

# INNOVATIVE RAW-MATERIAL SOLUTIONS FOR CHANGING PHARMA NEEDS

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BUSINESS  
NETWORKING  
SOCIAL NETWORK  
TECHNOLOGY  
MEDIA  
CREATIVE  
FINANCE  
INVESTMENT



## Excipients for Ophthalmics & Parenterals

### Corporate Office:

**Pharmonix Biologicals Pvt. Ltd.**

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### For Sales Enquiry:

+91 9619919019 | [sales@pharmonix.com](mailto:sales@pharmonix.com)

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## Excipients for Ophthalmics & Parenterals

**Note:** We provide product information and technical assistance to our customers to the best of our knowledge but without any liability. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products. The formulation manufacturing company is responsible to assure that the excipient is suitable for the intended application.





## At a Glance

We are leading Distributors of Excipients for Topical / Ophthalmic and Parenteral dosage forms. We provide solutions to pharmaceutical industry, for their customized requirements of complex excipients (NDDS & New Drug Discovery).

With this vision in mind, we have collaborated with globally renowned Parenteral solutions provider, with the aim of being accepted as our customer's most trustworthy partner.

Qualified pharmaceutical personnel are located on PAN India basis, to help you solve complex formulation issues from R&D to commercial.

All the products on catalogue are readily available at our Mumbai warehouse, from R&D packs to exhibit lots.

## Associated Global Excipient Manufacturers



Pharmonix Biologicals, is in a unique position to source both the most sought after and the most rare speciality excipients with the added assurance that this can be supplied with complete regulatory documentation and competitive prices.



Please do visit our website for full information on all our brands  
<http://www.pharmonix.com>

## Kirsch Pharma GmbH, Germany



### Product Features:

- Current EP, USP + LEC + Microbiological Controlled
- Low Endotoxin Control (LEC)
- Microbiological Controlled
- cGMP and ICHQ7 Compliance
- Elemental Impurity as per ICHQ3D (Parenteral)

### MINERAL SALTS AND BUFFERS

Product Name	Regulatory Status
• Calcium Chloride Dihydrate	EP, USP, LEC, Microbiological requirements
• Citric Acid Anhydrous	EP, USP, LEC, Microbiological requirements
• Citric Acid Monohydrate	EP, USP, LEC, Microbiological requirements
• Dextrose Anhydrous	EP, USP, dialysis/injectable grade
• Dextrose Monohydrate	EP, USP, LEC, Microbiological requirements
• Magnesium Chloride Hexahydrate	EP, USP, LEC, Microbiological requirements
• Potassium Chloride	EP, USP, LEC, Microbiological requirements
• Potassium Hydroxide	EP, NF, LEC, Microbiological requirements
• Sodium Acetate Trihydrate	EP, USP, LEC, Microbiological requirements
• Sodium Bicarbonate	EP, USP, LEC, Microbiological requirements
• Sodium Chloride	EP, USP, LEC, Microbiological requirements
• Sodium Dihydrogen Phosphate Monohydrate	BP, USP, LEC, Microbiological requirements
• Sodium Dihydrogen Phosphate Dihydrate	EP, USP, LEC, Microbiological requirements
• Di-Sodium EDTA	EP, USP, LEC, Microbiological requirements
• Di-Sodium Hydrogen Phosphate Anhydrous	EP, USP, LEC, Microbiological requirements
• Di-Sodium Hydrogen Phosphate Dodecahydrate	EP, USP, LEC, Microbiological requirements
• Sodium Hydroxide Pellets	EP, NF, LEC, Microbiological requirements

### AMINO ACIDS

Product Name	Regulatory Status
• L-Arginine	USP, LEC, Microbiological requirements
• L-Cysteine HCL Monohydrate	EP, USP, LEC, Microbiological requirements
• L-Methionine	EP, USP, LEC, Microbiological requirements



## Kirsch Pharma GmbH, Germany

Founded in 1980, Kirsch Pharma is the manufacturer of raw materials for the Pharmaceutical, Biotechnology and Veterinary industry.



- GMP Certified Company (GMP directorate GM- Braunschweig and DQS).
- cGMP compliant quality assurance and quality control.
- Certified by DQS according to HACCP 852/2004(EC) and DIN EN ISO 9001:2000.
- Compliance according to ICH Q7A and EU-GMP Guideline Part 2 for Pharmaceutical substances.
- Member of IPEC (International Pharmaceutical Excipients Council) Europe.
- Parenteral and Dialysis Grade excipients and certifications according to current International Pharmacopeia i.e USP/EP/JP Compliance.
- Physical modification such as Blending, Grinding, Sieving and Compacting under GMP, with respect to specific customer demands.



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## C G Chemikalien GmbH & Co. KG, Germany



### Product Features:

- Purity, Current USP, EP + Low Endotoxin + Low Bioburden
- Assay 99.9% (Minimum)
- cGMP validated manufacturing process
- Low content of Mono-ethylene Glycol (MEG) / Di-ethylene Glycol (DEG)
- Elemental Impurity as per ICHQ3D (Parenteral)

### EXCIPIENTS FOR PARENTERAL

Product Name	Regulatory Status
• Benzyl alcohol	USP/NF, Ph. Eur., Low Endotoxin + Low Bioburden
• Benzyl benzoate	USP/NF, Ph. Eur., Low Endotoxin + Low Bioburden
• Boric acid powder	Ph. Eur., USP, Low Endotoxin + Low Bioburden
• Citric acid anhydrous	Ph. Eur., USP, Low Endotoxin + Low Bioburden
• Glycerol 99%	USP, Ph. Eur., Low Endotoxin + Low Bioburden
• Hydrochloric acid 37%	USP/NF, Low Endotoxin
• Macrogol 400 powder	USP/NF, Ph. Eur., Low Endotoxin + Low Bioburden
• Macrogol 4000 powder	Ph. Eur., USP/NF, Low Endotoxin + Low Bioburden
• Macrogol 6000 powder	Ph. Eur., USP/NF, Low Endotoxin + Low Bioburden
• Methyl parabene	USP/NF, Ph. Eur., Low Endotoxin + Low Bioburden
• Polysorbate 80	USP/NF, Ph. Eur., Low Endotoxin + Low Bioburden
• Propyl parabene	USP/NF, Ph. Eur., Low Endotoxin + Low Bioburden
• Propylene glycol	EP, USP, Low Endotoxin + Low Bioburden
• Sodium benzoate powder	Ph. Eur., USP/NF, Low Endotoxin + Low Bioburden
• Sodium cetostearyl sulphate	EP, Low Endotoxin + Low Bioburden
• Sodium citrate 2-hydrate	Ph. Eur., USP, Low Endotoxin + Low Bioburden
• Sodium citrate, anhydrous	USP, Low Endotoxin + Low Bioburden
• Disodium phosphate anhydrous	Ph. Eur., USP, Low Endotoxin + Low Bioburden
• Sodium sulfite anhydrous	EP, USP, Low Endotoxin + Low Bioburden
• Sodium tetraborate decahydrate powder	Ph. Eur., USP, Low Endotoxin + Low Bioburden
• Sodium thiosulfate 5-hydrate	USP, EP, Low Endotoxin + Low Bioburden
• Tartaric acid	Ph. Eur., USP/NF, Low Endotoxin + Low Bioburden

## C G Chemikalien GmbH & Co. KG, Germany

Founded in Laatzen near Hanover, Germany in 1962 now produces more than 450 raw materials for Pharmaceutical industry at their cGMP production facility.

- All certifications like GMP, GDP, HACCP, DIN EN ISO 9001, DIN EN ISO 14001, and DIN EN ISO 2000.
- Performance capabilities include Production, Blending, Sieving, Milling, Grinding and Micronization etc.
- BET / MLT validated excipients and certifications according to current international Pharmacopeia i.e. USP/EP/JP compliance or individual customer specifications.
- Strategic Sourcing and co-development of critical excipients, through decades of relationships with renowned manufacturers from across the globe.



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## Asymchem Inc, USA

Founded in North Carolina in 1995, today recognized across the globe for proprietary technology development in the pharmaceutical industry.

- cGMP certified and US FDA registered site with no 483.
- Compliance with all ICH guidelines Q7/Q8/Q9/Q10/Q11,US/EU regulations.
- Proprietary manufacturing process development, which does not infringe any patents.
- Full technical and regulatory documentation support, for filing across the globe.
- Detailed MOA, Manufacturing process flow chart and Stability data available.
- Working standards, Reference standards and Markers can be made available upon request.
- Product conformity to customer specification and regulatory requirements through process control & achievement.
- Documentation management system, manage through "Change control and Quality manual".
- Dedicated advanced characterization & control of the product.
- Best in class Impurity Profiling throughout the shelf life.

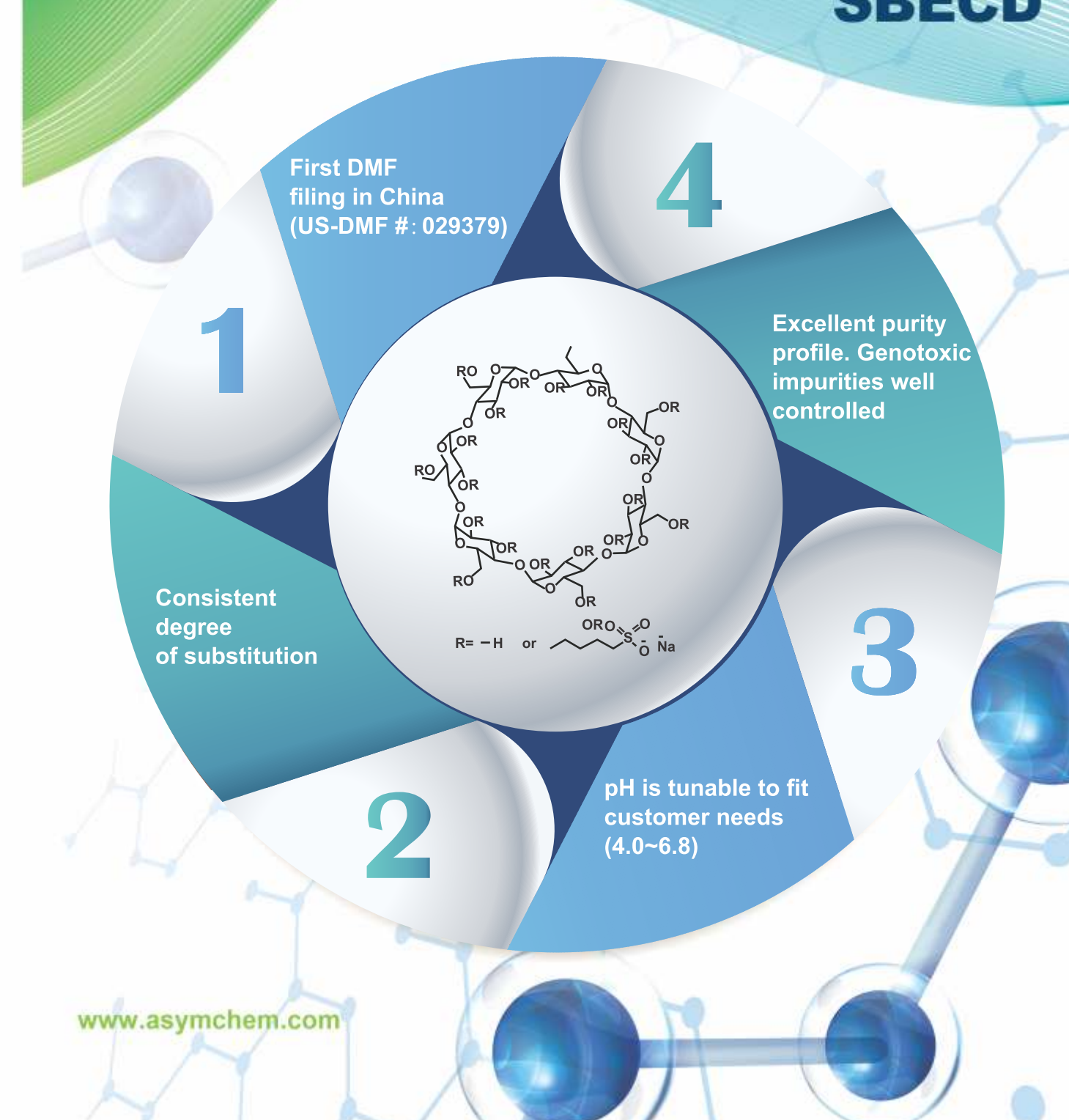
Product Name	Compendial Status	Grade	Application
<b>Sulpho Butyl Ether Beta Cyclodextrin Sodium (SBECD)</b>	USP (US DMF)	Parenteral	Solubility enhancement of poorly aqueous soluble drugs by complexation. The hydrophobic inner cavity of SBECD enables to form complexes with a wide variety of Actives, thereby increasing Bioavailability and Stability



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## Sulphobutylether beta-cyclodextrin SBECD





## Wilshire, Germany



### Product Features:

- Intended to be used in Parenteral formulation
- cGMP & USFDA registered facility
- High Purity+Low Endotoxin+Low Bioburden
- USP/Ph.Eur. Compliant
- Large Scale (MT) capacity
- Elemental Impurity report as per ICHQ3D- Parenteral Guidelines

### CARBOHYDRATES & SPECIALITY EXCIPIENTS

Product Name	Regulatory Status	Grade
• Cholesterol (Vegetable Derived)	USP / Ph. Eur. -USDMF	Labelled Parenteral
• D-(+)-Galactose	USP / Ph. Eur.	Labelled Parenteral
• Glycerol Synthetic	USP / Ph. Eur.	Labelled Parenteral
• Glycine Hydrochloride	Pharmaceutical cGMP	Labelled Parenteral
• Lactobionic Acid	Pharmaceutical cGMP	Labelled Parenteral
• L-lysine (Free Base)	Pharmaceutical cGMP	Labelled Parenteral
• D-Mannitol	USP / Ph. Eur.	Labelled Parenteral
• D-Mannitol (Sterile)	USP / Ph. Eur.	Labelled Parenteral
• Sodium Succinate Dibasic Hexahydrate	USP / Ph. Eur.	Labelled Parenteral
• Squalene (Olive oil derived)	USP / Ph. Eur.	Labelled Parenteral
• D-Sucrose (Beta vulgaris L.)	USP / Ph. Eur.-USDMF	Labelled Parenteral
• D-(+)-Trehalose Dihydrate	USP / Ph. Eur.	Labelled Parenteral



## Wilshire Technologies, USA

Founded in 1997, a cGMP manufacturer of High Purity Low endotoxin grade excipients using advanced purification techniques.

- FDA registered cGMP production facility.
- Conforms to USP/EP Pharma and Parenteral monographs.
- Compliant to ICHQ7, 21CFR-210-211 & IPEC.
- Inspected by FDA in April 2015; EMEA QP in April 2016, no critical observation in over 3 years.
- Audited and approved by leading global Parenteral and Biologics companies.
- Lot sizes 50gm to 5000kg to fulfill customer's specific requirements.
- Total 90,000 square feet facility, including 8 small scale cGMP manufacturing suites.
- ICH Q11 compliant process and product development
- DOE (Design of experiment) and QbD (Quality by Design) process approach.
- High purity low endotoxin grade sugars, suitable for biopharmaceutical processing.



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