Lubrizol

TECHNICAL DATA SHEET

Edition: January 2022

Carbopol® Polymers as Rheology Modifiers in Non-aqueous Systems

Carbopol® polymers are well known in the pharmaceutical industry for their unique ability to impart viscosity and suspending properties in ***aqueous systems***. When placed in contact with an aqueous medium, they hydrate and swell through hydrogen bonding or electrostatic repulsion (when neutralized) providing the desired rheology and aesthetics.

There is a growing trend to develop ***non-aqueous systems*** to improve solubility or stability of various actives (stannous fluoride, bioactive glass, peroxides, benzocaine, etc.).

Carbopol® polymers are suitable to increase the viscosity of non-aqueous (anhydrous) vehicles such as propylene glycol, polyethylene glycol (PEG), glycerin, and alcohols. Hydrogen bonding of the acrylic acid to the hydroxyl groups of alcohols/polyols (Figure 1) is the dominant mechanism in non-aqueous systems being facilitated by heat and agitation. Low usage levels with efficient viscosity increase make Carbopol® polymers the ideal excipients for thickening anhydrous solvent systems. Additionally, no neutralization is required to provide thickening and suspending properties as well as clarity.

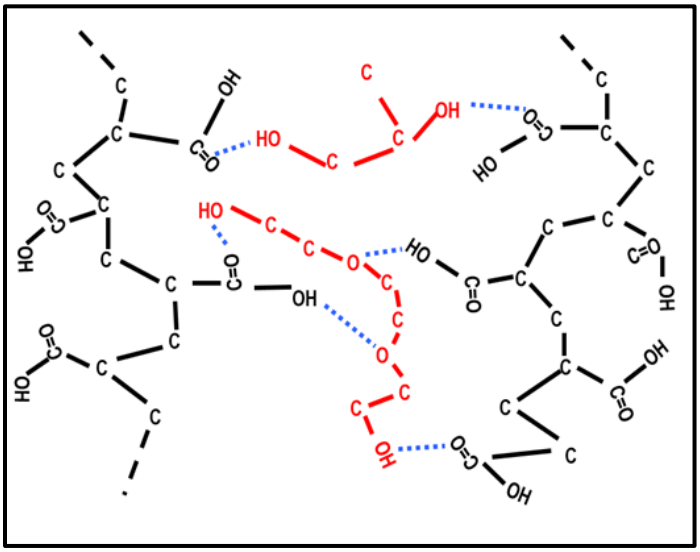

Figure 1 Thickening effect of Carbopol® polymers in anhydrous systems (i.e., propylene glycol) via hydrogen bonding

In anhydrous systems, typically Carbopol® 971P NF, a low crosslinked polymer, enables more efficient thickening at lower concentrations than the higher crosslinked Carbopol® 974P NF and Carbopol® 980 NF polymers. However, as the concentration of the polymer increases, Carbopol® 974P NF polymer becomes more efficient. Further increase in viscosity can be achieved with increased concentration of Carbopol® polymers (Figure 2)

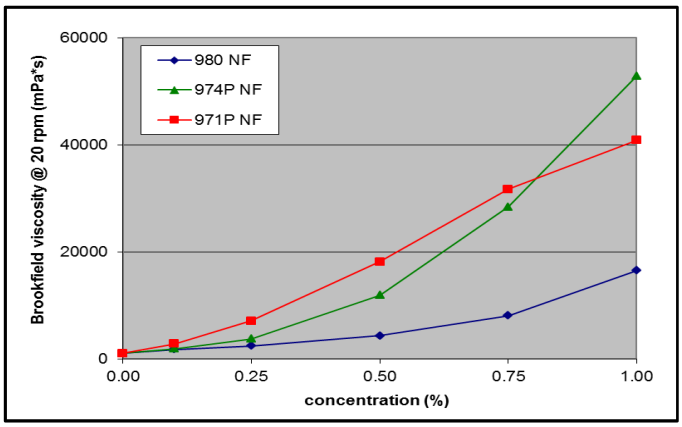

Figure 2: Viscosity of Carbopol® polymer dispersions in glycerin (no neutralization; Brookfield RVT at 20 rpm)

Processing Recommendations

Dispersions of Carbopol® polymers can be prepared by sifting the dry polymer into the vortex of the anhydrous vehicles (see **TDS 103 Dispersion Techniques for Carbopol® Polymers**). Once the polymer is dispersed, the system is heated at 50 °C for approximately 1 hour to facilitate hydrogen bonding and solvate the polymer to produce a clear gel.

It is generally recommended to pre-disperse the Carbopol® polymers at room temperature into a less polar solvent such as PEG 400, propylene glycol or their mixture, to control the initial hydrogen bonding and therefore to avoid un-solvated particles and non-uniform appearance. After the pre-dispersion step, the mixture is added to heated glycerin (50 – 60 °C) with continued mixing for an additional hour at that temperature for optimal results.

A study was conducted to evaluate the dispersion and thickening properties of various grades of Carbopol® polymers (1%) in glycerin utilizing a pre-dispersion step in PEG 400 and/or propylene glycol.

Table 1. Formulation of Carbopol® polymers in glycerin with pre-dispersion in PEG 400.

Ingredient	%w/w
Carbopol® polymer	1.0
PEG 400	25.0
Glycerin	74.0
Total	100

Pre-dispersing in a less polar solvent allowed for ease of processing Carbopol® polymers, but the type of pre-dispersing solvent did not influence the final gel viscosity (Table 2). Pre-dispersion also enables a smoother appearance by reducing the potential for defects from polymer gel particles in the final formulation (Figure 3).

Table 2. Effects of Carbopol polymer grades and pre-dispersing solvents on gel viscosity (no neutralization; Brookfield RVT at 20 rpm).

Carbopol® polymer	Pre-dispersing solvent (25%)	Gel viscosity @ room temperature (cPs)
974P NF	PEG-400	30,750
974P NF	PEG-400 / propylene glycol (1/1)	27,300
974P NF	Propylene glycol	31,200
971P NF	PEG-400	42,300
ETD 2020 NF	PEG-400	16,200

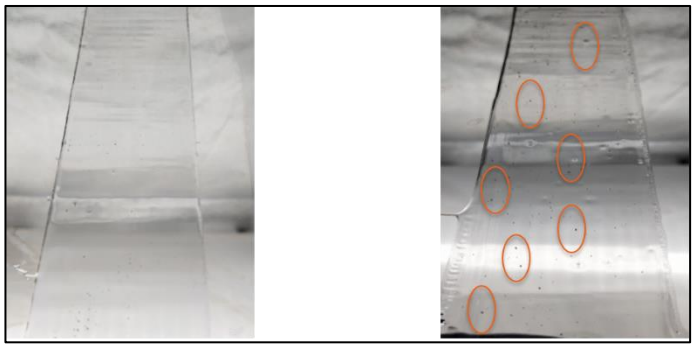

Figure 3: Gels of Carbopol® polymer in PEG 400/glycerin systems: complete vs. incomplete solvation

In summary, Carbopol® polymers enable efficient and versatile formulations in anhydrous systems. Polymer selection, concentration, and dispersion techniques play a critical role in final product performance. Optimal appearance and viscosity can be achieved via pre-dispersing solvent and polymer grade.

Benefits of Carbopol® polymers as rheology modifiers in non-aqueous systems

- Impart high viscosity
- No neutralization step required
- Ensure API stability and/or solubility
- Potential for preservative-free
- Mucoadhesive properties (Mucoadhesive Polymers - Lubrizol)