Frequently Asked Questions

1. **Which products does Lubrizol recommend for controlled release matrix tablets and what are the properties of these products?**

   The products that Lubrizol recommends for use in controlled release matrix tablets are Carbopol® 71G NF, Carbopol® 971P NF and Carbopol® 974P NF polymers. These polymers are manufactured in ethyl acetate which is a Ph. Eur./USP/ICH Class III solvent with GRAS status.

   Some commercially available formulations contain Carbopol® 934P NF polymer which is polymerized in benzene. This material should not be used for new product development due to regulatory restrictions on the presence of benzene in pharmaceutical products.

2. **What are the key differences between the granular and powder grades of Carbopol® polymers?**

   Lubrizol manufactures several powder grades of Carbopol® polymers for oral solid dosage forms such as Carbopol® 971P NF polymer and Carbopol® 974P NF polymer. A granular grade (Carbopol® 71G NF polymer) is manufactured by roller compaction of Carbopol® 971P NF polymer with no additives. Carbopol® 71G NF polymer has been designed for direct compression processes and can be incorporated extragranularly in formulations.

   ### Differences between Carbopol® Grades

<table>
<thead>
<tr>
<th>Product Trade Name</th>
<th>Residual Solvent</th>
<th>Crosslinker Type</th>
<th>Physical Form</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbopol® Polymer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>71G NF</td>
<td>Ethyl acetate</td>
<td>Allyl ethers of pentaerythritol</td>
<td>Granular</td>
<td>Chemically the same as Carbopol® 971P NF polymer with no additives. Ideal for direct compression processes due to its improved flow properties.</td>
</tr>
<tr>
<td>971P NF</td>
<td>Ethyl acetate</td>
<td>Allyl ethers of pentaerythritol</td>
<td>Powder</td>
<td>Lightly crosslinked polymer. Typically, the most efficient grade for controlling drug release.</td>
</tr>
<tr>
<td>974P NF</td>
<td>Ethyl acetate</td>
<td>Allyl ethers of pentaerythritol</td>
<td>Powder</td>
<td>Highly crosslinked polymer.</td>
</tr>
</tbody>
</table>

   The differences between Carbopol® 971P NF polymer and Carbopol® 71G NF polymer are particle size and density.

   ![Carbopol® 971P NF polymer (powder form)](image1) ![Carbopol® 71G NF polymer (granular form)](image2)
3. **What are the main benefits of using Carbopol® polymers in controlled release matrix tablets?**

The main benefits of using Carbopol® polymers in controlled release matrix tablets are as follows:

- Highly efficient at low polymer levels (typical use levels are 3 – 30%), enabling smaller tablet sizes and overall formulation cost savings.
- Provides flexibility in achieving a target release profile by varying the polymer level in the formulation. Compared to cellulosic materials, the drug release profile from a Carbopol® polymer matrix can be more easily modulated by changing the polymer level.
- Provides good binding characteristics, thus allowing formulation of matrix tablets without the addition of a tablet binder.
- Synthetic, reproducible polymer.
- Provides bioadhesive properties.
- Enables development of patentable technologies for product differentiation and/or life cycle extension.

4. **What is the difference between the designation “Carbopol®” polymer and “Carbomer”?**

Carbopol® polymer is a product brand name of The Lubrizol Corporation. There are a variety of Carbopol® polymer grades which differ in their performance characteristics. These grades are distinguished by a number designation following the product brand name (e.g. Carbopol® 971P NF polymer and Carbopol® 71G NF polymer).

In contrast, “Carbomer” is one of the generic names that can be used to describe Carbopol® polymers. Carbomer can be defined as a high molecular weight polymer of acrylic acid crosslinked with allyl ethers of polyalcohols. The United States Pharmacopeia (USP) and European Pharmacopeia (Ph. Eur.) include various carbomer monographs.

5. **What is the current compendial nomenclature that applies to Carbopol® polymers?**

The European Pharmacopeia has only one monograph which applies to Carbopol® polymers called “Carbomers”. Similarly, the Japanese Pharmaceutical Excipients also has a single monograph called “Carboxyvinyl Polymer”.

The United States Pharmacopeia/National Formulary has several monographs for different carbomer grades. The monographs called “Carbomer XXX” (where XXX is a numerical designation) are assigned to products manufactured with the use of benzene. Additionally, there are three umbrella monographs that separate carbomer products based on polymer structure. These three monographs are “Carbomer Copolymer”, “Carbomer Homopolymer” and “Carbomer Interpolymer” and they apply to products not polymerized in benzene. The differentiation within each umbrella monograph is based on viscosity characteristics (Type A, Type B and Type C).

### Lubrizol Polymers for Oral Applications

<table>
<thead>
<tr>
<th>Product Trade Name</th>
<th>Residual Solvent</th>
<th>Pharmacopeia Monograph Compendial Name</th>
<th>United States (USP/NF)</th>
<th>Europe (Ph. Eur.)</th>
<th>Japan (JPE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbopol® Polymer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>71G NF</td>
<td>Ethyl acetate</td>
<td>Carbomer Homopolymer Type A</td>
<td>Carbomers*</td>
<td>Carboxyvinyl Polymer</td>
<td></td>
</tr>
<tr>
<td>971P NF</td>
<td>Ethyl acetate</td>
<td>Carbomer Homopolymer Type A</td>
<td>Carbomers*</td>
<td>Carboxyvinyl Polymer</td>
<td></td>
</tr>
<tr>
<td>974P NF</td>
<td>Ethyl acetate</td>
<td>Carbomer Homopolymer Type B</td>
<td>Carbomers*</td>
<td>Carboxyvinyl Polymer</td>
<td></td>
</tr>
<tr>
<td>934P NF</td>
<td>Benzene</td>
<td>Carbomer 934P</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noveon® Polycarbophil</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AA-1 USP</td>
<td>Ethyl acetate</td>
<td>Polycarbophil</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The Carbomers Monograph in the European Pharmacopeia stipulates that benzene is limited to 2 ppm.

6. **What is the United States Pharmacopeia/National Formulary nomenclature that applied to Carbopol® homopolymers prior to January 1, 2006?**

Prior to January 1, 2006, the carbomer monographs within the U.S. Pharmacopeia/National Formulary (USP/NF) were based on mucilage viscosity and residual solvent levels. The monographs did not distinguish the type of polymerization solvent.
Initially, Carbopol® polymers were polymerized in benzene. Over time, Lubrizol has expanded its product offering to include products polymerized in toxicologically preferred solvents such as ethyl acetate or a cosolvent mixture of ethyl acetate and cyclohexane.

When the toxicologically preferred solvent products were first introduced, USP agreed that Lubrizol could utilize the same generic compendial name that was initially used for the benzene grade products (as long as they meet the viscosity and residual solvent level criteria). As a result, one compendial designation could apply to more than one Carbopol® polymer product trade name (e.g. Carbomer 940 applied to Carbopol® 940 NF polymer and to Carbopol® 980 NF polymer).

In January, 2006 the U.S. Pharmacopeia/National Formulary (USP 29-NF 24) introduced a new umbrella monograph called “Carbomer Homopolymer” which applies to homopolymers that are manufactured without the use of benzene as a polymerization solvent. The Carbomer Homopolymer monograph includes three different types based on viscosity (Type A, Type B and Type C) and allows a delayed implementation date up to January 1, 2011. Prior to January 1, 2011 the practice of labeling non benzene carbomer homopolymers as Carbomer 941, Carbomer 934P, Carbomer 934 or Carbomer 940 may be continued*.

<table>
<thead>
<tr>
<th>Product Trade Name</th>
<th>USP/NF Compendial Name (Prior to January 1, 2006)*</th>
<th>USP/NF Compendial Name (After January 1, 2006)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbopol® 71G NF Polymer</td>
<td>Carbomer 941</td>
<td>Carboxypolymethylene Homopolymer Type A</td>
</tr>
<tr>
<td>Carbopol® 971P NF Polymer</td>
<td>Carbomer 941</td>
<td>Carboxypolymethylene Homopolymer Type A</td>
</tr>
<tr>
<td>Carbopol® 974P NF Polymer</td>
<td>Carbomer 934P</td>
<td>Carboxypolymethylene Homopolymer Type B</td>
</tr>
</tbody>
</table>

7. What CAS registry numbers and naming conventions are currently noted on the U.S. FDA Inactive Ingredient Guide (IIG) that apply to Carbopol® polymers for oral administration?

Various CAS numbers are currently reported on the IIG list that apply to Carbopol® polymers. Carboxypolymethylene is a generic name that can be used to describe all Carbopol homopolymers including Carbomer® 71G NF, 971P NF and 974P NF polymers.

<table>
<thead>
<tr>
<th>IIG Name</th>
<th>IIG CAS Number</th>
<th>IIG Route/Dosage Form</th>
<th>IIG Maximum Potency</th>
<th>Chemical Index Name</th>
<th>Alternative CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboxypolymethylene</td>
<td>9007-20-9</td>
<td>ORAL (Suspension)</td>
<td>No calculable potency measurement available</td>
<td>Carboxypolymethylene</td>
<td>9003-01-4</td>
</tr>
<tr>
<td>ORAL (Tablet, sustained action)</td>
<td>195.00 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboxypolymethylene</td>
<td>9007-16-3</td>
<td>ORAL (Suspension)</td>
<td>5.00%</td>
<td>Carboxypolymethylene</td>
<td>9003-01-4</td>
</tr>
<tr>
<td>ORAL (Tablet, sustained action)</td>
<td>90.00 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carboxypolymethylene</td>
<td>None cited</td>
<td>BUCCAL (Tablet)</td>
<td>9.37 mg</td>
<td>Carboxypolymethylene</td>
<td>9003-01-4</td>
</tr>
<tr>
<td>ORAL (Capsule)</td>
<td>14.20 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORAL (Suspension)</td>
<td>1.40%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORAL (Tablet, extended release)</td>
<td>15.00 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORAL (Tablet, orally disintegrating)</td>
<td>0.30 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORAL (Tablet, sustained action)</td>
<td>1.50 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORAL (Tablet, sustained action, coated)</td>
<td>3.00 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer 941</td>
<td>9003-01-4</td>
<td>2-Propenoic acid, homopolymer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer 941</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer 934</td>
<td>9003-01-4</td>
<td>2-Propenoic acid, homopolymer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer 934</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer 974*</td>
<td>9003-01-4</td>
<td>No calculable potency measurement available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbomer 974P*</td>
<td>None cited</td>
<td>ORAL (Tablet, controlled release)</td>
<td>6.25 mg</td>
<td>Carboxypolymethylene</td>
<td>9003-01-4</td>
</tr>
<tr>
<td>ORAL (Tablet, sustained action)</td>
<td>6.25 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Carbomer 974 and Carbomer 974P are not compendial monograph names.
8. How does the drug release mechanism from Carbopol® polymer matrix tablets compare with that of linear, hydrophilic polymers (hypromellose)?

The drug release mechanism from Carbopol® polymers and linear, (soluble) hydrophilic polymers is similar in that both are forming hydrophilic matrices. In the case of soluble drugs, the predominant drug release mechanism is diffusion through the gel layer. While in the case of low solubility drugs, the predominant mechanism is polymer relaxation or erosion.

Unlike linear, hydrophilic polymers, Carbopol® polymers are chemically crosslinked. As a result, they are able to form gels at lower concentrations than linear polymers. Linear polymers form gels through virtual crosslinking (chain entanglement), and higher polymer levels are usually required to obtain extended release properties. Additionally, Carbopol® polymers do not dissolve, but only disperse/swell in aqueous environments.

9. What is the relationship between Carbopol® polymer viscosity and drug release rate?

Drug release from Carbopol® polymer matrix tablets is controlled more by the polymer structure (crosslink density) than by viscosity. Lightly crosslinked polymers have fewer crosslink sites to constrain the polymer, and a homogeneous gel structure forms at lower concentrations compared to highly crosslinked polymers. As a result, the active is less subject to diffusion through the gel layer.

In contrast to linear polymers, higher viscosity does not result in slower drug release with carbomers. Lightly crosslinked carbomers such as Carbopol® 971P NF polymer (lower viscosity) are generally more efficient in controlling drug release than highly crosslinked carbomers such as Carbopol® 974P NF polymer (higher viscosity).

10. In comparison with hypromellose, what are the typical levels of Carbopol® polymer that are used to obtain extended release properties?

For powder grade Carbopol® polymers (Carbopol® 971P NF and 974P NF polymers), typical usage levels are 3 – 10% wt. In comparison, typical usage levels of hypromellose are 20 – 40% wt.

The granular grade, Carbopol® 71G NF polymer is typically used at 10 – 30% wt. in direct compression formulations or when added extragranularly. Powder grades of Carbopol® polymer are more efficient in extending drug release than the granular grade due to the larger surface area (faster hydration), thus lower levels of polymer are generally needed.

<table>
<thead>
<tr>
<th>Product Trade Name</th>
<th>IIG Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbopol® 71G NF Polymer</td>
<td>Carboxypolymethylene; Carbomer 941</td>
</tr>
<tr>
<td>Carbopol® 971P NF Polymer</td>
<td>Carboxypolymethylene; Carbomer 941</td>
</tr>
<tr>
<td>Carbopol® 974P NF Polymer</td>
<td>Carboxypolymethylene; Carbomer 934P, Carbomer 974P</td>
</tr>
<tr>
<td>Carbopol® 934P NF Polymer</td>
<td>Carboxypolymethylene; Carbomer 934P</td>
</tr>
</tbody>
</table>
11. **Is drug release from Carbopol® polymer matrices pH-dependent?**

Due to the anionic nature of the polymers, drug release from Carbopol® polymers matrices may be pH-dependent.

At lower pH values, the polymer is not fully swollen and there are larger regions of microviscosity. The dissolution medium can penetrate fast and deep into the glassy core and the drug is released faster, before complete gel formation occurs.

As the pH increases, the ionization of the carboxylic acid groups causes maximum swelling, resulting in fewer and smaller regions of microviscosity. The rapid gel formation acts as a barrier for the release of the drug, thus prolonging the release.

However, Lubrizol has demonstrated that Carbopol® polymers have the ability to form robust tablets which can extend drug release in both acid and buffer media. No significant difference has been observed in the release profiles due to dissolution medium in the case of drugs with pH-independent solubility.

12. **Does the acidic nature of Carbopol® polymer provide any benefit in formulation?**

The acidic nature of Carbopol® polymer can modulate the microenvironmental pH in the tablet. This is important for API stability and solubility inside the matrix. Control of microenvironmental pH can provide consistent release of cationic drugs throughout the gastrointestinal tract.

13. **Is there a potential for ionic interaction with certain APIs when Carbopol® polymers are incorporated in a matrix tablet?**

Due to their anionic character, Carbopol® polymers may form ionic complexes with cationic drugs. Carbopol® polymers are weak acids (pKa=6 ±0.5). It is important to note that the complex formation is generally reversible as the endogenous cations displace the drug from the polymer upon administration. The potential for ionic interaction is determined by the API properties (pKa/alkalinity, steric hindrance and molecular size/shape) and polymer to API molar ratio. Typically, if an ionic interaction occurs, it will result in slower drug release.

Ionic interaction will not occur with all cationic drugs and is API and formulation dependent.

Examples of commercial products containing cationic APIs and Carbopol® polymers are tablets of dextromethorphan, diethylpropion, glucosamine, metformin, metoprolol, and pseudoephedrine.

14. **Can Carbopol® polymers be used as a controlled release excipient in combination with low solubility APIs?**

There is a variety of low solubility APIs formulated with Carbopol® polymers as extended release matrix tablets. Examples of commercial tablets include nifedipine, lithium carbonate and mesalamine. For this type of API, the predominant in vitro drug release mechanism from Carbopol® polymer matrix tablets is polymer relaxation (erosion).

15. **What are the potential benefits of a combination matrix (Carbopol® polymer and hypromellose) vs. use of a single polymer matrix? Are there other polymer combinations that can be used?**

Data demonstrates a synergistic interaction may occur when Carbopol® polymers are used in combination with hypromellose. Specifically, a lower total polymer level could be used in a formulation, thus enabling smaller tablet sizes and overall formulation cost savings. Additionally, more consistent drug release can be achieved. By varying the total polymer level and ratio of the two polymers it is possible to modulate the drug release profile.

Synergistic use of Carbopol® polymers with other extended release excipients (hydroxypropyl cellulose, sodium carboxymethyl cellulose, sodium alginate, polyethylene oxide and methacrylic polymers) has also been reported in the literature.
16. Are Carbopol® polymers effective tablet binders? What is the best way of incorporating them as binders in a matrix system?

Carbopol® polymers are efficient tablet binders. Formulations comprising Carbopol® polymers generally do not require an additional binder to be used.

In the case of wet granulation formulations, it is recommended to incorporate the polymer in the powder blend (0.5 - 3.0% w/w) versus adding it as an aqueous dispersion due to the high viscosity of the polymer. Carbopol® polymer dispersions (maximum 1%) can be used for fluid bed granulation.

17. What manufacturing processes can be used to produce solid dosage forms containing Carbopol® polymers?

Carbopol® polymers can be processed by direct compression or by various granulation technologies (wet, dry, fluid bed, spray drying, extrusion spheronization and hot melt extrusion).

18. Can Carbopol® polymers be used in wet granulation processes? How?

Carbopol® polymers can be used in wet granulation processes. Key recommendations to facilitate processing are as follows:

- In order to avoid fast and extensive swelling of the polymer, use a low amount of granulation liquid added at a slow rate in fine droplets (uniform distribution of the water in the wet mass). In general, a lower quantity of granulation liquid is used with Carbopol® polymers compared to hypromellose.
- Incorporation of microcrystalline cellulose improves the processability of the formulation. Generally less than 10% of microcrystalline cellulose should be used to prevent disintegration of the tablets.
- Granulation should be controlled in order to prevent overwetting (sticky, rubbery mass).
- It is very important to control the drying process and residual moisture in the granules (typical values 1 - 3%), however these parameters are formulation specific. If overdried, Carbopol® polymers form hard granules. High residual moisture might lead to tablets sticking to the punches and stability problems.

19. What is the recommended procedure for cleaning equipment after processing with Carbopol® polymers?

Water, solution of electrolytes (sodium chloride) or diluted caustic solutions can be used to clean equipment after processing with Carbopol® polymers. Spraying those solutions under pressure generally increases cleaning efficiency. The electrolyte solution facilitates equipment cleaning by collapsing the gel.

20. How do you quantify the API level in a Carbopol® polymer matrix tablet?

In order to ensure total recovery of the API from the Carbopol® polymer tablets, it is recommended to run the analysis after grinding the tablets. Key considerations are as follows:

- The API is extracted from the crushed tablets by sonication or other mixing techniques.
- The criteria for solvent selection are API solubility and reduced polymer swelling. Examples of solvents in which the polymer does not swell extensively are anhydrous ethanol or an acidic aqueous solution at pH~1.2.
- The extraction method has to be optimized; generally larger solvent volume and longer sonication time improve the API recovery, but have to be tested to determine if they affect the API stability.
- Addition of an electrolyte (sodium chloride) to the extraction solvent may improve the recovery (ion effect on the polymer).
21. How stable are Carbopol® polymer matrix tablets?

Carbopol® polymers are hygroscopic materials and packaging of tablets containing the polymers should provide moisture protection. It is recommended that the stability of the final product should be evaluated as part of the formulation development activities.

Lubrizol has conducted a study under ICH conditions on tablets containing Carbopol® polymers packed in dessi-cap vials. No change in dissolution profile was observed in tablets stored under accelerated conditions for 6 months or long term for 1 year.

22. Have any in vivo studies been conducted on Carbopol® polymer matrices?

There are several references in the literature regarding Carbopol® polymer matrices which confirm the ability of the polymer to extend drug release in vivo.


US 5,484,608: Sustained release drug delivery system
US 5,681,581: Controlled release pharmaceutical formulations of AZT
US 5,741,805: Controlled release pilocarpine delivery system
WO0224203: Controlled release formulations for oral administration
US20030224050: Drug delivery system for sustained delivery of glipizide
WO2005039555: Extended release tablet formulations of venlafaxine
US 20070031491: Bioadhesive progressive hydration tablets
WO0132165: Method for administering a phosphodiesterase 4 inhibitor
WO2005030178: Extended release formulation of beta-lactam antibiotics
WO2006082523: Pharmaceutical compositions of metformin

23. Do Carbopol® polymers add any taste masking properties to a tablet?

Carbopol® polymers have the ability to mask the taste of some APIs (mostly cationic drugs) by forming insoluble adsorbates through weak ionic bonding. Those adsorbates dissolve rapidly after ingestion (the endogenous cations displace the drug from the polymer). Literature references highlighting this property include macrolide antibiotics, enofloxacin and dextromethorphan.

Carbopol® polymers have been used in combination with film forming materials for taste masking coating compositions. Additionally, Carbopol® polymers have been reported to ameliorate the throat catch (unpleasant taste and sensation in the throat) caused by ibuprofen. Possible mechanisms involve binding to specific sites in the throat or coating the mucosa to prevent contact of the bitter and/or throat catch producing agent with the mouth and throat mucosa.

24. Do Carbopol® polymers provide bioadhesive properties?

Carbopol® polymers and Noveon® polycarbophils can provide bioadhesive and / or controlled release properties. A significant amount of information is available regarding the use of those polymers as a bioadhesive.

Carbopol® 971P NF polymer was included in a doxycycline sublingual tablet formulation to provide both bioadhesion and sustained drug release.

Formulations of buprenorphine sublingual tablets containing Carbopol® 974P NF polymer provided adequate mucoadhesive strength and drug release.
Detailed product information and samples of Lubrizol’s high performance specialty chemicals for the pharmaceutical industry can be obtained through our web site at www.pharma.lubrizol.com or contact your sales representative or nearest Lubrizol office.

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