

ble gel characteristics is in order. For optimum consumer appeal, the gel should have good optical clarity and sparkle. A high viscosity and a high-yield value are essential, but how high is primarily a matter of intended product application. To preserve product integrity, the gel should maintain its viscosity at all temperatures that may be encountered during shipment and storage. During formulation, there is frequently a trade-off between these optimum characteristics and the chemical requirements of active ingredients.

Carbomer is a commonly used gelling agent that produces gels having a number of these desirable characteristics. The grade, carbomer 934 P NF, is most commonly used in the pharmaceutical industry and has been selected as the exemplary polymer for formulation discussion. Chemically, carbomer 934 P is a cross-linked acrylic acid polymer having a molecular weight of approximately 3×10^6 (2). The gelation mechanism depends on neutralization of the carboxylic acid moiety to form a soluble salt. The polymer is hydrophilic and produces sparkling clear gels when neutralized. Although carbomer tolerates large amounts of alcohol, it does so with decreased viscosity and clarity. Gel viscosity is strongly dependent on pH and the presence of electrolytes. A maximum of approximately 3% electrolyte can be tolerated before precipitation occurs as a rubbery mass. Carbomer gels possess good thermal stability in that gel viscosity and yield value are essentially unaffected by temperature. As a topical product, carbomer gels possess optimum rheological properties. The inherent pseudoplastic flow permits immediate recovery of viscosity when shear is terminated and the high-yield value and quick break make it ideal for dispensing.

The viscosity building effects of carbomer are readily apparent when examining the gelation mechanism in association with the colloidal network structure. As Figure 2 illustrates, before neutralization, carbomer in water exists in its un-ionized form and yields a thin opalescent dispersion of approximately pH 3 (3). At this pH, the polymer is very flexible and behaves like a random coil. Addition of sodium hydroxide or a neutralizing amine to the dispersion shifts the ionic equilibrium in favor of the soluble salt form. This results in ionic repulsion of the carboxylate groups and the polymer becomes stiff and rigid, thereby increasing the viscosity of the water. Overneutralization and excess salts reduce the viscosity of carbomer gels or cause precipitation by the counterion effect.

Figure 3 shows the dramatic effect of pH on the viscosity development of carbomer gels. As pH increases and the carboxylic acid moieties of the polymer are neutralized, viscosity and clarity increase. Acceptable gel clarity and viscosity occur at approximately pH 4.5 to 5.0, but optimum viscosity and clarity are at pH 7. Overneutralization results in a decrease in viscosity that cannot be reversed by addition of acid to lower the pH because an electrolyte is formed.