





### VALENS PHARMACHEM PVT. LTD.

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## POLYMER BASED APIS, EXCIPIENTS AND **READY MIX**



## About us

Valens Pharmachem Pvt. Ltd. was established in 2016 in city of Ahmedabad, India and since then, it is growing rapidly and became one of the major player of the pharma and healthcare industry through constant innovation and research. The company is into manufacturing of polymer base APIs, Excipients, Intermediates and Ready-mix products.

Our State of the art facility is located in Nadiad, Gujarat. Valens Pharachem Pvt. Ltd.'s leadership has more than 100 years of combined experience in the Pharmaceutical Industry with respect to International & Domestic Marketing, R&D, Regulatory, Production, Quality Control & Quality Assurance.

### Our brands

Polyion | PolyGIT | HYDROSOL | Teisteint

### Vision

To serve the human beings with quality products at affordable prices by continuous development in drug delivery systems, technology, knowledge for excellent productivity to support formulation market.

### Mission

Our mission is to become global leader of the industry by constant innovation and development of products.

## Polyion<sup>®</sup> Taste Masking

**Product Name** 

: Polylon 900/Polylon 900(Azi)/ Polylon 927/Polylon 936/ Polylon 936(Cipro)/Polylon 1008

#### Application

Our Products are used in pharmaceutical formulations as a taste masking agent in Liquid Suspension, Mouth Dissolving/Chewable/Dispersible/Effervescent/ Lozenges tablets.

Pharmacopeial Name : In house product - crosslinked polymer of methacrylic acid, ethyl acrylate, acrylic acid and divinyl benzene with H<sup>+</sup>/K<sup>+</sup> /Na<sup>+</sup> as ionic form.

#### LIST OF APIS CAN BE TASTE MASKED USING POLYION PRODUCT RANGE

Polyion 900	Dimenhydrinate	Erythromycin Ethylsuccinate
Nystatin	Diphenhydramine Hcl	Ferrous Ascorbate
Roxithromycin	Erdosteine	Lamivudine
Polyion900 (AZI)	Famotidine Resinate	Ondansetron Hydrochloride
Azithromycin	Fluoxetine Hcl	Phenylephriene Hydrochloride
Polyion936 (CIPRO)	Ibuprofen Resinate	Pyridoxine Hcl
Ciprofloxacin	Levocetrizine	Pyrimethamine
Polylon 927	Levofloxacin	Quinine Sulphate
Ambroxol Hydrochloride	Meclizine Hcl	Racecadotril
Amisuipride Hcl	Mefenamic Acid With Paracetamol	Resperidone
Amodiaquine Hydrochloride	Moxifloxacin Suspension	Sildenafil Citrate
Atomoxetine Hcl	Norfloxacin Metronidazole	Sulfadoxine
Azelnidipine	Ofloxacin Suspension	Tadalafil
Cefixime Trihydrate	Paracetamol Suspension	Zinc Gluconate
Cetrizine Hcl	Pentoprazole Sodium Sesquihydrate	Zinc Sulphate
Cetrizine Hcl	Quinine Bisulphate	Polyion 954
Clonazepam	Polyion 936	Lincomycin Hcl
Dexibuprofen	Acetylcysteine	Polyion 1008
Dextromethorphan Hbr	Chloroquin Phosphate	Cephodoxime Proxetil
Dicycloamine Hcl	Domperidone	Cephodoxime Axitel   Linezolic
Dicyclomine Simethicone	Domperidone Meleate	Piperaquine Phosphate
Dihydroartemissinin	Erythromycin Estolate	Prednisolone Sodium Phosphat



#### Advantages

- Excellent taste masking of bitter drugs.
- Compatible with most of the drugs.
- Fine particles of polymer helps better adsorption leading to better taste masking.



## **Tablet Disintegration**

**Product Name** 

: Polylon 909 / Polylon 918

Pharmacopeial Name : Polacrillin Potassium USPNF

#### Application

Polyion 909 / Polyion 918 is having swelling capacity & wicking capacity ensures super fast disintegration of solid dosage form like table, capsules, pellets, ODT & other tables.

Quantity of Polyion 909/ Polyion 918 is from 0.5 to 10% of tablet weight.

## **Tablet Dissolution**

**Product Name** 

: Polylon 909 / Polylon 918

: Polacriline Potassium

USPNF

#### Pharmacopeial Name

#### Application

Our Products are used in pharmaceutical formulations as a dissolution enhancer in solid dosage forms like tablets, capsules, pellets etc. Example of dissolution - Cefuroxime Axetil, Cefpodoxime Proxetil, Atorvastatin Calcium, Telmisartan, Glimepiride, Gliclazide, Ondansetron etc.

## Sustain And **Control Release**

**Product Name** 

**Application** 

: Polylon 945 / Polylon 954 / Polylon 963 / Polyion 981 / Polyion 990

#### Pharmacopeial Name : In-house - Polistirex Resin,

Styrene Polymer - H<sup>+</sup>/ Na<sup>+</sup>/ Ca<sup>+2</sup>/Cl<sup>-</sup>

#### Our Products are used in pharmaceutical formulations as a sustain & control release polymer in Liquid Suspension, Mouth Dissolving/ Chewable/ Dispersible / Effervescent / Lozenges tablets and even Enteric Release of tablets.

#### **Advantages**

- Super fast disintegration agent
- Elimination of lump formation
- Suitable for both direct compression & wet granulation



#### **Advantages**

Improve dissolution by 5-10% by removing crystal energy or reticular energy of API. We recommend Addition of 50% in granulation and 50% in lubrication (of total usage) helps improve dissolution



#### **Advantages**

Can design sustain release in liquid formulation like cough suppressant and gives 12 hours release. Customized drug release profile can be achieved based on the requirement of API.



## **APIs**

Polylon 945	: Calcium Polystyrene Sulfonate BP/JP
Polylon 954	: Sodium Polystyrene Sulfonate USP/ EP

#### **Application:**

Calcium Polystyrene Sulfonate BP/JP and Sodium Polystyrene Sulfonate USP/EP is medicine used to help remove excess amount of potassium from the blood for Hyperkalemia patients.

## Stabilization of **APIs Product**

**Product Name** : Polylon 972 Pharmacopeial Name : Polacrilex Resin (Ref - Handbook of excipient) Application

Our Products are used as Stabilizer Polymer for pharmaceutical APIs which are not stable at environment condition such as Vitamin B12.

## Nicotine Polacrilex USP

**Product Name** 

: Polylon 972

Pharmacopeial Name : Polacrilex Resin

(Ref - Handbook of excipient)

#### Application

The finish product API - Nicotine Polacrilex USP used in Nicotine chewing gum, lozenge and chewable tablet of nicotine which helps to guit smoking.



#### Polylon 963 **Application:**

#### : Cholestyramine Resin USP/EP

Cholestyramine is a bile acid sequestrant used as an adjunt in the reduction of elevated serum cholesterol in patients with primary Hypercholesterolemia.



#### **Advantages**

Polymer binding will help to improve stabilization of those APIs Loading of drug on resin help to reduce the effect of environmental condition



#### **Advantages**

We manufacture Polacrilex Resin which is a key intermediate to manufacture NICOTINE POLACRILEX USP. Our Polacrilex Resin is matching as per USP reference standard.



# PelyGIT

### **VERSATILE POLYMERS FOR ORAL SOLID DOSAGE FORMULATIONS**

Applications	PolyGit Grades	Product Form	Functionality	<b>Dissolution Properties</b>
Drug delivery	Polygit L 30 D-55	Aqueous Dispersion 30 %		Dissolution
in duodenum	Polygit L 100-55	Powder	Anionic polymers with methacrylic acid as a functional group	above pH 5.5
Drug delivery	Polygit L 100	Powder		Dissolution above pH 6.0
in jejunum	Polygit L 12,5	Organic Solution 12.5 %		
	Polygit S 100	Powder		
Colon delivery	Polygit S 12,5	Organic Solution 12.5 %		Dissolution
	Polygit FS 30 D	Aqueous Dispersion 30 %		above pH 7.0

## **Protective Formulations**

Insulating coatings: • Taste masking	Polygit E 100	Granules	Cationic polymer with	Soluble in gastric fuid up to pH 5.0
Odor masking	Polygit E 12,5	Organic Solution 12.5 %	dimethylaminoethyl methacrylate as a	
<ul><li>Moisture protection</li><li>Light protection</li></ul>	Polygit E PO	Powder	functional group	above pH 5.0

## Sustained-Release Formulations

Sustained	Polygit RL 30 D Polygit RL PO Polygit RL 100 Polygit RL 12,5	Aqueous Dispersion 30 % Powder Granules Organic Solution 12.5 %	Meth-/acrylate copolymers with trimethyl- ammonioethyl- methacrylate as a functional group	e Insoluble High permeability pH independent swelling
release formulations	Polygit RL 30 D Polygit RL PO Polygit RL RS Polygit RL 12,5	Aqueous Dispersion 30 % Powder Granules Organic Solution 12.5 %		Insoluble Low permeability pH independent
Sustained release formulations, suitable for matrix structures and miscible with other Polygit grades	Polygit RL 30 D Polygit RL 40 D Polygit NM 30 D	Aqueous Dispersion 30 %Aqueous Dispersion 40 %Aqueous Dispersion 30 %	Neutral polymer of meth-/acrylates	swelling

## Series of Polygit

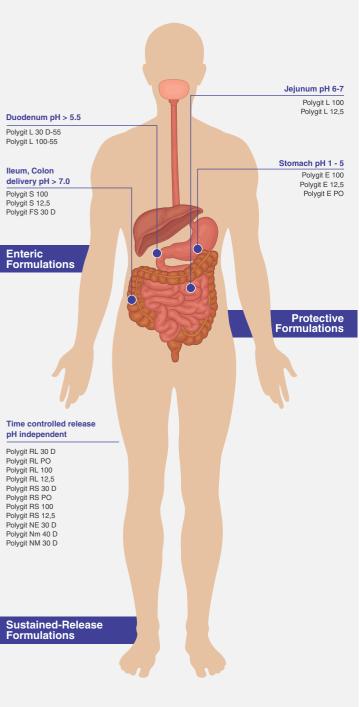
L Series | S Series | E Series | RL Series | RS Series

Advantages	Monographs	
Effective and stable enteric oatings with a fast dissolution in the upper bowel	Ph. Eur., USPNF, JPE	
Granulation of drug substances in powder form for controlled release	Ph. Eur., USPNF, JPE	
Site specifc drug delivery in intestine by combinations L/S of grades Variable release profles	Ph. Eur., USPNF, JPE	

Low viscosity, high pigment binding capacity, good adhesion, low polymer weight gain	Ph. Eur., USPNF, JPE
	Ph. Eur., JPE,

Customized release profles by combination	USPNF
	Ph. Eur., USPNF, JPE
of RL and RS	
grades in diferent ratios Suitable for matrix structures	USPNF
	Ph. Eur., USPNF, JPE
No plasticizer required,	Ph. Eur., USPNF, JPE
highly fexible Suitable for matrix structures	
	Ph. Eur.





## **HYDROSOL**

Hydrosol grades are chemically castor oil derivatives. They are non-ionic solubilizers and emulsifying agents obtained by reacting hydrogenated castor oil with ethylene oxide. They consist hydrophobic and hydrophilic part. They are almost tasteless and odorless. They are used as solubilizer for fat-soluble vitamins, perfumes, essential oils and other hydrophobic pharmaceuticals.

They have ability to solubilize or emulsify oil soluble ingredients and convert them into clear transparent solution or stable emulsion respectively. It improves the solubility of poorly soluble drugs. It improves the solubility of poorly soluble drugs.

Characteristics	Hydrosol 35	Hydrosol 40	Hydrosol 50
Pharmacopoeial	Polyoxyl 35 Castor Oil	PG, PEG-40	Polyoxyl 40 Hydrogenated
Monograph	USPNF.	Hydrogenated Castor Oil	Castor Oil USPNF and
	Ph. Eur: Macrogolglycerol	Ph. Eur:Macrogolglycerol	Propylene glycol USPNF
	Ricinoleate	Hydroxystearate	
Description	Yellow oily Liquid	White to pale yellow	White to pale yellow
		viscous liquid or soft	
		thin paste	
Odor	Odorless	Odorless	Odorless
Taste	Tasteless	Tasteless	Tasteless
Miscibility	At elevated temperature, it forms clear mixtures with fatty acid and fatty alcohols		
Effect of temperature	Hydrosol grades are stable and does not turn rancid unless subjected to excessive heat		

## **Applications**

Solubilizer : Hydrosol range improves water solubility of major water insoluble products. It is compatible with almost all actives.

**Dissolution Improver :** It is generally used between 3.0% to 5.0% w/w to improve dissolution of poorly soluble actives.

Emulsifier: Hydrosol range is excellent versatile nonionic emulsifying agent. It is suitable to obtain O/W cream and lotions.

Moisturizer : Hydrosol range improves moisturizing effect and soft feeling.

Transparency Improver : It solubilizes insoluble oily substances in aqueous system and hence it improves transparency and shining.

Volatility Retardant : Hydrosol range has capability to retard volatilities of solvents.

Film Former : Hydrosol is preferred in cream, lotion, lipstick etc. to improve film forming capacity.

Masking Agent : Hydrosol masks unpleasant taste and odor of typical formulations.

# Testent

We manufacture speciality taste masked granules, Sustain release granules, DC granules and Dry powder suspension granules which help customer to reduce their process and have better consistent result.

## Our products

Product Name	Product Name	Strength of API Formulation
Tastant	Azithromycin Taste Masked Granules	7.5% , 15%, 22.5%
(Taste masked	Ciprofloxacin Taste Masked Granules	20%, 30%, 40%
ready to fill or use	Clarithromycin Taste Masked Granules	27.5%
Granules)	Sildenafil citrate Taste Masked Granules	10%, 27%
	Cefuroxime Axitel Taste Masked Granules	
	Cefpodoxime Proxetil Taste Masked Granules	
DC Granules	Metformin Sustain Release Granules	SR Granules
	Telmisartan Immediate Release Granules	IR Granules





## Facility

## Manufacturing Facility

- FDA approved manufacturing plant
- Compliance with latest cGMP norms
- GMP & WHO GMP certificate by Indian drug authority
- All equipment have IQ/OQ/PQ/DQ documentation
- Class 1lac/Hepa filters in manufacturing plant



## QC lab

- cGMP & GLP compliance laboratory facility.
- All equipment like HPLC, GC, AAS, KF titrator, UV, Viscometers are available
- ISO 9001:2015, 14001:2015 & 1725:2017 compliant lab.
- Separate and fully equipped Microbial Lab is available
- Validated, trained & knowledgeable manpower to conduct all quality analysis.



## **Quality Assurance**

- cGMP norms & SOPs are followed at each & every step in Production, QC, Micro, Store & all department.
- GDP (Good Documentation Practice) is followed by QA team to ensure all regulatory compliances.
- Quality management system is implemented.



## **Regulatory Support**

- Tech pack document are available for all our products.
- DMF/CEP based documents are available for our KEY APIs & Excipients.
- Stability data, characterisation of product Nitrosamine impurity, Elemental impurities & other documents are available on request.

## Formulation, **Research & Development**

- We have full fledge formulation application development lab.
- Our FR&D support on formulation and development provide innovative solution for formulation
- Our R&D has polymer development facility with all required R&D equipments.
- Dedicated investment and man power for R&D and application lab.

## Packaging

## 5kg | 10kg | 20kg | 25kg | 50kg | 60kg









