Pharmaceutical excipient for external use

VISCOMATE™

Acrylic Acid / Sodium Acrylate Copolymer

Showa Denko K.K.
What is VISCOMATE™?

VISCOMATE™ is a partially neutralized polyacrylate that has been developed utilizing Showa Denko’s many years of accumulated knowledge of manufacturing techniques for water-soluble polymers. It has demonstrated proven results over many years as a base for cataplasms and cooling sheets.

\[
\begin{align*}
&\text{CH} & & \text{CH}_2 \\
&\text{COOH} & & m \text{CH}_2 \\
&\text{Acrylic acid} & & \text{Sodium acrylate}
\end{align*}
\]

Feature

VISCOMATE™ is a water-soluble polymer synthesized from acrylic acid. It has a straight chain structure, giving it stringing properties.

In addition, it contains abundant carboxy groups (-COOH) inside its molecules, so for example trivalent metal ions can be used as a crosslinking agent, allowing for resilient aqueous gels to be created. It is neither a crosslinking type of superabsorbent polymer (SAP) nor a microgel.

- Water solubility
- Adhesion
- Thickening properties
- Huge molecular weight
- Anionic (negatively-charged ion)

Product name: VISCOMATE™
Chemical name: Sodium polyacrylate
Japanese pharmaceutical excipient standard:
  Partially neutralized polyacrylate
Appearance: White powder
Grade of VISCOMATE™

There are three grades of VISCOMATE™ available, based on the degree of neutralization.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Viscosity*1 (reference value)</th>
<th>pH *2</th>
<th>Loss on drying</th>
<th>Packaging unit (kg)</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP-800</td>
<td>450 – 600</td>
<td>5.5 – 6.1</td>
<td>≤5%</td>
<td>20</td>
<td>This grade has the lowest pH, and is used to increase adhesion.</td>
</tr>
<tr>
<td>NP-700</td>
<td>500 – 650</td>
<td>6.2 – 6.8</td>
<td>≤5%</td>
<td>20</td>
<td>This is the general-purpose grade. We have many datum of this grade.</td>
</tr>
<tr>
<td>NP-600</td>
<td>500 – 650</td>
<td>7.0 – 7.4</td>
<td>≤5%</td>
<td>20</td>
<td>This grade is used when actives that are stable in alkali regions need to be mixed.</td>
</tr>
</tbody>
</table>

*1: Measurements with a model B viscometer, 0.2% aqueous solution, 30 rpm, 20°C
*2: 0.2% aqueous solution

An example of how to make a hydrogel using VISCOMATE™

Pour glycerin into a 200 mL beaker, add aluminum hydroxide gel, and stir with a spatula until homogenous. Next, add VISCOMATE™ and stir until homogenous. To that, add 5 mL of a pre-prepared aqueous solution of tartaric acid, and thicken with a spatula. Continue to stir for a while after all of the aqueous solution of tartaric acid has been added, then transfer the sol to a designated container. As an example, with the mixture in Table 1, to the right, it is known that when mixing the raw materials according to the procedure described above, grades of VISCOMATE™ with greater acrylic acid content will quickly start cross-linking and solidify (Figure 1).

(Table 1) Mixture

<table>
<thead>
<tr>
<th></th>
<th>NP-800</th>
<th>NP-700</th>
<th>NP-600</th>
</tr>
</thead>
<tbody>
<tr>
<td>VISCOMATE™</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Aluminum hydroxide gel*</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Tartaric acid</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Glycerin</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Purified water</td>
<td>60</td>
<td>60</td>
<td>60</td>
</tr>
</tbody>
</table>

*Dried aluminum hydroxide gel: Product of Japanese Pharmacopoeia

(Figure 1) Various VISCOMATE™ gel formations
1. The thickening properties of VISCOMATE™

When VISCOMATE™ is dissolved in water, sodium ions from side-chain carboxyl groups dissociate, forming negative ions. Due to ion repulsion between these negative ions, the molecules extend into straight chains, which is the source of VISCOMATE™'s thickening properties. Figure 2, to the right, shows the concentration-viscosity curve for VISCOMATE™. Its aqueous solution is non-Newtonian, but it is not thixotropic. It has an extremely high molecular weight, ranging in the millions. As such, its aqueous solution has enhanced stringing properties.

2. The stability of VISCOMATE™

VISCOMATE™ is heat stable in its powder form. Figure 3, to the right, shows the measurement results of sequential sampling of 0.2 wt% viscosity VISCOMATE™ in its powder form, exposed to a temperature of 120 °C.

3. The Solvent-philic properties of VISCOMATE™

The affinity of VISCOMATE™ is highest for water, but due to its high content of acrylic acid side chains, it also has an affinity for alcohol. Figure 4, to the right, shows the thickening properties of VISCOMATE™ when 0.2 wt% of various polymers are added to various concentrations of aqueous ethanol solutions. Polycrylic acid and hydroxypropyl cellulose will dissolve in 100% ethanol as well, but their capacity for thickening is known to be low. In addition, based on the data for 30% ethanol concentration, it is known that the higher the ratio of acrylic acid in copolymers, the higher affinity for alcohol VISCOMATE™ will have.
Primary applications

The functions of the various VISCOMATE™ end products include thickeners, adhesives, humectants, and shape-retaining agents. With proper application, VISCOMATE™ can be used for:

1 Industrial thickener applications

By adding VISCOMATE™ to emulsion latex, the resulting liquid is given a certain thickness and viscosity. The photo to the right shows a comparison of emulsion latex alone (left) and emulsion latex with added VISCOMATE™ (right) dribbled on a black board. As a result of the thickness and viscosity conferred by adding VISCOMATE™, liquids can be spread evenly and uniformly across surfaces with complex shapes.

2 Medical applications

After dispersing VISCOMATE™ onto a moistening agent such as glycerin, adding water, and kneading together with the crosslinking agents of aluminum compounds and organic acids, an aqueous gel raw material sol is formed. As a subsequent cross-linking reaction proceeds, the suspension forms into a gel. This technique has a variety of applications, including in pharmaceutical cataplasms (poultices), cooling patch, and medical devices. The role of VISCOMATE™ in this aqueous gel is as follows.

① Gives gels adhesive
② Confers an ability to maintain a shape
③ Retains water or solvents inside the gel

The photograph to the right shows an aqueous gel formed from VISCOMATE™ being stretched apart. Unlike the kinds of gels formed by agar or carrageenan, VISCOMATE™ gels have viscosity, are not easily torn when stretched apart, and have elastic resilience.
Registration status (NP-600, NP-700, NP-800)

- US DMF registration number: 22803 (Type IV)
- European REACH regulations: Registration obtained

CAS No.

- 9033-79-8

Packaging unit

- 20 kg

Free samples unit

- 100 g ~

Handling VISCOMATE™

- When handling this product, be sure to read the Safety Data Sheet (SDS).
- Applicability of this product to particular purposes is left up to the judgement of the customer.
- This product’s indications for pharmaceutical purposes are limited to general external and transcutaneous applications. It is not indicated for use in preparations for dermal injury.
- The numbers associated with this product’s contents, physical and chemical properties, etc., are not guaranteed.

Further detailed information is also available. Please feel free to contact us regarding the information you require.

〈Inquiries〉

http://www.sdk.co.jp/

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