TECHNICAL DATA SHEET

TDS-730
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Viscosity of Carbopol®* Polymers in Aqueous Systems

Introduction

Carbopol® polymers can be used to develop semisolid and oral liquid formulations with a wide range of flow and rheological properties (Figure 1). The polymers are highly efficient thickeners, suspending agents and stabilizers at low usage levels (0.1 - 3.0 wt%).

Figure 1: Flow Properties of Carbopol® Polymers, Neutralized Dispersions

Polymer Crosslink Density:	High/Medium	Low
Flow Property:	Short	Long (Pourable)

All Carbopol® polymers are high molecular weight, crosslinked polyacrylic acid polymers. The main differences among the polymers are the crosslinker type and density and solvent used to synthesize the polymer. A description of the polymers featured in this document is shown in Tables 1A and 1B. Please refer to Bulletin 1- *Polymers for Pharmaceutical Applications* for a complete list of polymers.

Table 1A: Carbopol® Polymers Overview

Carbopol® Polymer	Recommended Applications	Polymerization Solvent	Polymer Type	Crosslink Density	Aqueous Gel Viscosity
971P NF	Oral / Topical	Ethyl Acetate	Homopolymer	Low	Low
974P NF	Oral / Topical	Ethyl Acetate	Homopolymer	Medium	Medium - high
980 NF	Topical	Cosolvent[1]	Homopolymer	High	Very high
5984 EP	Topical	Cosolvent	Homopolymer	Medium	Medium - high
ETD 2020 NF	Topical	Cosolvent	Interpolymer	Medium	Medium - high
Ultrez 10 NF	Topical	Cosolvent	Interpolymer	High	Very high

[1] Cosolvent is a mixture of ethyl acetate and cyclohexane.

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Table 1B: Compendial Status of Polymers

Product Trade Name	United States USP/NF*	Europe (Ph. Eur.)	Japan (JPE)[1]
Carbopol® 971P NF Polymer	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer
Carbopol® 974P NF Polymer	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer
Carbopol® 980 NF Polymer	Carbomer Homopolymer Type C	Carbomers	Carboxyvinyl Polymer
Carbopol® 5984 EP Polymer	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer
Carbopol® ETD 2020 NF Polymer	Carbomer Interpolymer Type B	---	---
Carbopol® Ultrez 10 NF Polymer	Carbomer Interpolymer Type A	---	---

* USP/NF after 2006

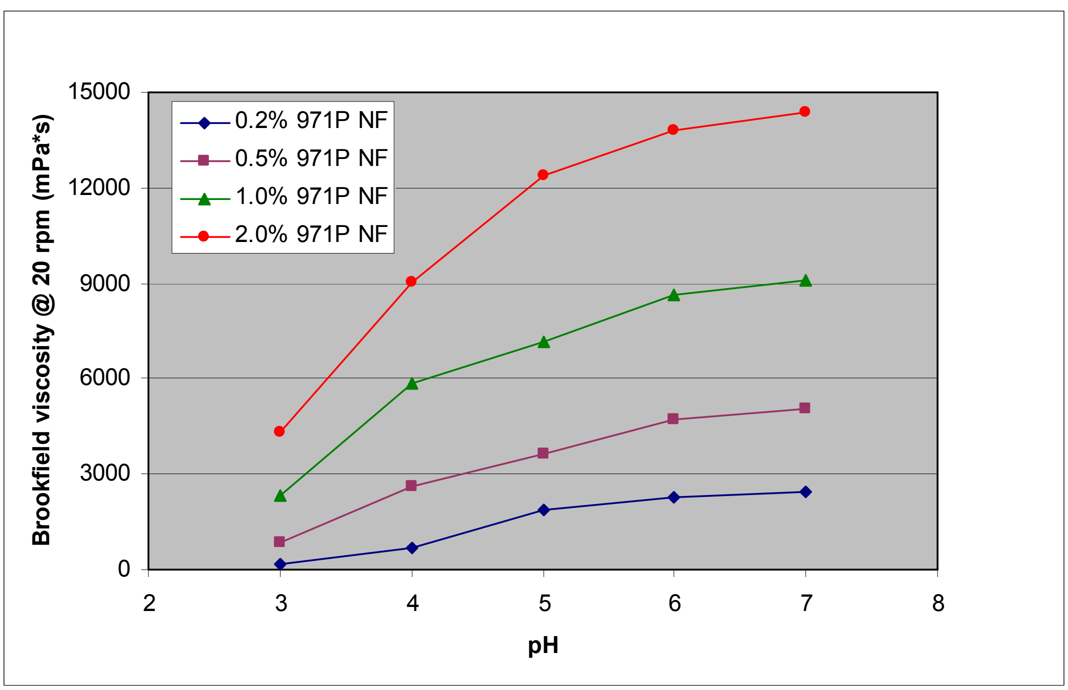
Brookfield Viscosity of Carbopol® Polymer Dispersions

Carbopol® polymers must be neutralized in order to achieve maximum viscosity. Once a neutralizer is added to the dispersion, thickening gradually occurs. Maximum viscosity is typically achieved at a pH of 6.0 - 7.0.

The viscosity of Carbopol® polymers will begin to decrease at a pH of 9.0 and higher. This is caused by the presence of excess electrolytes which affect the electrostatic repulsion of the ionized carboxylic groups. In order to obtain high viscosity at pH values below 5 and above 9, an increased concentration of Carbopol® polymer is recommended. Additionally, use of a low concentration of polymer at low pH values should be avoided in an effort to achieve a robust formulation.

Brookfield viscosity measurements were obtained for aqueous dispersions of several Carbopol® polymers at concentrations of 0.2 - 2.0 wt. %. The general behavior of each polymer is shown in Figures 2 - 7 based on the data for one lot of each polymer. The dispersions were tested as prepared (conventionally represented as pH 3.0) or after neutralization with sodium hydroxide solution to pH 4.0 - 7.0. An increase in polymer concentration results in an increase in viscosity. In general, a pH plateau is achieved more readily with higher concentrations of Carbopol® polymers.

Figure 2: Effect of pH and Concentration on the Viscosity of Carbopol® 971P NF Polymer Dispersion



[1] Based on customer request, Lubrizol certifies select lots of product against the JPE Carboxyvinyl Polymer Monograph

Figure 3: Effect of pH and Concentration on the Viscosity of Carbopol® 974P NF Polymer Dispersion

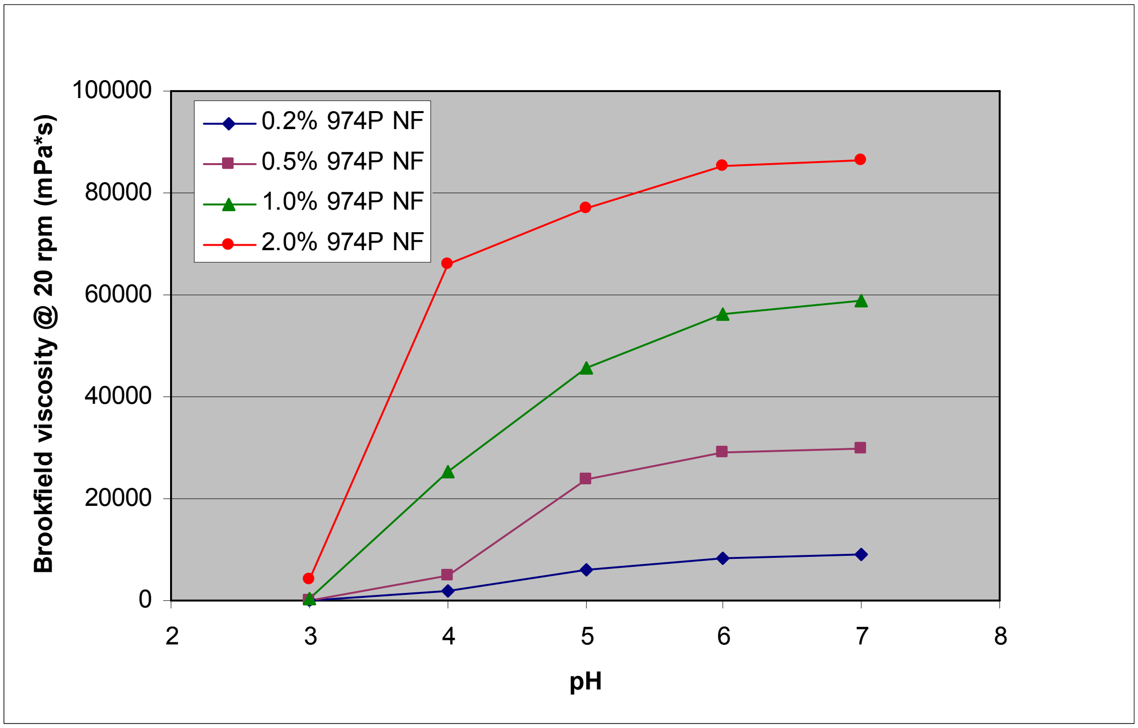


Figure 4: Effect of pH and Concentration on the Viscosity of Carbopol® 980 NF Polymer Dispersion

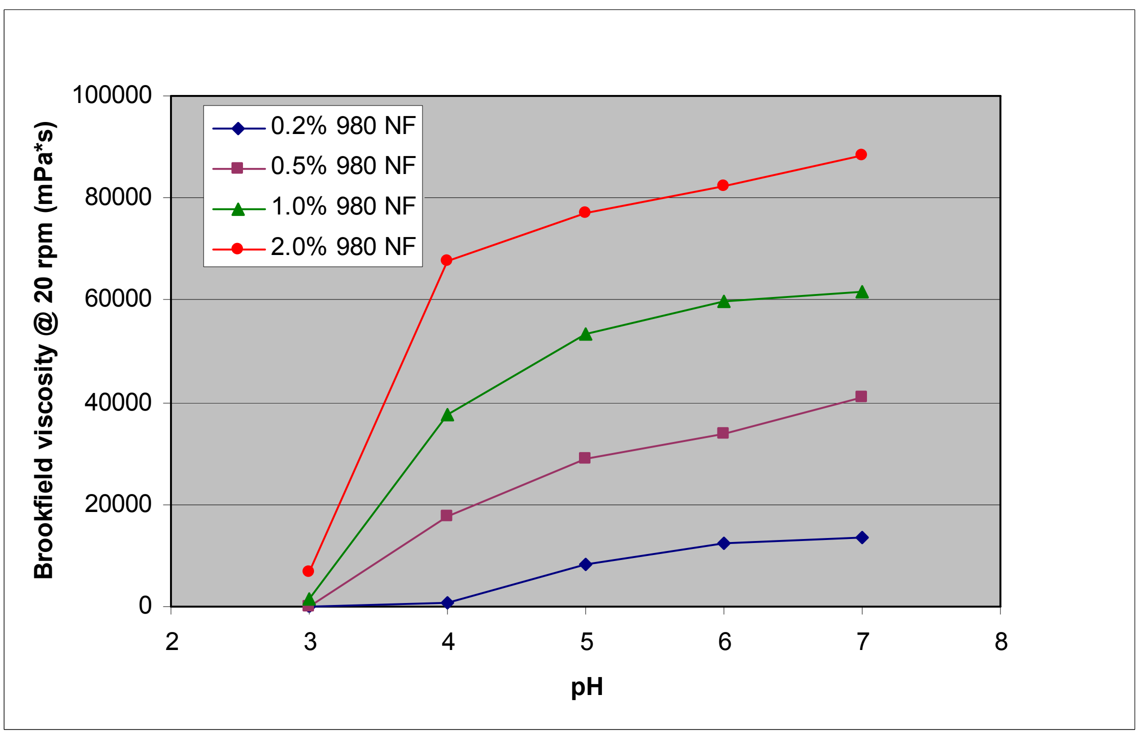


Figure 5: Effect of pH and Concentration on the Viscosity of Carbopol® 5984 EP Polymer Dispersion

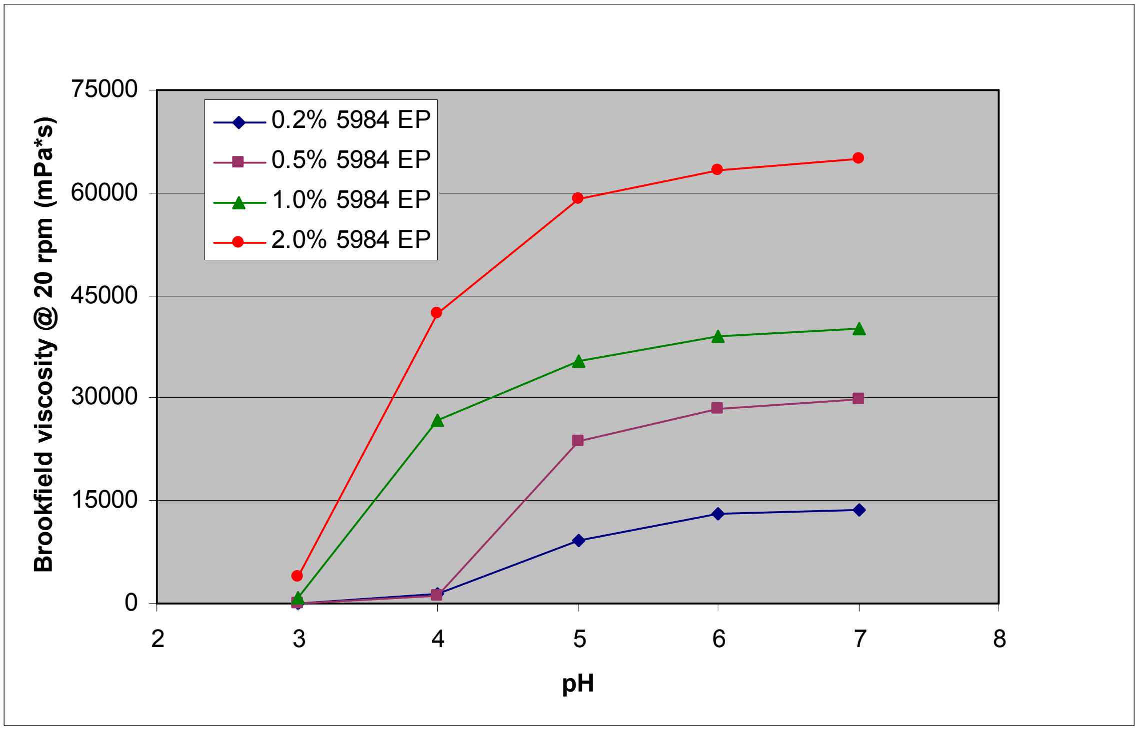


Figure 6: Effect of pH and Concentration on the Viscosity of Carbopol® ETD 2020 NF Polymer Dispersion

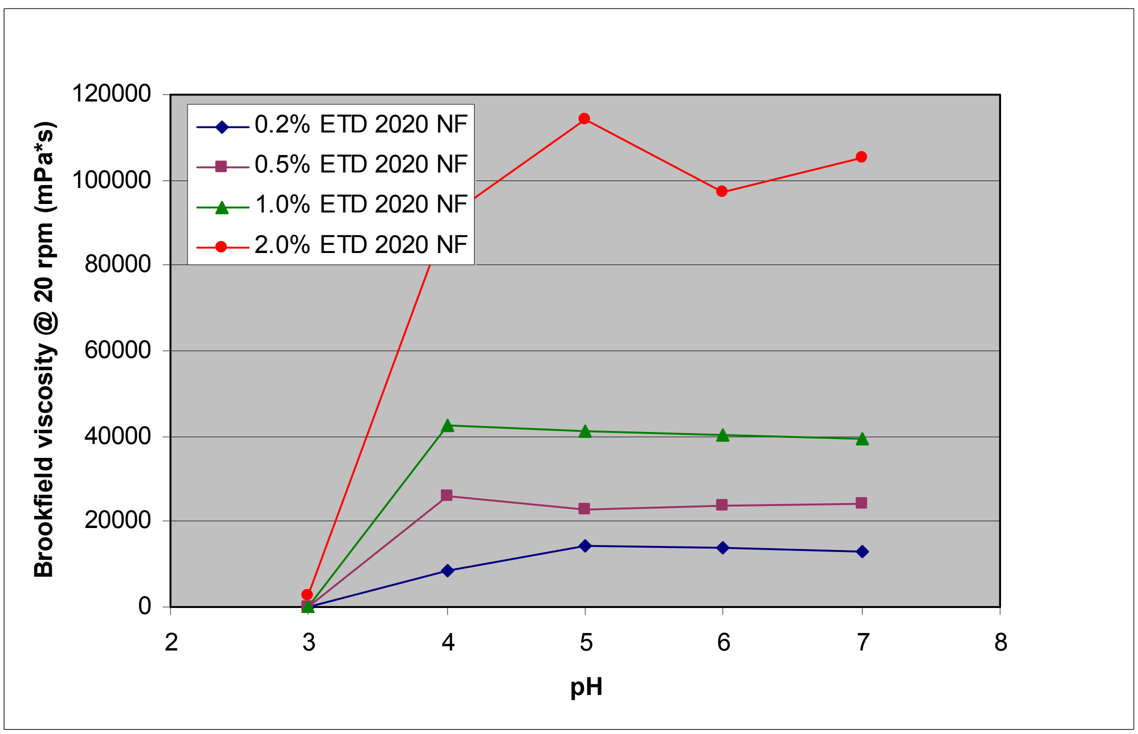
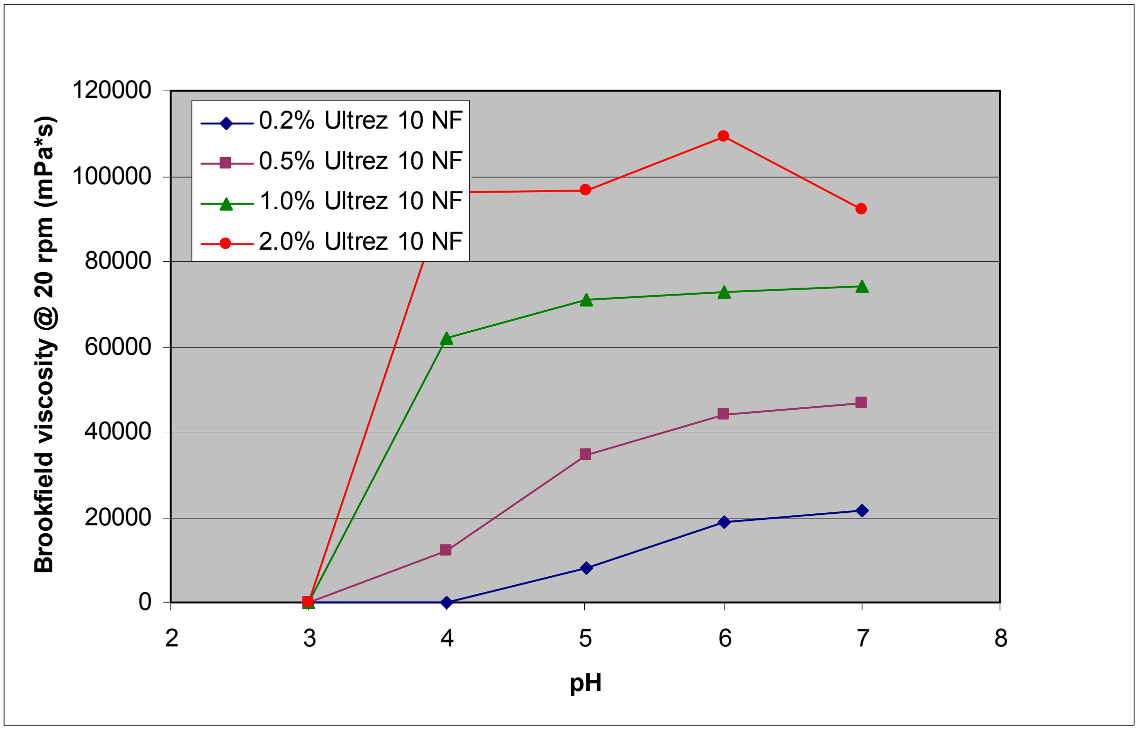
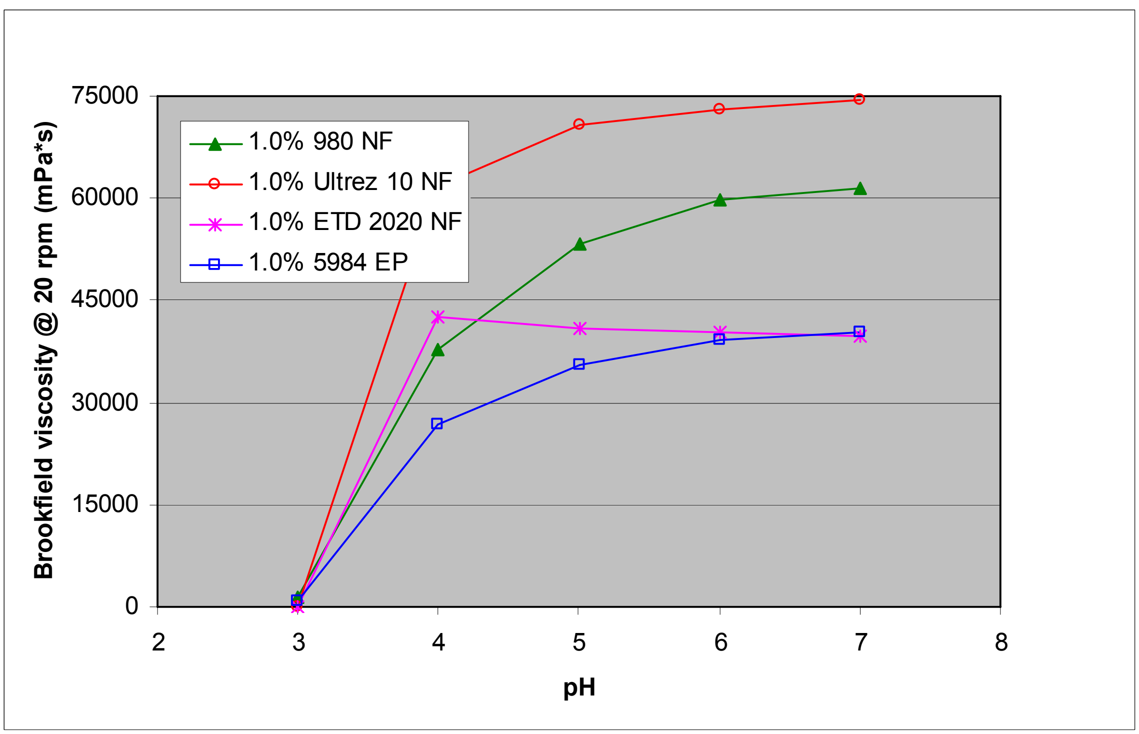


Figure 7: Effect of pH and Concentration on the Viscosity of Carbopol® Ultrez 10 NF Polymer Dispersion



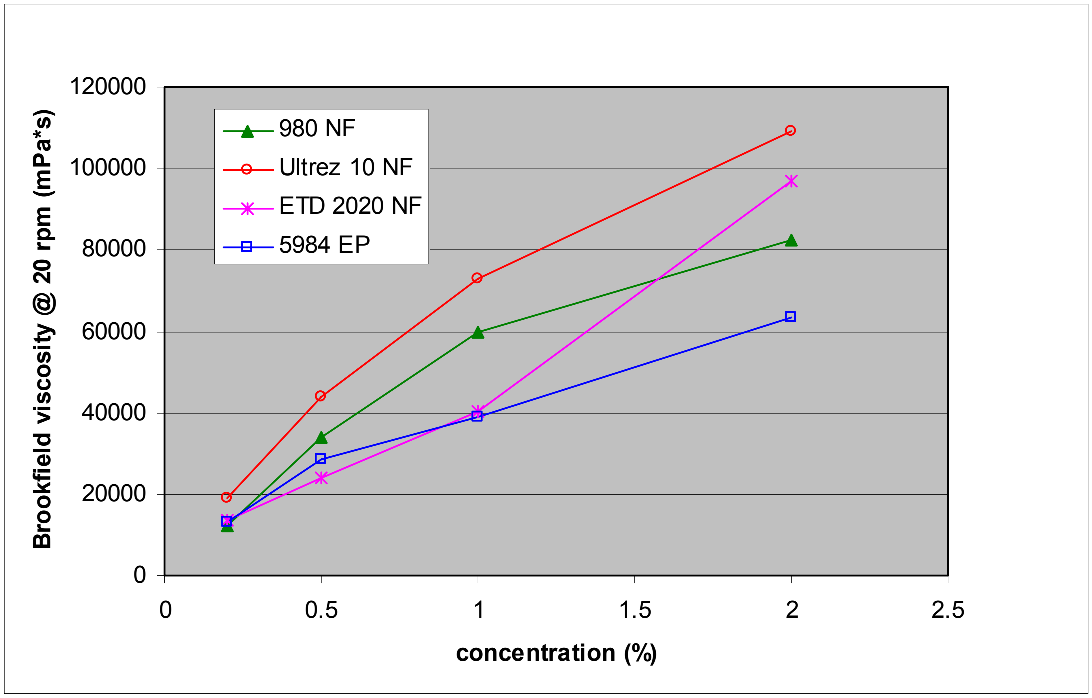
A comparison of the viscosity of 1.0 wt. % aqueous dispersions of several topical grades of Carbopol® polymers is shown in Figure 8.

Figure 8: Effect of Polymer Type on the Viscosity of 1.0% Dispersions – Topical Products



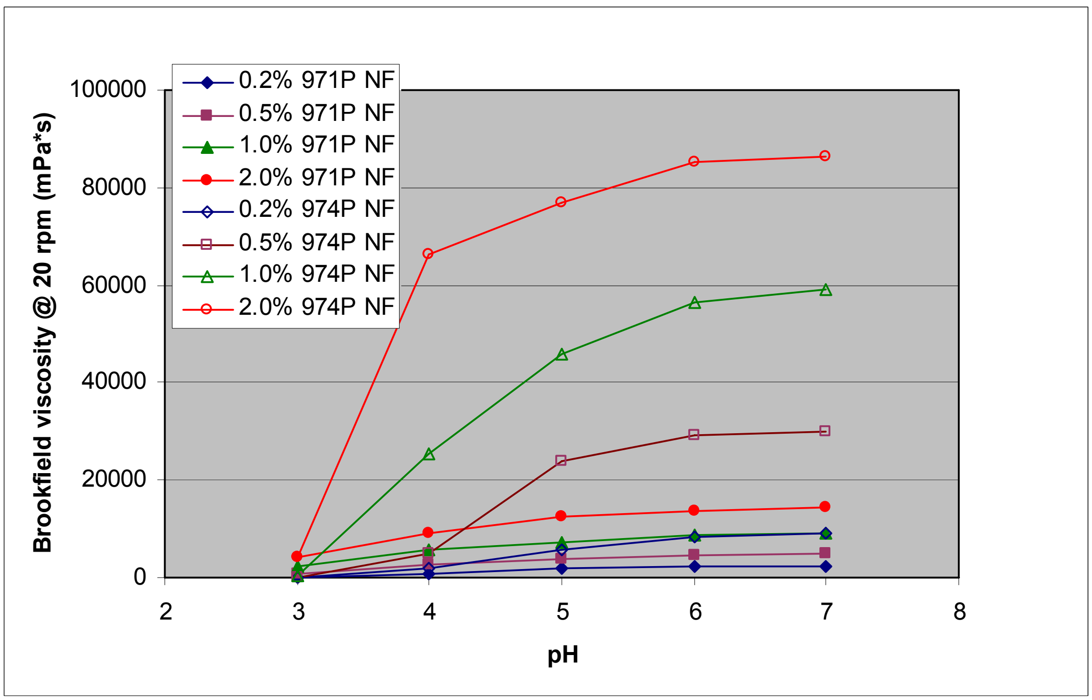
The effect of polymer type and concentration on the viscosity at pH 6.0 is represented in Figure 9 for several topical grades of Carbopol® polymers.

Figure 9: Effect of Polymer Type and Concentration on the Viscosity at pH 6.0 – Topical Products



A comparison of the viscosity of oral grade Carbopol® 971P NF and 974P NF polymers at various pH levels and concentrations is shown in Figure 10.

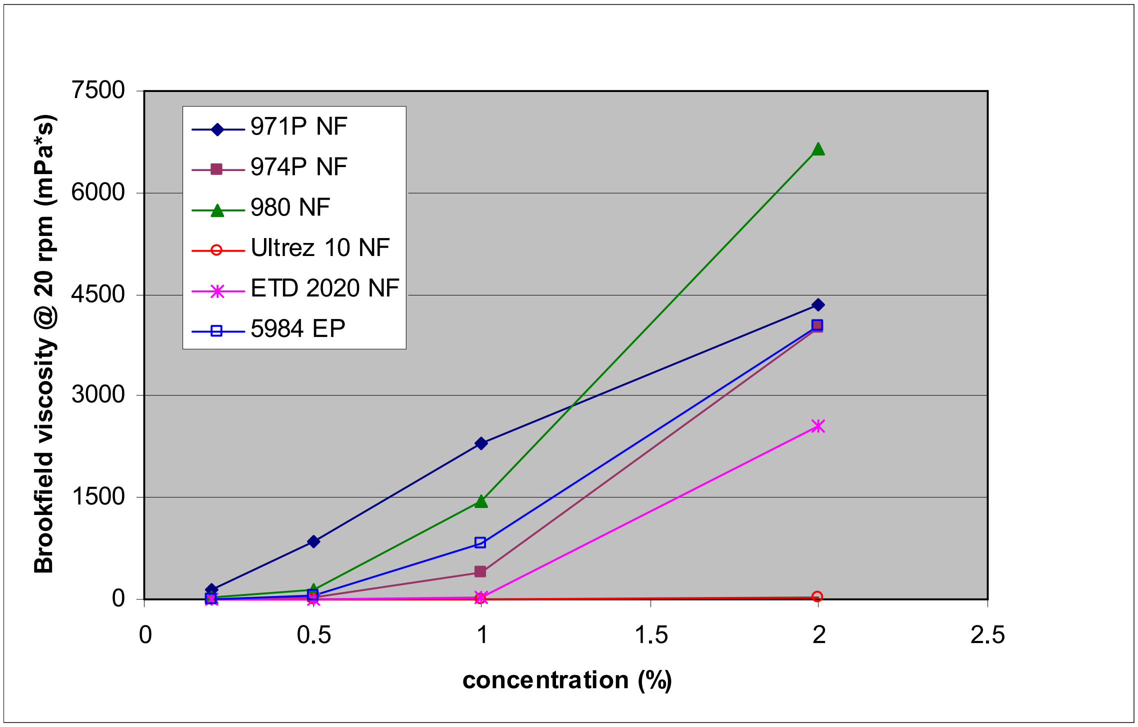
Figure 10: Effect of pH and Concentration on the Viscosity of Carbopol® 971P NF and 974P NF Polymer Dispersions



Unneutralized dispersions as prepared have an approximate pH range of 2.5 - 3.5 depending on the polymer concentration. The unneutralized dispersions have very low viscosities as shown in Figure 11, especially for Carbopol® Ultrez 10 NF polymer and Carbopol® ETD 2020 NF polymers.

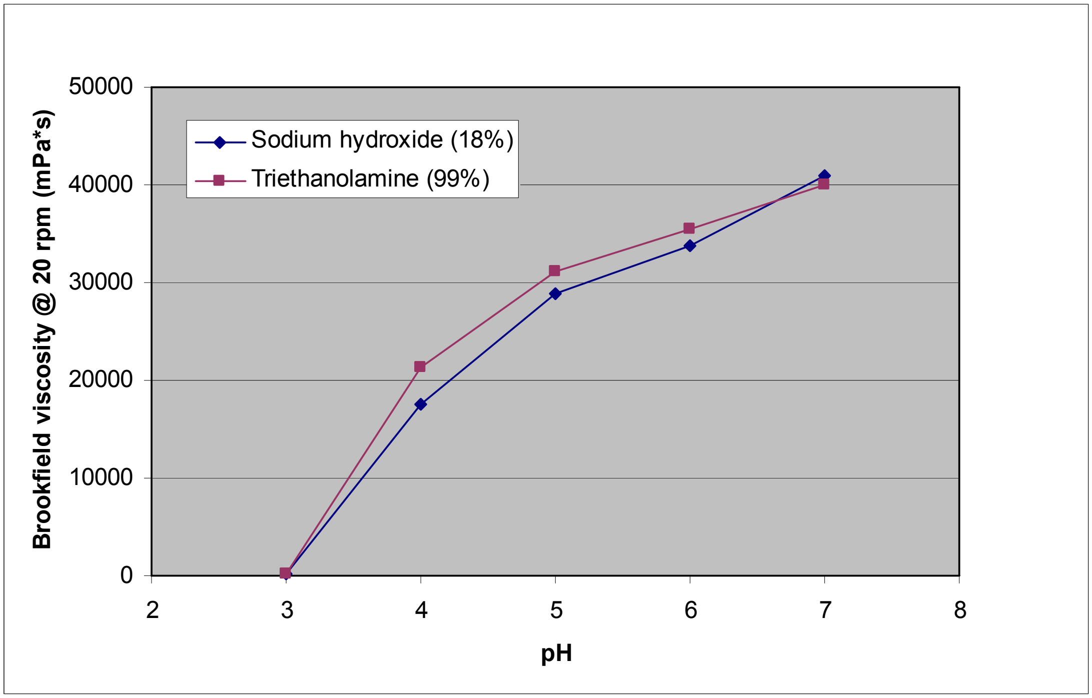
Carbopol® Ultrez 10 NF polymer and Carbopol® ETD 2020 NF polymers provide excellent versatility in processing for topical formulations. Their unique dispersion performance allows the polymers to wet quickly, yet hydrate slowly. This minimizes agglomeration, which can be a problem if turbulent mixing is not available during dispersion. Compared with traditional Carbopol® polymers, Carbopol® Ultrez and ETD polymers provide dispersions in water that are much lower in viscosity prior to neutralization which enables easier handling in mixing tanks and process lines. Once the polymers are neutralized, they are highly efficient thickeners.

Figure 11: Effect of Polymer Type and Concentration on the Viscosity of Dispersions as Prepared



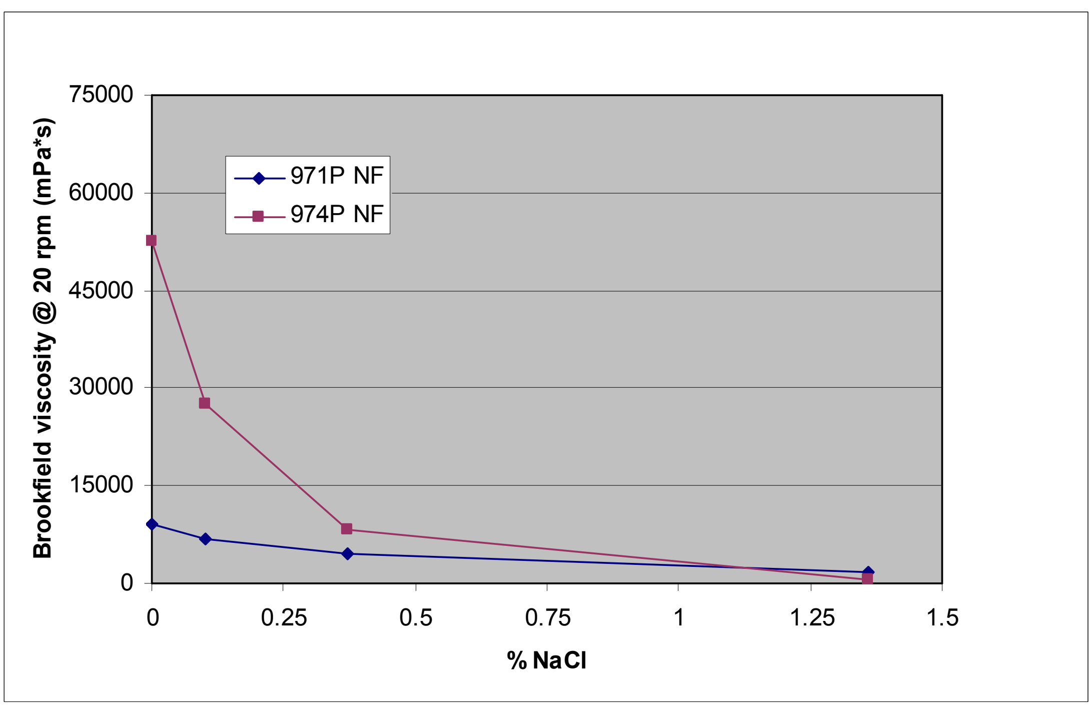
In aqueous systems, inorganic bases, such as sodium hydroxide or potassium hydroxide, or low molecular weight amines and alkanolamines will provide satisfactory neutralization. Figure 12 shows similar thickening efficiencies when sodium hydroxide and triethanolamine are used to neutralize a 0.5 wt% aqueous dispersion of Carbopol® 980 NF polymer. No significant differences are expected if potassium hydroxide is used for neutralization.

Figure 12: Effect of Neutralizer Type on the Viscosity of 0.5% Carbopol® 980 NF Dispersion



Electrolytes tend to reduce the viscosity of Carbopol® polymer based gels. Therefore, a higher concentration of polymer should be used to minimize the viscosity loss. In general, the viscosity of lightly crosslinked Carbopol® polymer systems is less affected by electrolytes than highly crosslinked Carbopol® polymers. (Figure 13).

Figure 13: Effect of Salt on the Viscosity of 1.0% Carbopol® 971P NF and 974P NF Polymer Dispersions at pH 6.0



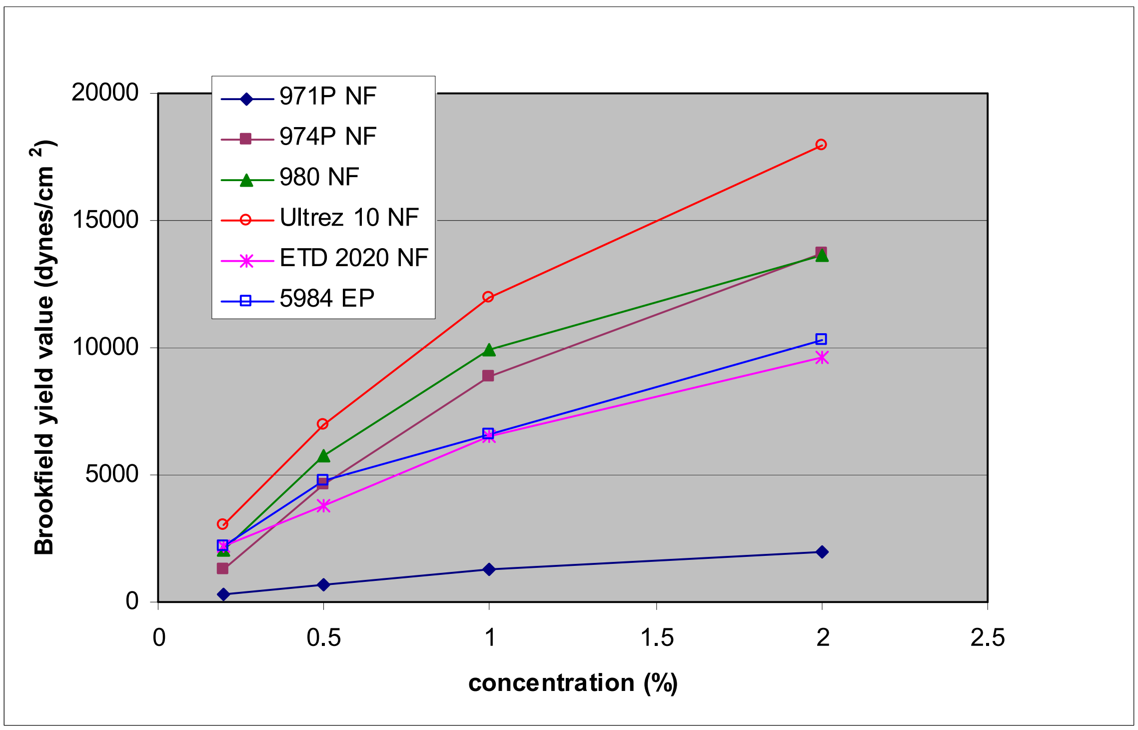
Brookfield Yield Value of Carbopol® Polymer Dispersions

Carbopol® polymers are unique in that they provide a wide range of viscosity profiles and have very high yield values, even at low concentrations. These combined features enable the formulation of oral or topical suspensions that are stable with low levels of polymer.

Yield value is more important than viscosity when determining suspending ability of a vehicle. While viscosity can only slow down the rate of sedimentation, a high yield value is necessary to create permanent suspensions.

While all Carbopol® polymers are efficient suspending agents, medium/highly crosslinked polymers have higher yield value than lightly crosslinked polymers such as Carbopol® 971P NF polymer (Figure 14). Refer to TDS-244 to calculate a theoretical yield value for a suspension.

Figure 14: Effect of Polymer Type on the Brookfield Yield Value of Carbopol® Polymer Dispersions at pH 6.0



The data included represents one lot of each polymer in an aqueous system. The performance of the polymers in other conditions (alternative vehicles, coexcipients and active pharmaceutical ingredients) might be different. It is recommended that key performance properties be ascertained and regulatory considerations be taken into account in the process of formulation development.

Carbopol® polymers have been used in a variety of commercial liquid and semisolid formulations containing the active pharmaceutical ingredients (APIs) noted in Table 2. These APIs have been incorporated in a variety of dosage forms: solutions, suspensions, emulsions, lotions, creams, gels and toothpaste for peroral or topical administration (skin, mucosa - oral, ophthalmic, nasal, rectal, vaginal).

Table 2: Commercial Liquid and Semisolid Formulations Containing Carbopol® Polymers

• Adapalene • Aescin • Allantoin • Amorolfine hydrochloride • Azelaic acid • Benzocaine • Benzoyl peroxide • Betamethasone dipropionate • Betaxolol hydrochloride • Brinzolamide • Ciclopirox • Clarithromycin • Clindamycin • Clobetasol propionate • Clocortolone pivalate/ hexanoate • Clotrimazole • Crotamiton • Cyclosporine • Dexamethasone • Dexpanthenol • Domperidone • Diclofenac • Diethylamin-Salicylate • Estradiol	• Estriol • Etofenamate • Eucalyptus oil • Extracts (Capsicum, Arnica) • Fluocinonide • Fluorouracil • Fusidic acid • Ganciclovir • Glycerin • Heparin sodium • Hydrocortisone • Hydroquinone • Hydroxyethylsalicylate • Ichthammol • Indomethacin • Isotretinoin • Ketoconazole • Ketoprofen • Lidocaine • Menthol • Mesalamine • Methyl salicylate • Metronidazole • Miconazole nitrate	• Naftifine hydrochloride • Nepafenac • Nevirapine • Nonoxynol 9 • Nystatin • Octyl methoxycinnamate • Permethrin • Polidocanol) • Prilocaine • Progesterone • Retinol palmitate • Rimexolone • Simethicone • Sodium alginate • Sodium fluoride • Sodium hyaluronate • Testosterone • Thioridazine • Timolol maleate • Tretinoin • Tyrothricin • Urea