

# Polacrilin Potassium

## 1 Nonproprietary Names

USPNF: Polacrilin potassium

## 2 Synonyms

Amberlite IRP-88; methacrylic acid polymer with divinylbenzene, potassium salt; polacrilinum kalii.

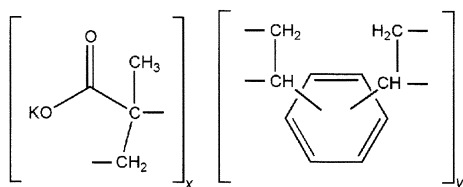
## 3 Chemical Name and CAS Registry Number

2-Methyl-2-propenoic acid polymer with divinylbenzene, potassium salt [39394-76-5]

## 4 Empirical Formula      Molecular Weight

See Sections 5, 13, and 18.

## 5 Structural Formula



## 6 Functional Category

Tablet and capsule disintegrant.

## 7 Applications in Pharmaceutical Formulation or Technology

Polacrilin potassium is a cation-exchange resin used in oral pharmaceutical formulations as a tablet disintegrant.<sup>(1-3)</sup> Concentrations of 2–10% w/w have been used for this purpose although 2% w/w of polacrilin potassium is usually sufficient. Other polacrilin ion-exchange resins have been used as excipients to stabilize drugs, to mask or modify the taste of drugs, and in the preparation of sustained-release dosage forms<sup>(4)</sup> and drug carriers.

Polacrilin resins are also used in the analysis and manufacture of pharmaceuticals and food products.

## 8 Description

Polacrilin potassium occurs as a cream-colored, odorless and tasteless, free-flowing powder. Aqueous dispersions have a bitter taste.

## 9 Pharmacopeial Specifications

See Table I.

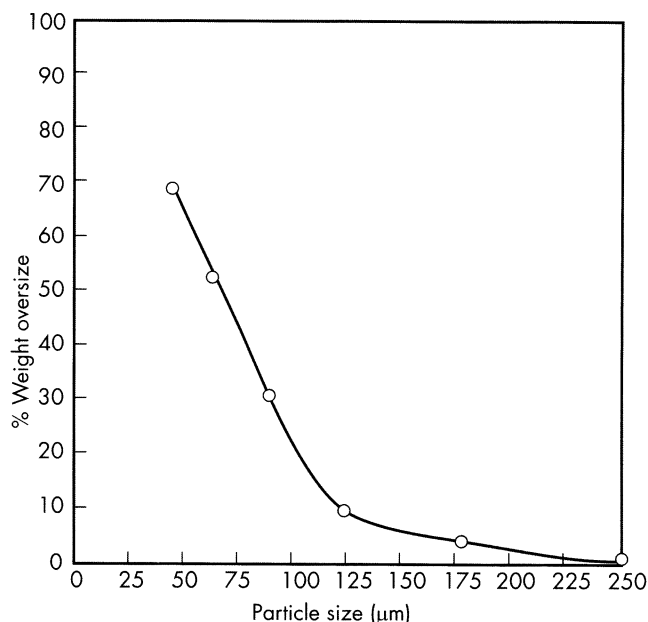


Figure 1: Particle size distribution of polacrilin potassium (Amberlite IRP-88).

Table I: Pharmacopeial specifications for polacrilin potassium.

Test	USPNF 20
Identification	+
Loss on drying	≤ 10.0%
Powder fineness	≤ 1.0% on a #100 mesh ≤ 30.0% on a #200 mesh
Iron	≤ 0.01%
Sodium	≤ 0.20%
Heavy metals	≤ 0.002%
Organic volatile impurities	+
Assay of potassium (dried basis)	20.6%–25.1%

## 10 Typical Properties

Density (bulk): 0.48 g/cm<sup>3</sup> for Amberlite IRP-88.<sup>(3)</sup>

Density (tapped): 0.62 g/cm<sup>3</sup> for Amberlite IRP-88.<sup>(3)</sup>

Particle size distribution: see Figure 1.<sup>(3)</sup>

Solubility: practically insoluble in water and most other liquids, although polacrilin resins swell rapidly when wetted.

## 11 Stability and Storage Conditions

Polacrilin potassium and other polacrilin resins are stable to light, air, and heat up to their maximum operation temperature; see Table II. Excessive heating can cause thermal decomposition of the resins and may yield one or more oxides of carbon, nitrogen, sulfur, and/or amines.

Polacrilin resins should be stored in well-closed containers in a cool, dry place.

**Table II:** Summary of physicochemical properties of pharmaceutical grade Amberlite resins.

Amberlite Grade	Copolymer	Type	Functional structure	Ionic form	Particle size (mesh)	Parent resin	Maximum moisture (%)	pH range	Maximum temperature (°C)	Application
<b>Cation-exchange resins</b>										
IRP-69	Styrene and DVB <sup>(a)</sup>	Strongly acidic	SO <sub>3</sub> <sup>-</sup> Na <sup>+</sup>	Na <sup>+</sup>	100–500	IR-120	10	0–14	120	Carrier for cationic drugs that are bases or salts
IRP-64	Methacrylic acid and DVB	Weakly acidic	COO <sup>-</sup> H <sup>+</sup>	H <sup>+</sup>	100–500	IRC-50	10	5–14	120	Carrier for cationic drugs
IRP-88	Methacrylic acid and DVB	Weakly acidic	COO <sup>-</sup> K <sup>+</sup>	K <sup>+</sup>	100–500	IRC-50	10	5–14	120	Tablet disintegrant
<b>Anion-exchange resins</b>										
IRP-58	Phenolic polyamine	Weakly basic	NH <sub>2</sub> NH <sub>2</sub>	Free base	100–500	IR-4B	10	0–7	60	Carrier for anionic drugs that are acids
IRP-67	Styrene and DVB	Strongly basic	N(CH <sub>3</sub> ) <sub>3</sub> <sup>+</sup> Cl <sup>-</sup>	Cl <sup>-</sup>	100–500	IRA-400	10	0–12	60	Carrier for anionic drugs that are acids or salts

Note that all of the above grades, with the exception of Amberlite IRP-88, are available in particle-size grades < 325 mesh.

<sup>(a)</sup> DVB: divinylbenzene.

## 12 Incompatibilities

Incompatible with strong oxidizing agents, amines, particularly tertiary amines, and some other substances that interact with polacrillin resins.<sup>(5)</sup>

## 13 Method of Manufacture

Polacrillin resin (Amberlite IRP-64) is prepared by the copolymerization of methacrylic acid with divinylbenzene (DVB). Polacrillin potassium (Amberlite IRP-88) is then produced by neutralizing this resin with potassium hydroxide.

Other resins are similarly produced by copolymerization between styrene and divinylbenzene (Amberlite IRP-69, Amberlite IRP-67, Amberlite IR-120, and Amberlite IRA-400). Phenolic-based polyamine condensates (Amberlite IRP-58) may also be produced.

The homogeneity of the resin structure depends on the purity, nature, and properties of the copolymers used as well as the controls and conditions employed during the polymerization reaction. The nature and degree of crosslinking have significant influence on the physicochemical properties of the resin matrix. The functional groups introduced on the matrix confer the property of ion exchange. Depending upon the acidity or basicity of the functional groups, strongly acidic to strongly basic types of ion-exchange resins may be produced.

## 14 Safety

Polacrillin potassium and other polacrillin resins are used in oral pharmaceutical formulations and are generally regarded as nontoxic and nonirritant materials. However, excessive ingestion of polacrillin resins may disturb the electrolyte balance of the body.

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Polacrillin potassium may be

irritating to the eyes; eye protection and gloves are recommended.

## 16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (oral capsules and tablets).

## 17 Related Substances

Polacrillin.

### Polacrillin

CAS number: [54182-62-6]

Synonyms: Amberlite IRP-64; methacrylic acid polymer with divinylbenzene; 2-methyl-2-propenoic acid polymer with divinylbenzene.

See also Section 18.

## 18 Comments

A number of other polacrillin (Amberlite) resins are commercially available that have a variety of industrial and pharmaceutical applications; see Table II.

## 19 Specific References

- 1 Van Abbé NJ, Rees JT. Amberlite resin XE-88 as a tablet disintegrant. *J Am Pharm Assoc (Sci)* 1958; 47: 487–489.
- 2 Khan KA, Rhodes CT. Effect of disintegrant concentration on disintegration and compression characteristics of two insoluble direct compression systems. *Can J Pharm Sci* 1973; 8: 77–80.
- 3 Rudnic EM, Rhodes CT, Welch S, Bernardo P. Evaluation of the mechanism of disintegrant action. *Drug Dev Ind Pharm* 1982; 8: 87–109.
- 4 Smith HA, Evanson RV, Sperandio GJ. The development of a liquid antihistaminic preparation with sustained release properties. *J Am Pharm Assoc (Sci)* 1960; 49: 94–97.

- 5 Borodkin S, Yunker MH. Interaction of amine drugs with a polycarboxylic acid ion-exchange resin. *J Pharm Sci* 1970; **59**: 481-486.

**20 General References**

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**21 Author**

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**22 Date of Revision**

30 May 2002.