds. Granular structure enabling dust free production. Optimized compressibility, optimized production flow & increase processing speed.

All products as per PhEur, USP NF.

Certifications: ISO 9001, HACCP

MagGran® Products	Description/Advantages
Calcium Carbonate granulated/ light precipitated	White pure granulate/ white powder
Magnesium Carbonate heavy/ light	White granulate
Magnesium Oxide light/ heavy	Free-flowing, white granulate
Calcium Carbonate coated with Calcium Stearate	White pure granulate
Calcium Carbonate + 5% Maltodextrin	White to off-white granulated powder
Calcium Carbonate + 5% Gum Acacia	White pure granulate



India

MEB Pharma - India (formerly NM Pharma) was established in 2015, with its plant in Akola District (near Nagpur)

Products

Sphiro™ SS, Sugar Spheres (Non Pareil Seeds)

Sphiro™ SG, Sugar Globules for Allopathic Formulations

Sphiro™ T, Tartaric Acid Pellets

Highlights/Advantages:

- MEB have installed Camsizer IP4 from Retsch Technologies/Germany, to analyse/ control: particle size distribution, sphericity, aspect ratio (Breadth/Length) of starter pellets.
- Pharma dedicated plant, WHO-GMP approved
- USDMF No. 033289 allotted by USFDA for Sugar Spheres
- Low friability and excellent crushing strength, hence can withstand the mechanical stress for fluid bed processor/ Rotoprocessor.
- Available particle size ranging from 150 µm to 2000 µm
- Narrow range particle size distribution, helps to meet quality demand.
- Uniform surface area on every pellet, resulting in uniform drug loading is assured.



Netherlands

- Compliance with USP/NF, Ph.EUR JP and ChP
- Certifications: Kosher, Halal, EXCiPACT, RSPO, ISO 9001:2015, ISO 14001:2015, FSSC 22000, GMP+, COSMOS
- Plant based in Venlo, the Netherlands
- RSPO certified products (roundtable on sustainable palm oil)

LIGAMED®

Dedicated brand for high quality pharma products, produced using special precipitated manufacturing process & from vegetable based renewable sources. Free from impurities. LIGAMED® grades are produced in accordance with IPEC PQG GMP conditions.

Applications: Tableting agent, lubricant, flowing agent, separating agent, water repellent, emulsifying agent, gelling agent & stability improvement agent.

LIGAFOOD®

Dedicated brand for food products according to FSSC 22000 and HACCP food safety standards. Free from impurities.

LIGAFEED®GMP+ B2

Feed range products, free from impurities.



Netherlands

Products	Description	Applications
LIGAMED MF-2-V-MB Magnesium Stearate	Specific surface area: 6-10 m ² /g Median particle size (D50): 7-11 µm	<ul style="list-style-type: none"> High specific surface area & fine particles offers high releasing speed during tablet pressing and constant physical performance of tablets such as hardness & dissolution Require lower usage%: 0.2 to 1% by tablet wt.
LIGAMED MF-3-V-MB Magnesium Stearate	Specific surface area: 8-12 m ² /g Median particle size (D50): 5-9 µm	<ul style="list-style-type: none"> High SSA & smaller median PSD Used in critical processing conditions and very fine excipients or herbal formulations
LIGAMED MF-2V Premium-MB Magnesium Stearate	Median particle size (D50): 8-11 µm	<ul style="list-style-type: none"> High quality specification with additional tests for fatty acid profile & microbial count For highly complex pharma application- Inhalation medicine
LIGAMED MF-2-V-BI-MB Magnesium Stearate	Specific surface area: 6-8 m ² /g Median particle size (D50): 7-11 µm	<ul style="list-style-type: none"> Tighter SSA range with favorable crystalline structure Used where low & stable viscosity required
LIGAMED MF BLS-MB Magnesium Stearate co-processed with Sodium Lauryl Sulphate	Special production process	<ul style="list-style-type: none"> Produced according to special production process it offers the characteristic of being water dispersible Suitable for use within water soluble drugs



Netherlands

Products	Description	Applications
LIGAMED CPR-2-V-MB Calcium Stearate	Specific surface area: 5-9 m ² /g Median particle size (D50): 5-9 µm	<ul style="list-style-type: none"> • Water repellent agent in production of effervescent tablets • Premature reaction of effervescent tablet is avoided by preventing unwanted absorption of moisture
LIGAMED SA-1V-MB Stearic Acid	PSD mean: 40-60 µm	<ul style="list-style-type: none"> • Produced by innovative and complex production process • Used as tableting & flowability agent in specific pharma formulations
PALMSTAR ZPR 2-V-MB Zinc Stearate	Zinc Salt of Vegetable Fatty Acids	<ul style="list-style-type: none"> • Special application in pharma and cosmetics as anti-caking agent, anti-bacterial and water repellent.
PALMSTAR AL Pharma-MB Aluminium Stearate	Aluminium Stearate of Vegetable Fatty Acid	<ul style="list-style-type: none"> • Grade with excellent gelling performance for pharma and cosmetic applications
LIGASTAR AL DT/C-V-MB Aluminium Stearate	Aluminium Salt of Vegetable Fatty Acid	<ul style="list-style-type: none"> • Grade offers moderate gel strengths at a gelling temperature between 80° and 120°C
LIGASTAR ALG-V-MB Aluminium Stearate	Aluminium-di-Stearate	<ul style="list-style-type: none"> • With high gelling abilities • Usable in ointments as thixotropic agent & viscosity enhancer • It also improves flowability
PALMSTAR NAV PC-MB Sodium Stearate	Sodium soap of Vegetable Stearic Acids	<ul style="list-style-type: none"> • Used as emulsifier for production of powder or as gelatinizing agent for alcohols • Highest use is in deodorant sticks



Brazil & India

Roquette is a leading supplier of sustainably sourced, high quality raw materials to the pharmaceutical industry for more than 40 years.

MICROCEL® - Microcrystalline Cellulose

Microcrystalline cellulose (MCC) is widely used in the pharmaceutical industry in the manufacture of tablets, capsules and others, either in direct compression or in dry and wet granulation processes.

It is produced at two manufacturing sites in Brazil and in India.

MICROCEL™ SD products are spray dried from an EXCiPACT (International Pharmaceutical Excipients Certification) certified plant using high quality pulp.

- Highly controlled manufacturing process
- Certifications: ISO, GMP, Kosher, Halal, EXCiPACT
- Products with batch-to-batch consistency
- Pharmacopoeia specifications: JP, EP, USP NF, ChP.

MCC Grade	Applications
MICROCEL® 101 SD MICROCEL® MC 101	Filler and binder for tableting in wet granulation process
MICROCEL® 102 SD MICROCEL® MC 102	Filler and binder for tableting in wet granulation process and direct compression
MICROCEL® 112 SD MICROCEL® MC 112	Filler and binder for tableting with moisture sensitive API



Brazil & India

MCC Grade	Applications
MICROCEL® 200 SD MICROCEL® MC 200	Filler and binder for tableting in direct compression process and dry granulation
MICROCEL® 301 SD	Filler and binder for tableting in granulation process
MICROCEL® 302 SD MICROCEL® MC 302	Filler and binder for tableting in direct compression process
MICROCEL® MC 12	Filler and binder for tableting in direct compression process

MICROCEL® is a registered trademark in Benelux, Brazil, Canada, Chile, France, Germany, Italy, Mexico, the United Kingdom and the United States of America and is pending in other countries or regions.

TABULOSE® SC COLLOIDAL MICROCRYSTALLINE CELLULOSE

TABULOSE® SC is a co-processed product composed of microcrystalline cellulose (MCC) and sodium carboxymethylcellulose (CMC), which makes a thixotropic suspension used as a secondary stabilizer and suspension agent in semi-solid formulas such as suspensions, emulsions, aerosols, creams, lotions and gels.

Type	Components		Viscosity	
	MCC %	CMC %	CPS	Solid content %
591	86.2 - 91.7	8.3 - 13.8	39 - 91	1.2
591F	85.0 - 91.0	9.0 - 15.0	75 - 175	1.2
611	81.2 - 88.7	11.3 - 18.8	85 - 200	2.6
681	86.2 - 91.7	8.3 - 13.8	72 - 168	1.2



Brazil & India

SOLUTAB® CROSCARMELOSE SODIUM

SOLUTAB® croscarmellose sodium is a highly efficient super disintegrant, widely used in oral solid pharmaceutical formulas and with high efficiency even when used in lower doses.

Recommended use: It is indicated for use in tablets, capsules and pellets, either in formulas manufactured by direct compression, dry and wet granulation, or with intra or extragranular use.

	SOLUTAB® A	SOLUTAB® A-IP	SOLUTAB® EDP*
Average particle size (Microns)	60	60	45
Retained on 200 mesh (%)	NMT 10	NMT 10	NMT 2
Retained on 325 mesh (%)	-	-	NMT 10
Loss on drying (%)	NMT 10	NMT 6	NMT 10

*Also available SOLUTAB® Low solvent grade:

Product with particle size specification by laser diffraction and lower residual solvent:

PSD d10 25 microns max.

PSD d50 25 - 55 microns

PSD d90 60 microns min.



USA

- World's leading manufacturer of high quality colors, flavors & printing inks
- Products complying regulatory requirements - Colors approved in EC/JP/FAO/WHO/JECFA/USFDA
- Manufacturing sites include India, Australia, New Zealand, China, Philippines, Germany, Mexico, South Africa, USA and UK
- FD&C and D&C Colors: USFDA-certified
- ISO 9001, ISO 14001, ISO 22000, Kosher and Halal certified products

Natural colors	Synthetic Colors in Dye and Lake Forms (FD&C and D&C Colors, are tested and certified by the USFDA)	Others
Beetroot	Quinoline Yellow	Iron Oxides
Beta-Carotene	Tartrazine	
Carmine and Cochineal Extracts	Sunset Yellow	Titanium Dioxide
Copper Chlorophyllin	Ponceau 4 R	
Caramel	Allura Red	Printing inks
Annatto	Carmoisine	
Spirulina Extract	Erythosine	Avalanche™ Titanium Dioxide Replacers
Antocyanins	Indigo Carmine	
Tumeric	Brilliant Blue	Spectrablend™ TFN (Titanium dioxide- and mineral-free coating)
Other colors and custom blends are available	Patent Blue V	



USA

Flavors range

- World-class natural and synthetic flavors
- Smoothenol® masking agents for bitter, metallic, astringent and other off-notes

Flavor types	General usage
Water-soluble flavors	Syrups, drops, mouthwash, oral sprays, jellies
Oil-soluble flavors	Oil-based syrups, chewable tablets, thin-films, suspensions
Encapsulated powder flavors	Tablets, sachets, fast-melt applications
Blended powder flavors	Nutraceutical products, meal replacement for weight management

New Innovations: Natural and clean-label products

Microfine™: Replaces certified lake colors with natural colors

- Aluminum-free
- Delivers plating characteristics commonly found in synthetic pigments
- Delivers customizable bright and intense color shades
- No flavor impact

Spectrablend™ TFN: Titanium Dioxide - and mineral-free natural coating system

- Offers natural opacity without titanium dioxide and minerals
- No flavor impact
- Heat and light-stable

Avalanche™: Titanium Dioxide Replacers

- Custom formulations offering natural opacity without titanium dioxide and minerals
- Applications include hard capsules, soft gels, suspensions, gummies and hard-boiled lozenges
- No flavor impact
- Heat and light-stable



Aurorium

USA

Aurorium, USA - Formerly known as Vertellus Pharma.

Vertellus Pharma Citrate Plasticizers - Citrate esters derived from Citric Acid

Compliance: PhEur/USPNF.

Offers broad range of benefits - Solvent alternatives, performance enhancers in aqueous and non-aqueous pharmaceutical coating & medical formulations.

Certifications: ISO 9001: 2008, Kosher, Halal

Products	Characteristics	Advantages
Triethyl Citrate NF	<ul style="list-style-type: none"> Water soluble and organic solvent miscible at about 5.5% Works in most formulations without an emulsifying agent 	To get effective coatings without crack or splitting defects
Acetyltri-n-Butyl Citrate NF	<ul style="list-style-type: none"> Require emulsifier to get in the aqueous phase Miscible with organic solvents 	Helps to lower melt viscosity and glass transition temperature
Dibutyl Sebacate NF	<ul style="list-style-type: none"> Require emulsifier to get in the aqueous phase Miscible with organic solvents 	Lipophilic plasticizer
Acetyl Triethyl Citrate NF	<ul style="list-style-type: none"> Works well with the blends of the water soluble and water insoluble plasticizers 	To increase the workability and flexibility of the polymer
Citroflex® B-6: n-Butyryltri-n-hexyl citrate	<ul style="list-style-type: none"> Low extractability into lipid media, making it particularly useful for bloody products 	Plasticizer for PVC based blood bags & catheters It nearly duplicates the properties of di-(2-ethylhexyl) phthalate, but a good "phthalate free" option



Primary
Packaging





UK & France

Berry - Astra Plastique SAS France, Berry-UCP Zeller Plastik UK and Berry M&H Plastics, UK brands combine to make Berry Bramlage the health care market leader in the world for child resistant, tamper evident closures, droppers and bottles.

Their quality control systems and manufacturing standards continue to meet the ever-increasing demands of a highly regulated market including ISO standards for child resistance and dose accuracy.

Their R&D network has the ability and experience to work with your packaging team to create new and innovative closure solutions for the healthcare sector.

Child Resistant Closures

offering the full range of functionality and security required by regulation.

MEDI-LOC®

Industry standard compact PP28 TE CRC with wad seal to suit product application, fully compliant with ISO 8317:2003 on a range of glass and PET bottles. Also tested successfully on the 60-80 year age group. (with tamper evidence)

SAFEVISTOP®

CRC PP 28 TE for glass, plastic and PET bottles compliant with ISO 8317 standard.





UK & France

Tamper evident screw caps

VISTOP® PP 28 or PP 25

For all types of products : liquid, tablets or powder

In addition to its patented TE system, Vistop brings the best in class sealing system thanks to its deep profile plug, all manufactured in class 10,000 clean room.



VISTOP® DROPPER PP 28

For glass bottles

To complement the fluid applications for Vistop closures, a dropper range has been developed, to suit aqueous and alcohol solutions. GL18 - Our standard range of vertical droppers offers a wide variety precision dosing solutions for liquid products.



VISTOP® PP36 & VISTOP® PP36 with liner

Wadded tamper evident screw cap designed to fit pill jars with PP36 neck finish.

Plug version for glass bottles.

Specific version with PP plug for PP bottle suitable for sterilization by autoclave.



Measure Devices

A range of CE marked measure devices to complement closures and to satisfy current dosing regulations



Bottles

A whole range of PET bottles in various sizes, colors and neck finishes for syrups and various applications.





Belgium

Hubert De Backer NV (HDB) is a fully integrated family-owned company founded in 1932 and is structured to provide you with quick time-to-market, high-quality products.

This makes HDB the global benchmark for both human and veterinary pharmaceuticals, medical devices and diagnostics.

In close cooperation with your technical engineers and marketing department, HDB's R&D with their extensive experience, can create innovative, technologically-advanced and commercially successful products.

Their products are registered with:

- US Drug Master File
- Complies with US & European Pharmacopeias
- CE marked



Products	Category	Sizes Available	Description
Oral Dosing Devices	Dosing device	1ml to 20ml	<ul style="list-style-type: none">• Dosing volumes: 1ml, 2ml, 3ml, 5ml, 10ml and 20ml• CRC/TE closure DIN28 and DIN18• Plug DIN28 and DIN18• Cap for pre-dosing and sealing• All PMS colours available for barrel and plunger• Pre-assembly of closure and plug optional, syringe and plug optional• Individual packaging in flow pack optional• Printing on the barrel or plunger with standard or customized scale division



Belgium

Products	Category	Sizes available	Description
Cream & Gel Applicator	Vaginal applicators	5ml	<ul style="list-style-type: none">• Medical grade materials• M9/M11 screw thread• Individual flow pack packaging optional• Blister packaging optional• Printing on the plunger with standard or customized scale division optional
Capsules & Liquids	Vaginal applicators	6ml	<ul style="list-style-type: none">• Individual flow pack packaging optional• Blister packaging optional• Printing on the barrel or plunger with standard or customized scale division optional
Applicators	Applicators	Various	<ul style="list-style-type: none">• Dairy and Cattle - Intramammary• Syringes• Equine oral paste syringes• Companion animals oral suspension• Companion animals• Creams, gel and paste



Austria

KWK was founded in 1950 and is known as a highly qualified producer of plastic closures and dosing devices for pharmaceutical packaging and healthcare packaging. All production of the innovative packaging solutions is located in Kremsmünster, Austria. KWK uses its decades of experience as well as the newest technology to produce high quality primary packaging. The company focuses on packaging items for the pharmaceutical industry and offers articles produced in an environment with a high quality-standard according to the requirements for pharmaceutical use.

KWK produces a wide range of closures, closure systems and dosing devices in standard sizes or according to customer specific designs.

The company is certified according to:

- Quality Management System ISO 15378, ISO 9001, ISO 13485
- CE certified to produce medical devices with measuring function (directive 93/42/EEC)
- USDMF
- Certified producer of pharmaceutical packaging for Russia and Ukraine

Products:

Closures:

Screw-caps for different standards such as GL or PP

- GL 18
- PP28 S
- PP31 S
- Snap caps without thread such as for the standard GC (cap to cap)

Dosing devices:

- Dropper nozzles
- Dispensing inserts
- Pouring spouts
- Dosage cups
- Dosage spoons

Jars or cream pots:

- Cream pots (jars) with screw-lids in different sizes





Israel

Since 1967, Lageen Tubes has been offering tailor-made, cutting-edge packaging tube solutions for diverse customers in the cosmetics, personal care, hair care, oral care, pharmaceutical, and food sectors in over 30 countries worldwide.

Leveraging more than 50 years of innovation, they design, develop, produce, decorate and supply smart collapsible plastic and aluminum packaging tubes.

Lageen Tubes uses the most technologically advanced production and printing methods on mono-layer, two-layer, and multi-layer plastic tubes, as well as aluminum tubes.

They offer nearly endless decoration possibilities, achieving the highest standards of quality and excellence. Meeting the highest international standards, products are approved by:

- USFDA DMF
- ISO 9001 Certified
- ISO 15378 Primary packaging materials for medicinal products

Products:

Wide range of aluminum tubes

Lageen Tubes offers rigid aluminum tubes in an extensive range of diameters and sizes for filling capacity of 5ml up to 150ml with variety of caps.

They are ideal for pharmaceutical products, hair coloring, that contain aggressive chemicals.

Our aluminum tubes are produced through an impact extrusion process, which includes the application of internal and external lacquers, decoration, capping, etc.





Israel

Products:

Wide range of aluminium tubes

Ø13.5 | 1/2"



Volume 8 ml (0.27 fl. oz)
Length 85-90 mm



FEZ + spike M7

Ø19 | 3/4"



Volume 15-25 ml (0.5- 0.85 fl.oz)
Length 85-125 mm



FEZ + spike M9



Cylinder +
spike M9



Reverse+Spike
FEZ T92

Ø22



Volume 25-40 ml(0.84- 1.35 fl.oz)
Length 100-140 mm



FEZ + spike M9



Israel

Products:
Wide range of aluminium tubes

Ø22.2 | 7/8"



Volume 25-40 ml (0.84- 1.35 fl.oz)
Length 100-140 mm



FEZ + spike M9



Reverse+Spike
FEZ T92

Ø25 | 1"



Volume 30-55 ml (1- 1.85 fl.oz)
Length 100-155 mm



FEZ + spike M9



FEZ + spike T11



Cylinder +
spike M11



Cylinder +
spike M11

Ø28.6 | 1 1/8"



Volume 40-80 ml (1.35- 2.7 fl.oz)
Length 100-170 mm



FEZ +
spike M9



Cylinder +
spike M11



FEZ +
spike T11



Reverse+Spike
FEZ T92



Cylinder +
spike M11



Israel

Products:

Wide range of aluminium tubes

Ø30



Volume 40-83 (1.35- 2.8 fl.oz) **Length** 100-162 mm



FEZ + spike T11



Cylinder + spike M11



Cylinder + spike M11

Ø31.75 | 1 1/4"



Volume 45-110 ml (1.52 -3.71 fl.oz) **Length** 100-185 mm



Reverse FEZ T92



FEZ + spike M9

Ø32



Volume 45-110 ml (1.52-3.71 fl.oz) **Length** 100-185 mm



FEZ + spike M9



FEZ + spike T11



Cylinder + spike M11



Cylinder + spike M11



Israel

Products:
Wide range of aluminium tubes

Ø35



Volume 60-115 ml (2.02-3.88 fl.oz) **Length** 120-190 mm



Cylinder + spike M11



Cylinder + spike M11



Cylinder + spike M11



FEZ + spike T11

Ø38.1



Volume 75-145ml (2.53- 4.9 fl.oz) **Length** 120-180 mm



FEZ + spike T11

Ø40



Volume 80-150 ml (2.7-5.07 fl.oz) **Length** 120-175 mm



FEZ + spike T11



Austria

- More than 200 years of experience in the production of glass
- 7 production sites in Austria, Great Britain, France, Czech Republic, Poland and the US
- 3 decoration sites in Great Britain, France and Poland
- 3.4 billion glass containers produced per year
- One-stop-shop for development, production, decoration and closures

Pharma-healthcare & safety from Stoelzle includes a wide range of packaging glass not only for the pharmaceutical industry but for consumer spirits and consumer food, as well.

Due to the strategic importance of its pharma-healthcare & safety business, Stoelzle is one of the few manufacturers who produce pharmaceutical packaging glass according to International ISO GMP 15378 standards, which complies with ISO 900. EUPharmacopoeia & US-Pharmacopoeia can be applied upon request.

Stoelzle also holds an active Drug Master File at FDA and in Canada.

The company is willing to subject itself to further special controls and will issue certificates about heavy metal concentration or microbiological examination results if required.



Austria

Product range:

The Stoelzle standard product portfolio covers the pharmaceutical industry's full range of packaging glass for Type 2 and Type 3 glass bottles:

- Dropper bottles
- Medicinal and syrup bottles
- Veral bottles
- Injection and infusion bottles
- Tablet jars
- Wide mouth packers





Other products:

- OPTIM™ Glycerine 99.7%, USP/EP
- Diclofenac Sodium
- Secondary Butyl Chloroformate, Cas:17462-58-7
- Phenyl Chloroformate
- Advance intermediates





Innovation
through
formulation



Registered Office & Application Lab

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