

Excipients for oral solids, solutions, and suspensions

The Health business of Lubrizol Life Science (LLS Health) offers an array of solutions for oral drug delivery, including extended-release, taste masking, rheology and mucoadhesive pharmaceutical excipients. We combine in-depth understanding of drug delivery systems with a portfolio of specialty materials to deliver application-specific solutions to ease your development process, for both prescription and over-the-counter drug products.

Our Carbopol® polymers, Pemulen™ polymers, and Noveon® polycarbophil have been used successfully in prescription and over-the-counter commercial formulations for decades, allowing for efficient rheology modification, extended drug release, taste masking, and mucoadhesion and are listed at various strengths in the FDA Inactive Ingredient Database.

Oral Treatment Applications - All polymers listed in the chart below are suitable for use in oral applications and are present in commercialized oral products.

| Product Trade Name | Suspensions or Solutions | Extended Release (Tablets and Capsules) | Bioadhesive Applications |
|--------------------------------|--------------------------|--|--------------------------|
| Carbopol® 971P NF polymers | • | • | • |
| Carbopol® 71G NF polymers | _ | • | • |
| Carbopol® 974P NF polymers | • | • | • |
| Noveon® AA-1 Polycarbophil USP | • | _ | • |



Enabling innovation through our multifunctional excipients, which are:

- Compatible with a broad spectrum of active pharmaceutical ingredients (APIs), and co-excipients
- Highly **efficient** at low polymer usage levels
- Ideal for imparting rheology properties to oral liquids and stability for permanent suspensions, at low inclusion levels (0.2 - 1%)
- Effective extended release polymers, with the ability to produce smaller, easier to swallow tablets compared to other polymers such as cellulosics (typical use level 5 - 30%)
- Available in both powder and granular forms (Carbolpol® 71G NF polymers) and can be used in all types of tablet manufacturing processes (wet and dry granulation, direct compression) without the addition of a tablet binder.
- Impart functional attributes such as bioadhesion and taste-masking
- Proven safe for **oral** administration
- Compliant with global pharmacopeial and regulatory requirements

| Product Trade Name | Polymerization Solvent | United States (USP/NF) | Europe (Ph. Eur.)/ India (I.P.) | Japan (JPE) ¹ | China (Ch.P.) |
|-----------------------------------|---------------------------|-----------------------------|------------------------------------|--------------------------|-------------------------|
| Carbopol® 971P NF polymers | Ethyl Acetate | Carbomer Homopolymer Type A | Carbomers | Carboxyvinyl Polymer | Carbomer Homopolymer |
| Carbopol® 71G NF polymers | Ethyl Acetate | Carbomer Homopolymer Type A | Carbomers | Carboxyvinyl Polymer | Carbomer Homopolymer |
| Carbopol® 974P NF polymers | Ethyl Acetate | Carbomer Homopolymer Type B | Carbomers | Carboxyvinyl Polymer | Carbomer Homopolymer |
| Noveon® AA-1 Polycarbophil USP | Ethyl Acetate | Polycarbophil | _ | - | Carbomer Homopolymer |

¹Based on customer request, Lubrizol certifies select lots of product against the JPE Carboxyvinyl Polymer monograph.

Formulating with confidence: Our Excipients:

- Are manufactured under GMPs in ISO:9001 certified facilities
- Have established DMFs
- Have been extensively tested for safety

Partnering for all Development Phases:

- Worldwide technical and application support services
- Dedicated global regulatory staff and quality assurance



- Sustainable supplier owned by Berkshire Hathaway
- Decades of manufacturing and polymer expertise

Driven by Consumers:

- Improving patient lives by providing a full excipient portfolio for nearly all dosage forms
- Advancing innovation by progressing partner products quickly to market
- Proactively responding to ever-changing regulatory and market needs



9911 Brecksville Road Cleveland, OH 44141-3201 USA

Lubrizol.com/Health

The information contained herein is believed to be reliable, but no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for particular applications or the results to be obtained. The information often is based on laboratory work with small-scale equipment and does not necessarily indicate end-product performance or reproducibility. Formulations presented may not have been tested for stability and should be used only as a suggested starting point. Because of the variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the products for the applications disclosed. Full-scale testing and end-product performance are the responsibility of the user. Lubrizol Advanced Materials, linc, shall not be liable for and the customer assumes all risk and liability for any use or handling of any material beyond Lubrizol Advanced Materials, linc's direct control. The SELLER MAKES NO WARRANTIES, EXPRESS OR IMPLED, INCT LIMITED TO, THE IMPLED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Nothing contained herein is to be considered as permission, recommendation nor as an inducement to practice any patented invention without permission of the patent owner. Lubrizol Advanced Materials, inc., is a wholly owned subsidiary of The Lubrizol Corporation.