



Not All
Carbomers Are
Created Equal!

How Safe Are Your Excipients?

Carbopol® polymers were invented in 1958 as the first carbomer polymers. Through continuous investment in quality and differentiation, **Lubrizol Life Science Health (LLS Health)** has been a market leader in the carbomer field for more than 60 years. LLS Health pharmaceutical grade Carbopol® polymers are produced under cGMP conditions using dedicated manufacturing equipment and procedures. They are tested and certified to meet requirements in respective United States Pharmacopoeia (USP-NF), European Pharmacopoeia (EP), China Pharmacopoeia (ChP) and Indian Pharmacopoeia (IP) compendia monographs.

Over the years other manufacturers have introduced their own 'me too' grades of carbomer polymers for pharmaceutical applications. While they often claim equivalency to Carbopol® polymers, Lubrizol has observed several deficiencies in these other carbomers related to various global compliance requirements.

Compliance to USP general chapter <467> "Residual Solvents" is considered a key subject for excipient users. Unlike other suppliers of carbomers, LLS Health tests for applicable residual solvents in our Carbopol polymers to ensure full compliance with USP general chapter <467>.

Residual Solvents: USP <467> Requirements

- Residual solvents present in excipients will result in the presence of those residual solvents in a drug product
- Drug product manufacturers must identify and quantify any Class 1 solvents (e.g. 1,2 dichloroethane) that may be likely to be present in their drug products

Testing Requirements for Pharmacopoeia Compliance - Table 1 compares the full compendial compliance of Carbopol® polymers vs. competitor 1 and competitor 2 carbomers. Solvent testing has been conducted by Lubrizol based on USP/NF carbomer homopolymer monograph and USP general chapter <467>.

Table 1 - Product Compendial Compliance				
	Carbopol® Polymers (Pharmaceutical Grade)*	Competitor 1 Carbomers	Competitor 2 Carbomers	
		Product using 1,2 Dichloroethane Solvent	Product using Methylene Chloride Solvent	Product using Cosolvent
Product Testing Results				
Polymerization Solvent	Ethyl acetate (class 3) or a mixture of ethyl acetate and cyclohexane (class 2)	1,2 Dichloroethane (Class 1)	Methylene Chloride (Class 2)	Mixture of ethyl acetate and cyclohexane (Class 2)
Residual Solvent Level	Consistent low amount of residual solvent	Very high levels of residual solvent; not specified or reported	Complies	Above individual/combined monograph limits
Product Documentation				
Limit of Ethyl Acetate and Cyclohexane	Complies	Not Tested	Not Applicable	Total Solvent Reported, Not Individual
Limit of Benzene	Complies	Not Tested	Not Tested	Not Tested
Limit of Acrylic Acid/ Residual Monomer	Complies	Test Method Not Indicated	Complies	Unknown
Assay - Carboxylic Acid Content	Complies	Test Method Not Indicated	Complies	Unknown
Viscosity	Complies	Test Method Not Indicated	Complies	Complies
Loss on Drying	Complies	Test Method Not Indicated	Complies	Complies
Heavy Metals Content	Complies	Test Method Not Indicated	Complies	Complies
Residue on Ignition	Complies	Test Method Not Indicated	Complies	Unknown
Pharmaceutical compliance	Full Compliance	To be Determined	To be Determined	To be Determined

*Carbomer Homopolymer Type A: Carbopol® 71G NF, 971P NF and 981 NF Polymers

Carbomer Homopolymer Type B: Carbopol® 974P NF and 5984 EP Polymers

Carbomer Homopolymer Type C: Carbopol® 980 NF Polymers

Compendial method or cross-validated house method



As the leader in this field, LLS Health provides comprehensive technical and regulatory support in addition to compliance to monograph and general chapter requirements. Customers should review all data listed in Table 2 from their suppliers to ensure their finished drug product conforms to all regulatory standards.

Table 2 - Technical and Regulatory Support Available for Customers				
	Carbopol® Polymers (Pharmaceutical Grade)*	Competitor 1 Carbomers	Competitor 2 Carbomers	
		Product using 1,2 Dichloroethane Solvent	Product using Methylene Chloride Solvent	Product using Cosolvent
Product Testing Results				
Excipient Information Package	Available	Unknown	Unknown	Unknown
Oral Toxicity Data	Available	Unknown	Unknown	Unknown
Stability Data	Available	Unknown	Unknown	Unknown
Quality by Design Support	Yes	Unknown	Unknown	Unknown
Drug Master Files	Type IV and Type V	Type IV	Type IV	Unknown
Manufacturing Standards	GMP	GMP	Unknown	Unknown
Elemental Impurities	Available	Unknown	Unknown	Unknown
Global Change Control	Available	Unknown	Unknown	Unknown
Global Regulatory Support	Available	Unknown	Unknown	Unknown
Global Technical Service	Available	Unknown	Unknown	Unknown

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 Carbomer Homopolymer Type C: Carbopol® 980 NF Polymers

Conclusion

Carbopol® polymers are fully compliant with compendial requirements in the US, Europe, China, and India. When you partner with LLS Health, customers receive high quality excipients for seamless registration. Our excipients enable efficient raw material testing and final product approval, ensuring patient safety when using pharmaceutical products.

