



# AMBERLITE® IRP88

Pharmaceutical Grade Cation Exchange Resin

## (POLACRILIN POTASSIUM NF)

### PRODUCT DATA SHEET

AMBERLITE IRP88<sup>[1]</sup> resin is a weakly acidic potassium form cation exchange resin supplied as a dry powder. It is widely used as a tablet disintegrant in oral dosage formulations of drug products. AMBERLITE IRP88 resin is the potassium salt of a crosslinked polymer derived from methacrylic acid. Its swelling properties upon hydration provide its utility as a tablet disintegrant. AMBERLITE IRP88 resin has been proposed for use in taste masking applications, specifically for B-lactam antibiotics.

Letters of authorization granting access to the file by FDA in support of NDA and ANDA submittals will be provided upon request. Similar help can also be offered in support of the registration of formulations containing AMBERLITE IRP88 in many other countries worldwide. AMBERLITE IRP88 resin is manufactured in accordance with Good Manufacturing Practices (cGMP) for bulk pharmaceutical chemicals.

#### IDENTIFICATION

AMBERLITE IRP88 can be identified by infrared spectroscopy, as shown in the example in Figure 1.

#### TYPICAL PHYSICAL PROPERTIES

AMBERLITE IRP88 resin complies with the compendial specifications for Polacrillin Potassium NF when tested in conformance to the compendial test methods presented in USP 23/NF18.

These compendial properties are shown below A Drug Master File for this product is maintained with the United States Food and Drug Administration.

Amberlite IRP88 IR Spectrum

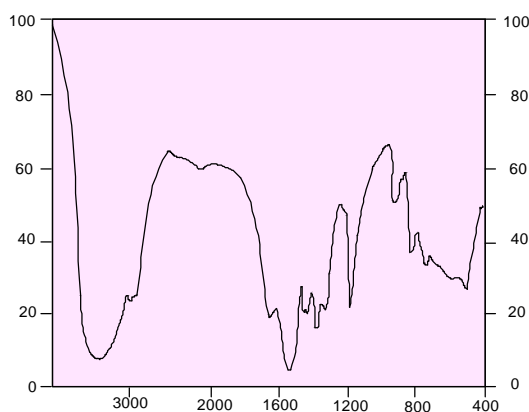


Figure 1

TABLE I : TYPICAL PHYSICAL PROPERTIES

Identity (by IR Spectrum) _____	Identical to USP reference standard
Loss on Drying <sup>[2]</sup> <sup>[3]</sup> _____	10.0 % maximum
Powder Fineness	
0.075 - 0.150 mm <sup>[2]</sup> <sup>[3]</sup> _____	30.0 % maximum
> 0.150 mm <sup>[2]</sup> <sup>[3]</sup> _____	1.0 % maximum
Iron <sup>[2]</sup> <sup>[3]</sup> _____	100 ppm maximum
Sodium <sup>[2]</sup> <sup>[3]</sup> _____	0.20 % maximum
Heavy Metals <sup>[2]</sup> <sup>[3]</sup> _____	0.002 % maximum
Potassium <sup>[2]</sup> <sup>[3]</sup> _____	20.6 % to 25.1 %
Residual Methacrylic acid <sup>[3]</sup> _____	200 ppm max.
Organic Volatile Impurities <467> <sup>[3]</sup> _____	Meets requirements

<sup>[1]</sup> The use of AMBERLITE pharmaceutical grade ion exchange resins as components of drug formulations is subject to the Food, Drug and Cosmetic Act as amended

<sup>[2]</sup> Appears in USP23/NF18, pp2278-2279.

<sup>[3]</sup> Contractual value





