

PRODUCT DOCKET

doshion[®]
Translating Source Into Resource

API AND EXCIPIENTS FOR CREATIVE FORMULATION





About Doshion Group

Doshion started its journey by manufacturing Ion exchange resins & pharma polymers expanded in making water treatment plants & R.O. plants.

Doshion provides water and waste water management solutions to industry and public since 1975. With installation base in more than 59 countries and a strong workforce of qualified professionals, we deliver seamless and integrated solutions for all water management needs.

To suit precise needs of our customers in various segments and applications we operate on concept of strategic business units covering wide range of technologies and applications. The independent business streams are managed and maintained by top industry professionals ensuring the right solution for optimum performance and highest level of customer service.

Our head office is located in Ahmedabad-India to provide engineering support, technical expertise with full fledged marketing and service setup in India and abroad. The manufacturing and assembly centers are located in India.

Growth of business, together with our customer is imbibed in our culture and we are willing to learn and walk with our customers continuously to remain strong and add value to their business in improving their profitability and quality.

About Doshion Polyscience Pvt. Ltd.

The passion for chemistry has propelled us to constantly renovate ourselves and reinvent the chemistry behind Ion exchange resin.

DPSPL was carved out to offer comprehensive solutions to its customers with focused approach and the core competencies of providing performance oriented solutions to its customers world over. The division offer following range of products;

- **Water treatment grade of Ion Exchange Resins**
- **Special application of Ion Exchange Resins**
- **Pharmaceutical Polymers**
- **Water and Waste Water Treatment Chemicals**
- **Membrane Performance Chemicals**

Our performance chemicals are enriched through our diverse experience in water treatment, membrane technology, ion exchange process, molecular biology, polymer chemistry and so on.

The sprawling complex of the division with all international class facilities, which include the new age resin manufacturing plant, Membrane performance chemicals manufacturing, evaluation laboratory, pharma polymer manufacturing unit and world class R&D set up are the testimony towards our commitment to provide our customers the advanced solutions in water treatment / chemical treatment.



ACTIVE PHARMACEUTICAL INGREDIENTS (API)

GRADE	GENERIC NAME	PHYSICAL FORM	MATRIX	FUNC. GROUP	IONIC FORM	EXISTING pH	DMF	APPLICATION
P-504	(Sodium Polystyrene Sulphonate USP)/EP	Brown color powder	Styrenic	Sulphonic Acid	Na+	.--	US / EU	Sustained / Delayed release of Drugs (Dextrometharphan HBR / Psudoefidrine- HCL), Treatment of hyperkalemia
P-550	(Cholestyramine Resin USP)/EP	White powder	Styrenic	Quartenary Ammonical	Cl-	4.0 to 6.0	US/ EU	Cholesterol reduction, Control Release of Diclofenae pottasium
P-548	(Calcium Polystyrene Sulphonate BP / JP)	Cream to light brown color powder	Styrenic	Sulphonic Acid	Ca++	.	EU / JP	Sustained / Delayed release of Drugs, Dextrometharphan HBR / Psudoefidrine, Treatment of hyperkalemia

EXCIPIENTS - TASTE MASKING (Please ask our executives for product specific technical packge)

P-551	Polacrilex Resin USP	White powder	Methacrylic	COO-	H+	3.0 to 5.0	US / EU	Taste masking of bitter drugs , dextrometharphan HBR, Psudoefidrive HCL,Used to manufacture Nicotine Polacrilex USP, Stabilization of Vitamin B12
P-542	Weak Acid cation exchange resin	White powder	Acrylic	COO-	H+	3.0 to 5.0	US	Taste masking of bitter drugs in suspension / tablets like Norfloxacin & combinations
P-514	Weak Acid cation exchange resin	White powder	Acrylic	COO-	H+	3.0 to 5.0		Taste masking of bitter drugs in suspension / tablets like Ofloxacin & combinations
P-544 S	Polacrilin potassium USP	White powder	Methacrylic	COO-	K+	8.5 to 10.0	US	Taste masking of bitter drugs in suspension / tablets like Quinine sulphate, Zinc Sulphate, Corbohyl Iron
P-544 R	Weak Acid cation exchange resin	White powder	Acrylic	COO-	K+	9.5 to 10.5		Taste masking of bitter drugs in suspension / tablets like Roxithromycin
P-544 C	Weak Acid cation exchange resin	White powder	Methacrylic	COO-	K+	7.5 to 9.0		Taste masking of bitter drugs in suspension / tablets like Chloroquine phosphate, Zinc Gluconate
P-542 D	Weak Acid cation exchange resin	White powder	Acrylic	COO-	H+	3.0 to 5.0		Taste masking of bitter drugs in suspension / tablets like Dicyclomine HCL
P-544 DS	Polacrilin potassium USP	White to off white powder	Methacrylic	COO-	K+			Taste masking of API Like Zinc Sulphate, Chloroquine phosphate, Zinc Gluconate, Sildenafil Citrate, Sulfadoxine, Domperidone Maleate, Tadalafil, Pyrimethamine etc. in suspension / tablets
P-544 DS (CIPRO)	Potassium Salt of week acid cation resin	White to off white powder	Acrylic Metharylic	COO-	K+	8.0 to 10.0		Taste masking of ciprofloxacin Hcl for dry syrup

EXCIPIENTS - TABLE DISINTEGRATION

P-544 DS (Polyflash)	Polacrilin potassium USP	White powder	Methacrylic	COO-	K+		US	Tablet disintegration
P-544 D (Polyflash)	Polacrilin potassium USP	White powder	Methacrylic	COO-	K+		US	Super Disintegrant

PURIFICATION & SEPARATION

P-535	Strong Base Anion Exchange Resin	Gel type solid beads	Styrenic	Quartenary Ammonical	Cl-	4.0 to 6.0		Separation of Aminoacids, Enzymes & Alkloids
P 545 8x	Strong Acidic Cation Exchanger	Yellow to Light brown Solid base gel type	Styrenic	Sulphonic Acid	H+	2.0 to 4.0		Purification, Separation, Isolation of products Mfg. of Dextromethorphan Polistirex
P-520	Strong Base Cation Exchange Resin	Solid opaque beads	Styrenic	Sulphonic Acid	H+	2.0 to 4.0		Purification of Vitamin C

Excipient - Application



Tablet Disintegration

Polacrilin Potassium USP NF

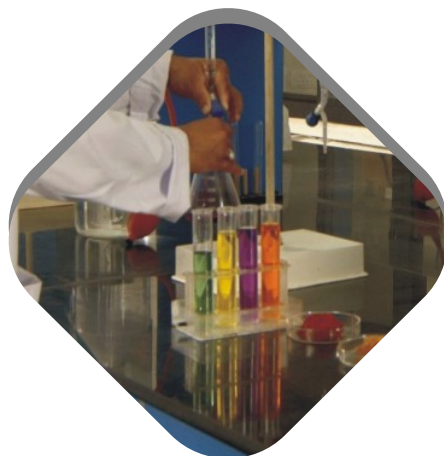
Polyflash - Doshion P544(D) & Doshion P544(DS)

- ◆ When polyflash comes in contact with water -
 - Resin particles rapidly hydrate
 - Resin expands in volume
 - Swells rapidly and wicks water into the particles by capillary action
 - Results in to faster disintegration
- ◆ Low Sodium content - good for Cardiac Patients
- ◆ No lump formation

Taste Masking

- ◆ An Ionic complex of the drug and an insoluble Polymer
- ◆ Little or no drug release in the mouth
- ◆ Drug is released in GI tract
- ◆ Excellent for taste masked suspension, DT Tablet, Logenges, MD Tablets and effervescent Tablets

Excipient - Application



Poorly Soluble Drug

- ◆ Slow dissolution due to insoluble API and / or crystal form of drug
- ◆ Use of resin can increase the dissolution by avoiding the reticular or crystal energy

Controlled Release / Sustain Release

- ◆ A right selection of resin can give controlled or sustain release up to several hours
- ◆ The Resinate controls the release of drug into the body
- ◆ Reduce the dosage frequency
- ◆ Further control can be obtained by coating on resinate
- ◆ Doshion P504 and Doshion P550 can be used for controlled release and sustained release application

Stabilization

- ◆ Stabilization of certain drug molecules are affected by environmental condition
- ◆ Loading drug on speciality resin can prevent the effect
- ◆ It increases the shelf life of drug molecule
- ◆ Vitamin B-12 is an example for stabilization

Purification & Separation of drug, use in mfg processes

- ◆ Enzymes, Alkaloids, Amino-acid needs purification & separation
- ◆ Ion exchange resin helps to achieve the desired results by selection of right resin
- ◆ Vitamin C mfg using Doshion P-520 resin
- ◆ Mfg of Dextromethorphan Polistirex

Process of Streptomycine

- ◆ Resin is used to purify and load the Sulphate Ion in the process of manufacturing Streptomycine Sulphate

Nicotine Polacrilex USP

- ◆ We manufacture Polacrilex Resin which is a key ingredient to manufacture the Nicotine Polacrilex USP
- ◆ The finish product goes into nicotine chewing gum

Active Pharmaceutical Ingredients - (API)



Calcium Polystyrene Sulfonate BP / JP-Doshion P548

Calcium Polystyrene Sulfonate is a Cation Exchange Resin prepared in the Calcium form. Each gram of Resin has a theoretical in vitro exchange capacity of about 1.3 to 2 mmol of Potassium. In vivo the actual amount of Potassium bound will be less than this. Calcium Polystyrene Sulfonate acts by a cumulative process throughout the GI Tract, removing Potassium Ions which are carried away in the feces. The typical dosage amounts are 15 - 60 gms per day.



Sodium Polystyrene Sulfonate USP-Doshion P504

The kidneys usually excrete excess Potassium Ion from the body. In case of severe Hyperkalemia, patients can be given a Cation Resin to bind with Potassium Ion. Sodium Polystyrene Sulfonate remains in intestine, where it adsorbs Potassium Ion and form a complex of Resin and excrete the Potassium Ion through feces.



Cholestyramine Resin USP / EP-Doshion P550

Cholestyramine Resin USP adsorbs and combines with the bile acids in the intestine to form an insoluble complex which is excreted in the feces. This results in a partial removal of bile acids from the enterohepatic circulation by preventing their absorption.

The increased fecal loss of bile acids due to Cholestyramine Resin leads to an increased oxidation of cholesterol to bile acids, a decrease in beta lipoprotein or low density lipoprotein plasma levels and a decrease in serum cholesterol level. The typical dosage amounts are 8 - 24 gms per day.

Doshion Pharma Polymer



Manufacturing Facility

- ◆ FDA approved manufacturing plant
- ◆ Compliance with cGMP norms
- ◆ GMP certification by Indian Health Authorities

Quality Control

- ◆ cGMP Compliance lab & ISO 9001 & 14001 certification
- ◆ Quality Control Lab is following all GLP norms
- ◆ Well equipped testing facility with all latest instruments
- ◆ Separate microbial testing available for micro tests
- ◆ Expert, Validated & trained analysts are responsible to perform day to day analytical work

Quality Assurance

- ◆ Product quality is ensured by Quality Assurance at every step from raw material to finished goods
- ◆ Quality Assurance ensures appliances of cGMP norms at every manufacturing process step
- ◆ Good documentation practices are followed to match regulatory requirement

Regularity Support

- ◆ Document related to plants are well maintained
- ◆ All registration documents are available on request
- ◆ Documents related to DMF

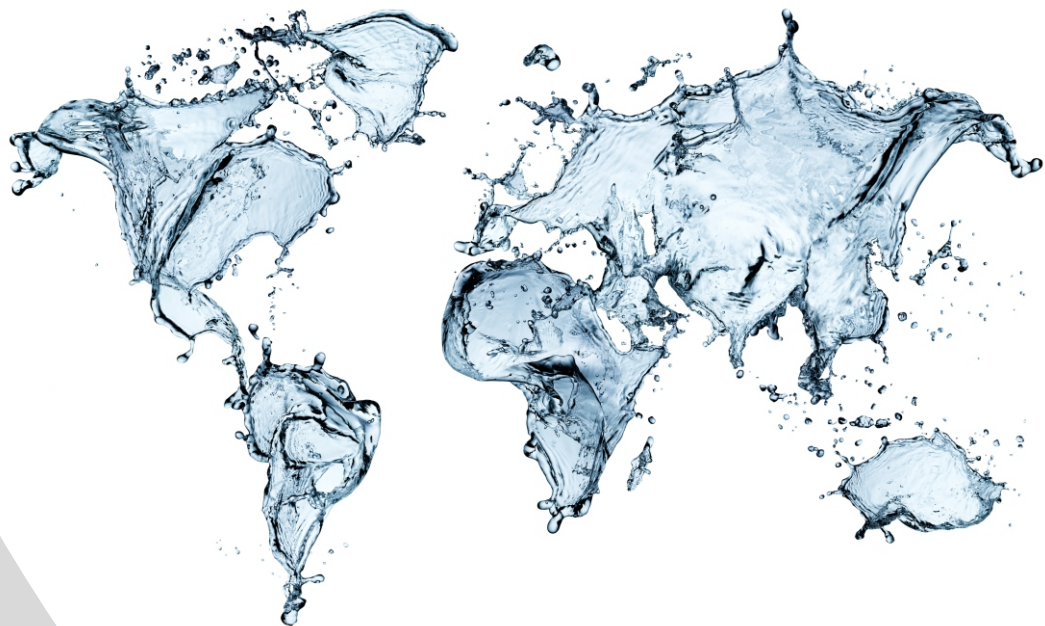
Research & Development and Application Centre

- ◆ Doshion Poly Science Pvt. Ltd. invests good amount of revenue in personnel, equipment & facility for R&D activity.
- ◆ State of the Art application lab consist of API, Liquid and Tablet application facilities
- ◆ We provide customized solution with technical support to our customers
- ◆ Experienced and dedicated scientist team which included polymer science graduated and chemical engineers for designing and developing polymer
- ◆ Our team is harnessing this advantage & breaking new grounds in developing polymer applications.

Packing

Sufficient amount of Phrma Polymers are kept in an inventory at the works and across the country with dealers for quick and responsive services. Doshion believes that the pharma industry needs Pharma Polymer at an even faster pace.

- ◆ Packing – 10kg, 20kg, 25kg and 50kg fiber drum



Doshion Global Footprint

Algeria	Oman
Australia	Pakistan
Bangladesh	Phillippines
Brazil	Poland
Canada	Portugal
Chile	Russia
Congo	Saudi Arabia
Czech Republic	South Africa
Dom. Republic	Spain
Egypt	Sri Lanka
Indonesia	Sweden
Iran	Syria
Israel	Taiwan
Italy	Tanzania
Japan	Thailand
Jordan	Tunisia
Kenya	Turkey
Latvia	U.S.A.
Lithuania	U.A.E.
Malaysia	Ukraine
Namibia	Vietnam
New Zealand	Zambia

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Translating Source Into Resource

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