

ISO 9001:2015, EXCIPACT CERTIFIED DATE OF REVISION: MAY, 2018

<u>ACRYPOL 974P</u> (Carbomer Homopolymer Type B)

INCI Name: Carbomer CAS No: 9003-01-4 US DMF Registration: 20139, 9th January, 2007

Description:

Acrypol 974P is a synthetic high molecular weight cross linked acrylate polymer. It offers excellent stability at medium and high viscosity and has short flow properties in aqueous system. It is high purity grade which confirms to USP/ NF specifications. It is specially used in oral care formulations of pharmaceutical industries as a thickening, suspending and emulsifying agent. It can be used in liquid or semi-solid oral dosage forms and also in tablets formulations for binding and sustained release formulations. It is benzene free grade of Acrypol 934P.

Typical Applications:

- Sustained release formulations
- Tooth paste
- Skin drug delivery
- Ophthalmic gel and eye lotions
- Taste masking
- Suspension and emulsion

Typical Physical Properties:

Parameter	Typical Properties
Appearance	White, hygroscopic, fluffy powder
Odor	Slight characteristic odor
Brookfield Viscosity	25,000 – 45,000 mPa·s
(25°C, 0.5% aqueous gel neutralized)	
Limit of Benzene	NMT 2 (µg/g)
Loss on Drying	NMT 2.0%
Residual Solvent	
Ethyl Acetate	0.5%
Cyclohexane	0.3%

Advantages:

- High viscosity at low concentration.
- There is no significant effect of temperature on viscosity performance.
- Carbomer gives uniform viscosity performance.

- Excellent shelf life.
- Years of successful use of Carbomer.
- Resists bacterial attack and do not supports mould growth.
- Although primarily used in aqueous system with neutralization, it can also be used in solvent systems, with or without neutralization.
- Smooth and luxurious feeling.

Regulatory Status:

United States (USP/NF)

Carbomer Homopolymer Type B

Europe (Ph. Eur.)

Carbomers (The Carbomers Monograph in the European Pharmacopoeia stipulates that benzene is limited to 2 ppm)

Japan (JPE)

Carboxyvinyl Polymer

Neutralizers:

Acrypol polymers are dry, highly coiled acidic molecules. After dispersion in water, it begins to hydrate and partially uncoil. Maximum thickening can be achieved by converting the acidic Acrypol polymer to neutral pH.

Neutral pH is easily achieved by neutralizing the Acrypol range with recommended neutralizers to adjust the pH of Acrypol range solution are:

- Sodium hydroxide (NaOH),
- Potassium hydroxide (KOH),
- Triethanolamine (TEA),
- Ammonia (28%) & other alkalies.

Toxicity:

Acrypol range is high molecular weight polymer. It does not absorbed by body tissues and is totally safe for human oral consumption.

Test for toxicological tolerance shows that it does not have any pronounced, physiological action and is non-toxic.

Storage and handling:

Store in a tightly closed container and away from direct contact with water and excessive humidity condition.

Shelf life:

Three years from the date of manufacturing in intact condition.

Packing:

20 kg net in corrugated box with polyethylene liner.

ACRYCOAT – ACRYPOL – ACRYSOL – COLORCOAT - KYRON THE NEXT GENERATION POLYMER TECHNOLOGIST