PHAEX POLYMERS
PRIVATE LIMITED

Synonym For Quality

PHARMACEUTICAL ION EXCHANGE RESINS

# IONEX

## Product Portfolio

Resins for hyperkalaemia, bile-acid binding, taste masking, sustained release and tablet disintegration.

STRONGLY ACIDIC · CATION

SC 25 | SC 28 | SC 40 | SC 42 | SC 47

STRONGLY BASIC · ANION

SB 43 | SB 45 | SB 48

WEAKLY ACIDIC · CATION

WC 20 | WC 23 | WC 29 | WC 46

**Phaex Polymers Private Limited**
M.I.D.C. Murbad, Maharashtra, India

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## IONEX grades in this portfolio

**STRONGLY ACIDIC CATION EXCHANGE RESINS**

| | |
|---|---|
| SC 25 | Sodium Polystyrene Sulfonate (USP–NF) |
| SC 28 | Sustained-Release Resin |
| SC 40 | Calcium Polystyrene Sulfonate (BP) |
| SC 42 | Sodium Polystyrene Sulfonate (EP) |
| SC 47 | Calcium Polystyrene Sulfonate (JP) |

**STRONGLY BASIC ANION EXCHANGE RESINS**

| | |
|---|---|
| SB 43 | Colestyramine (BP) |
| SB 45 | Cholestyramine Resin (USP) |
| SB 48 | Colestyramine (EP) |

**WEAKLY ACIDIC CATION EXCHANGE RESINS**

| | |
|---|---|
| WC 20 | Taste-Masking Resin |
| WC 23 | Disintegrant & Taste-Masking Resin |
| WC 29 | Polacrilin Potassium (USP–NF) |
| WC 46 | Polacrilex Resin |

**Not sure which grade?** Start with the application matrix on page 6. Full datasheets for every grade are supplied separately.

# 01 About us

Pharmaceutical ion exchange resins, made in Murbad, Maharashtra

Phaex Polymers Private Limited manufactures pharmaceutical-grade ion exchange resins at its WHO GMP-certified plant in M.I.D.C. Murbad, Maharashtra, India. Our IONEX range covers resins used as **active pharmaceutical ingredients** (calcium and sodium polystyrene sulfonate, cholestyramine resin) and as **functional excipients** (polacrilex resin and polacrilin potassium) for taste masking, sustained release and tablet disintegration.

Our grades are made to the monographs of the United States Pharmacopeia–National Formulary, the European Pharmacopoeia, the British Pharmacopoeia and the Japanese Pharmacopoeia, giving formulators and API buyers one source for the grade their market requires.

We supply customers in the European Union, Southeast Asia, the Middle East and Africa.

Phaex also supplies ion exchange resins and speciality chemicals to the catalysis, potable water, hydrometallurgy, chemical process, boiler water and sugar industries.

## At a glance

MANUFACTURING SITE
**M.I.D.C. Murbad, Dist. Thane, Maharashtra, India**

CERTIFICATION
**WHO GMP**

MARKETS
**European Union · Southeast Asia · Middle East · Africa**

PRODUCT RANGE
**12 IONEX grades in three resin families**

STANDARDS
**USP–NF · EP · BP · JP**

| 12 | 4 | 3 | 40 kg |
|---|---|---|---|
| IONEX grades | pharmacopoeial standards | resin chemistries | largest pack size |

## Our three resin families

**Strongly acidic cation exchange resins** SC 25 · SC 28 · SC 40 · SC 42 · SC 47
Sulfonated copolymers of styrene and divinylbenzene (DVB), supplied in sodium or calcium form. Active ingredients for hyperkalaemia and carriers for sustained-release and taste-masked resinates.

**Strongly basic anion exchange resins** SB 43 · SB 45 · SB 48
Cholestyramine resin: a styrene–DVB copolymer with quaternary ammonium groups, in chloride form. A bile-acid-binding active ingredient and a carrier for acidic (anionic) drugs.

**Weakly acidic cation exchange resins** WC 20 · WC 23 · WC 29 · WC 46
Crosslinked acrylic polymers with carboxylic acid functionality, in hydrogen or potassium form. Taste masking of bitter drugs and fast tablet disintegration.

## How IONEX resinates work

### Taste masking
The drug–resin complex stays intact at the average salivary pH of 6.7 and about 40 meq/L cations, but is broken down by stomach acid, giving a stable, taste-masked formulation.

### Sustained release
The drug is released from the resinate in vivo as it reaches equilibrium with the high electrolyte concentration typical of the gastrointestinal tract.

# 02 Why Phaex

Six reasons to choose IONEX pharmaceutical resins

### 1 One source, four standards

Polystyrene sulfonate in USP–NF, EP, BP and JP grades, and cholestyramine in USP, EP and BP grades, so you can match the monograph your market requires.

### 2 Actives and excipients

Resins for therapy (hyperkalaemia, bile-acid binding) and for formulation (taste masking, sustained release, tablet disintegration) from the same manufacturer.

### 3 Three resin chemistries

Strongly acidic, strongly basic and weakly acidic resins, so you can choose the functionality that suits your drug–resin complex.

### 4 WHO GMP manufacturing

Produced at our WHO GMP-certified plant at M.I.D.C. Murbad, Maharashtra, India.

### 5 Clear, complete specifications

Every grade is documented with identification, ionic content, exchange capacity, impurity and particle-size limits, as relevant to its monograph.

### 6 Practical packing

Pack sizes from 5–6 kg to 40 kg in HDPE carboys with LDPE bag primary packing, for trial through commercial batches.

## Find your grade by pharmacopoeia

| Standard | Polystyrene sulfonate | Cholestyramine resin | Polacrilin potassium |
|---|---|---|---|
| USP–NF | IONEX SC 25 | IONEX SB 45 | IONEX WC 29 |
| EP | IONEX SC 42 | IONEX SB 48 | — |
| BP | IONEX SC 40 | IONEX SB 43 | — |
| JP | IONEX SC 47 | — | — |

IONEX SC 28, WC 20, WC 23 and WC 46 are supplied to the specifications in their datasheets.

**Synonym For Quality**

The standard we hold ourselves to in every batch of every grade.

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# Product range at a glance

All 12 IONEX grades with their standard, form and key uses

| Grade | Generic name | Standard | Ionic form | Physical form | Key uses |
|---|---|---|---|---|---|
| **STRONGLY ACIDIC CATION EXCHANGE RESINS** | | | | | |
| SC 25 | Sodium Polystyrene Sulfonate | USP–NF | Sodium | Free-flowing powder | Taste masking · sustained release |
| SC 28 | Sustained-Release Resin (Sodium form) | — | Sodium | Moist spherical beads | Sustained release |
| SC 40 | Calcium Polystyrene Sulfonate | BP | Calcium | Free-flowing powder | Hyperkalaemia |
| SC 42 | Sodium Polystyrene Sulfonate | EP | Sodium | Free-flowing powder | Hyperkalaemia |
| SC 47 | Calcium Polystyrene Sulfonate | JP | Calcium | Free-flowing powder | Hyperkalaemia |
| **STRONGLY BASIC ANION EXCHANGE RESINS** | | | | | |
| SB 43 | Colestyramine | BP | Chloride | Dry, fine powder | Bile-acid binding · drug carrier |
| SB 45 | Cholestyramine Resin | USP | Chloride | Dry, fine powder | Bile-acid binding · drug carrier |
| SB 48 | Colestyramine | EP | Chloride | Dry, fine powder | Bile-acid binding · drug carrier |
| **WEAKLY ACIDIC CATION EXCHANGE RESINS** | | | | | |
| WC 20 | Taste-Masking Resin (Hydrogen form) | — | Hydrogen | Free-flowing powder | Taste masking |
| WC 23 | Tablet Disintegrant & Taste-Masking Resin | — | Potassium | Free-flowing powder | Tablet disintegrant · taste masking |
| WC 29 | Polacrilin Potassium | USP–NF | Potassium salt | Free-flowing powder | Tablet disintegrant · taste masking |
| WC 46 | Polacrilex Resin | — | Hydrogen | Free-flowing powder | Taste masking |

Standards: USP–NF = United States Pharmacopeia–National Formulary; EP = European Pharmacopoeia; BP = British Pharmacopoeia; JP = Japanese Pharmacopoeia. A dash (—) means the grade is not supplied against a named monograph in its datasheet. Full datasheets for every grade are supplied separately.

# 04 Application matrix

Which IONEX grade is used for which application

Every application stated in the product datasheets, mapped to the grades that carry it. A tick means the application is described in that grade's datasheet.

| Application<br>IONEX grade → | STRONGLY ACIDIC | | | | | STRONGLY BASIC | | | WEAKLY ACIDIC | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | SC 25 (USP–NF) | SC 28 | SC 40 (BP) | SC 42 (EP) | SC 47 (JP) | SB 43 (BP) | SB 45 (USP) | SB 48 (EP) | WC 20 | WC 23 | WC 29 (USP–NF) | WC 46 |
| **THERAPEUTIC USE (ACTIVE INGREDIENT)** | | | | | | | | | | | | |
| Treatment of hyperkalaemia | | | ✓ | ✓ | ✓ | | | | | | | |
| Bile-acid binding (cholesterol lowering) | | | | | | ✓ | ✓ | ✓ | | | | |
| **FUNCTIONAL EXCIPIENT / DRUG CARRIER** | | | | | | | | | | | | |
| Taste masking of bitter drugs | ✓ | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sustained / controlled release (resinates) | ✓ | ✓ | | | | ✓ | ✓ | ✓ | | | | |
| Tablet disintegrant | | | | | | | | | | ✓ | ✓ | |
| **DOSAGE FORMS STATED IN DATASHEETS** | | | | | | | | | | | | |
| Suspensions (dry, wet and oral) | ✓ | | | | | | | | ✓ | ✓ | ✓ | ✓ |
| Dispersible tablets | ✓ | | | | | | | | ✓ | ✓ | ✓ | ✓ |
| Mouth-dissolving tablets | ✓ | | | | | | | | ✓ | | | ✓ |
| Chewable tablets and chewing gums | | | | | | | | | | ✓ | ✓ | |
| Lozenges | ✓ | | | | | | | | ✓ | | | ✓ |

✓ Application stated in the product datasheet. A blank cell means it is not stated for that grade.

## Quick picks

| | |
|---|---|
| **Hyperkalaemia** | SC 40 (BP) · SC 42 (EP) · SC 47 (JP) |
| **Bile-acid binding** | SB 43 (BP) · SB 45 (USP) · SB 48 (EP) |
| **Taste masking** | WC 20 · WC 46 · WC 23 · WC 29 · SC 25 · SB series |
| **Sustained release** | SC 25 · SC 28 · SB series |
| **Tablet disintegrant** | WC 23 · WC 29 |

Suitability of a grade for a given drug substance or dosage form depends on the formulation and should be confirmed by the user. Please contact us for technical guidance.

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# Specification comparison

Polystyrene sulfonates: sodium and calcium forms across four pharmacopoeias

| Parameter | IONEX SC 25 USP–NF | IONEX SC 40 BP | IONEX SC 42 EP | IONEX SC 47 JP |
|---|---|---|---|---|
| Generic name | Sodium Polystyrene Sulfonate | Calcium Polystyrene Sulfonate | Sodium Polystyrene Sulfonate | Calcium Polystyrene Sulfonate |
| Pharmacopoeial standard | USP–NF | BP | EP | JP |
| Ionic form | Sodium | Calcium | Sodium | Calcium |
| Appearance | Light cream to buff-coloured powder, free from foreign matter | Cream to light brown fine powder | Almost white or light brown powder | Pale yellowish white to light yellow fine powder, odourless and tasteless |
| Solubility | — | Practically insoluble in water and in ethanol (96%) | Practically insoluble in water, ethanol (96%) and methylene chloride | Practically insoluble in water, ethanol and diethyl ether |
| Identification – IR spectra | — | Complies with BP | Complies with EP | Complies with JP |
| Identification – reaction C for calcium | — | Complies with BP | — | Complies with JP |
| Loss on drying / water | NMT 10.0% | NMT 8% | NMT 7% w/w | NMT 10.0% w/w |
| Particle size – retained on 150 µm (100 BSS) | NMT 1.0% | NMT 1% | — | — |
| Microparticles | — | — | — | NMT 0.1% w/w |
| Sodium content | 9.4 – 11.5% (dried basis) | NMT 0.1% w/w | 9.4 – 11.0% w/w | NMT 1.0% w/w |
| Calcium content | — | 6.5 – 9.5% | NMT 0.1% w/w | 7 – 9% |
| Potassium exchange capacity | 110 – 135 mg/g (anhydrous basis) | 1.3 – 2.0 meq/g (dry basis) | 2.8 – 3.4 mmol of K/g | 53 – 71 mg/g (dry basis) |
| Potassium content | — | NMT 0.1% w/w | NMT 0.1% w/w | — |
| Styrene | — | Complies with BP | NMT 1 ppm | NMT 1 ppm |
| Iron content, as Fe | NMT 100 ppm | — | — | — |
| Heavy metals | NMT 10 ppm | Complies with BP | — | NMT 10 ppm |
| Arsenic content, as As | NMT 3 ppm | Complies with BP | — | NMT 2 ppm |
| Ammonia / ammonium | Passes USP test | — | — | NMT 5 ppm |
| Microbial contamination | — | Complies with BP | Complies with EP | Complies with JP |

A dash (—) means the parameter is not listed in that grade's datasheet. Values are shown in the units used by each monograph or datasheet, so exchange-capacity figures are not directly comparable across grades.

IONEX SC 28 is a sustained-release grade supplied as moist beads and is not included in this table. See its separate datasheet.

# Cholestyramine resins

Strongly basic anion exchange resin in BP, USP and EP grades

| Parameter | IONEX SB 43 BP | IONEX SB 45 USP | IONEX SB 48 EP |
|---|---|---|---|
| Generic name | Colestyramine | Cholestyramine Resin | Colestyramine |
| Pharmacopoeial standard | BP | USP | EP |
| Ionic form | Chloride | Chloride | Chloride |
| Appearance | White or almost white, hygroscopic powder | White to off-white, hygroscopic fine powder | White or almost white, hygroscopic powder |
| Matrix | — | Crosslinked styrene/DVB copolymer | — |
| Solubility | Insoluble in water, ethanol (96%) and methylene chloride | Insoluble in water, alcohol, chloroform and ether | Insoluble in water, ethanol (96%) and methylene chloride |
| Loss on drying | NMT 12% w/w | NMT 12% | NMT 12% w/w |
| Sulfated ash | NMT 0.1% w/w | — | NMT 0.1% w/w |
| Residue on ignition | — | NMT 0.1% | — |
| Elemental impurities | — | As reported (USP <232>/<233>) | — |
| Identity (IR spectrum) | Identical to Colestyramine CRS | Identical to USP reference standard | Identical to Colestyramine CRS |
| pH of slurry | 4.0 – 6.0 | 4.0 – 6.0 | 4.0 – 6.0 |
| Dialysable quaternary amine | NMT 500 ppm | NMT 0.05% | NMT 500 ppm |
| Chloride content | 13.0 – 17.0% (dried basis) | 13.0 – 17.0% (dried basis) | 13.0 – 17.0% (dried basis) |
| Sodium glycocholate exchange capacity | 1.8 – 2.2 g/g (dried basis) | 1.8 – 2.2 g/g (dried basis) | 1.8 – 2.2 g/g (dried basis) |
| Styrene | NMT 1 ppm | — | NMT 1 ppm |
| Particle size – retained on 100 BSS mesh | — | NMT 1% | — |
| Particle size – retained on 200 BSS mesh | — | NMT 45% | — |
| Residual solvents | — | Meets USP <467> | — |

A dash (—) means the parameter is not listed in that grade's datasheet. Values are shown in the units used by each monograph or datasheet, so exchange-capacity figures are not directly comparable across grades.

# Weak acid resins

Taste-masking and tablet-disintegrant grades

| Parameter | IONEX WC 20 | IONEX WC 23 | IONEX WC 29 USP–NF | IONEX WC 46 |
|---|---|---|---|---|
| Generic name | Taste-Masking Resin (Hydrogen form) | Tablet Disintegrant & Taste-Masking Resin | Polacrilin Potassium | Polacrilex Resin |
| Pharmacopoeial standard | — | — | USP–NF | — |
| Ionic form | Hydrogen | Potassium | Potassium salt | Hydrogen |
| Appearance | White to pale cream-coloured powder, free from foreign matter | White to off-white, free-flowing powder | White to off-white, free-flowing powder | White to pale cream-coloured powder |
| Matrix | Crosslinked acrylic polymer | Crosslinked acrylic polymer | Crosslinked acrylic polymer | — |
| Functional group | Carboxylic acid | Carboxylic acid | Carboxylic acid | — |
| Solubility | Insoluble in water and in common solvents | Insoluble in water and in common solvents | Insoluble in water and in common solvents | Insoluble in water and in common solvents |
| Particle size – retained on 100 BSS mesh | NMT 1% | NMT 1% w/w | NMT 1% w/w | NMT 1% |
| Particle size – retained on 200 BSS mesh | NMT 45% | NMT 30% w/w | NMT 30% w/w | NMT 45% |
| Moisture / loss on drying | NMT 5% | NMT 10% | NMT 10.0% | NMT 5% |
| Potassium content | — | 20.6 – 25.1% | 20.6 – 25.1% (dried basis) | — |
| Exchangeable potassium | — | NLT 5.25 meq/g (dry basis) | — | — |
| Residual methacrylic acid | — | — | NMT 200 ppm | — |
| Ion exchange capacity | NLT 10 meq/g (dry basis) | — | — | NLT 10 meq/g (dry basis) |
| pH of 10% slurry | — | 7.0 – 9.0 | 7.0 – 9.0 | — |
| Sodium content | — | NMT 0.2% | NMT 0.2% | — |
| Iron content, as Fe | NMT 100 ppm | NMT 100 ppm | NMT 100 ppm | NMT 100 ppm |
| Heavy metals, as Pb | NMT 20 ppm | NMT 20 ppm | NMT 20 ppm | NMT 20 ppm |
| Arsenic content, as As | NMT 3 ppm | NMT 3 ppm | NMT 3 ppm | NMT 3 ppm |

A dash (—) means the parameter is not listed in that grade's datasheet. Values are shown in the units used by each monograph or datasheet, so exchange-capacity figures are not directly comparable across grades.

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# Packing, storage and safety guide

Handling information for every IONEX grade

| Grade | Pack sizes | Storage | If moisture is absorbed, dry at | Acute toxicity, mice ($LD_{50}$) |
|---|---|---|---|---|
| **STRONGLY ACIDIC CATION EXCHANGE RESINS** | | | | |
| SC 25 | 5 · 20 · 40 kg | Free-flowing powder; tightly closed, shaded, away from sunlight | 90 – 100 °C, to below 10% moisture | approx. 10,000 mg/kg |
| SC 28 | 5 · 20 · 40 kg | Moist beads; tightly closed, shaded, away from sunlight | — | approx. 7,500 mg/kg |
| SC 40 | 6 · 20 · 40 kg | Dry powder; tightly closed, shaded, away from sunlight | 90 – 100 °C, to below 8% moisture | approx. 17,000 mg/kg |
| SC 42 | 6 · 25 · 40 kg | Dry powder; tightly closed, shaded, away from sunlight | 100 – 105 °C, to within LOD limit | approx. 10,000 mg/kg |
| SC 47 | 6 · 25 · 40 kg | Dry powder; tightly closed, shaded, away from sunlight | 100 – 105 °C, to below 8% moisture | approx. 17,000 mg/kg |
| **STRONGLY BASIC ANION EXCHANGE RESINS** | | | | |
| SB 43 | 6 · 25 · 40 kg | Hygroscopic; tightly closed container | Below 80 °C, ~6 h, to below 12% | Not absorbed (high-molecular-weight polymer) |
| SB 45 | 6 · 20 · 40 kg | Hygroscopic; tightly closed container | 90 – 100 °C, ~6 h, to below 12% | Not absorbed (high-molecular-weight polymer) |
| SB 48 | 6 · 25 · 40 kg | Hygroscopic; tightly closed container | Below 80 °C, ~6 h, to below 12% | Not absorbed (high-molecular-weight polymer) |
| **WEAKLY ACIDIC CATION EXCHANGE RESINS** | | | | |
| WC 20 | 6 · 20 · 40 kg | Hygroscopic; tightly closed container | 95 – 105 °C, ~6 h, to below 5% | approx. 5,000 mg/kg |
| WC 23 | 6 · 20 · 40 kg | Hygroscopic; tightly closed container | 95 – 105 °C, ~6 h, to below 10% | approx. 3,000 mg/kg |
| WC 29 | 5 · 20 · 40 kg | Hygroscopic; tightly closed container | 95 – 105 °C, ~6 h, to below 10% | approx. 3,000 mg/kg |
| WC 46 | 6 · 25 · 40 kg | Hygroscopic; tightly closed container | — | approx. 5,000 mg/kg |

**Primary packing**

**LDPE bags**

Direct product contact

**Secondary packing**

**HDPE carboys**

Outer container for transport

**Net weights**

**5 – 40 kg**

6, 20, 25 and 40 kg by grade (see table)

IONEX resins are high-molecular-weight polymers that are not absorbed by body tissues. Store all grades in tightly closed containers. Re-drying conditions apply only if moisture has been absorbed.

# 07 Technical notes

Abbreviations and important information

## Abbreviations

| | | | |
|---|---|---|---|
| **BSS** | British Standard Sieve (mesh size) | **LDPE** | Low-density polyethylene |
| **BP** | British Pharmacopoeia | **LOD** | Loss on drying |
| **DVB** | Divinylbenzene (crosslinker) | **meq** | Milliequivalent |
| **EP / Ph. Eur.** | European Pharmacopoeia | **NLT** | Not less than |
| **HDPE** | High-density polyethylene | **NMT** | Not more than |
| **ICH** | International Council for Harmonisation | **ppm** | Parts per million |
| **IR** | Infrared (spectroscopy) | **USP–NF** | United States Pharmacopeia–National Formulary |
| **JP** | Japanese Pharmacopoeia | **w/w** | Weight by weight |
| **LD50** | Median lethal dose | **WHO GMP** | World Health Organization good manufacturing practice |

## Reading the specifications

- Limits are those stated in each grade's datasheet. NMT means not more than and NLT means not less than.
- Exchange capacities are reported in the units of each monograph (mg/g, meq/g or mmol/g) and are not directly comparable between grades.
- Particle size is given as the percentage retained on the stated BSS mesh. 100 BSS mesh = 150 µm and 200 BSS mesh = 75 µm.
- Compendial grades conform to the monograph named on the datasheet. Please refer to the current edition of the relevant pharmacopoeia.

## Important information

To the best of our knowledge, the information contained in this publication is accurate. Phaex Polymers Private Limited maintains a policy of continuous development and reserves the right to amend the information given herein without notice. Performance as a taste-masking agent or disintegrant depends on the drug substance and formulation. NMT = not more than; NLT = not less than.

Taste-masking, sustained-release and disintegrant performance depends on the drug substance, dosage form and process. Users should confirm suitability in their own formulation before commercial use.

PHAEX POLYMERS
PRIVATE LIMITED
Synonym For Quality

# Let's talk resins

Samples, specifications and technical enquiries are welcome.


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