



Aqueous Vagina Gel

This aqueous vaginal gel features **Carbopol® 974P NF polymer** which imparts viscosity, acidic and bioadhesive properties to the formulation.

| Number | Ingredients | % w/w |
|--------|---------------------------|--------|
| | Part A: | |
| 1. | Carbopol* 974P NF polymer | 2.00 |
| 2. | Deionized water | 78.80 |
| | Part B: | |
| 3. | Sodium methylparaben | 0.18 |
| 4. | Sodium propylparaben | 0.02 |
| 5. | Deionized water | 4.00 |
| | Part C: | |
| 6. | Glycerin | 15.00 |
| | TOTAL: | 100.00 |

Lab batch size - 600 g

Process:

- 1. Part A (Carbopol polymer dispersion phase): Add purified water in a vessel equipped with dispersing type or propeller type impeller. Disperse Carbopol® 974P NF polymer into the water by submerging the impeller until it is very close to the bottom of the vessel. Angle the impeller to generate a vortex that is 1 to 1½ impeller diameters. Slowly sift the polymer through a stainless steel 20 mesh screen into the vortex of the rapidly agitating liquid (about 800-1500 rpm). Increase the agitation as the viscosity of the dispersion increases to maintain a vortex. After all the dry polymer has been introduced, reduce the agitation to 400-600 rpm and reposition the mixer to vertical position to avoid or minimize air entrapment. Continue the agitation for about 45 minutes, or until a uniform dispersion is obtained.
- 2. Part B: Dissolve the sodium parabens in water and add this salt solution to the Part A ingredients.
- **3.** Add glycerin to the Part A + B mixture and mix with a low-shear impeller thoroughly.





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| Product Properties | Stability | |
|--|---|--|
| Appearance: Clear Gel | Passed 3 freeze/thaw cycles | |
| pH: 3.6 | Stable for a minimum of 6 months when stored under the following ICH conditions: Long term (25 \pm 2°C / 60 \pm 5% relative humidity) | |
| Viscosity (cP)*: 45,500 ● *Brookfield RVT @25°C, 20 rpm, Spindle #7, measured at 24 hours | Accelerated (40 ± 2°C / 75 ± 5% relative humidity) | |

Design of mixing elements:





Summary:

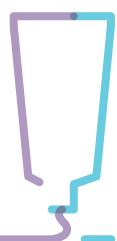
Carbopol® polymers have demonstrated to be useful and highly efficient as rheology modifiers for low-pH aqueous gel.

Alternative Lubrizol products to use in this formulation are Carbopol® 971P NF and Noveon® AA-1 polycarbophil.

The Lubrizol Life Science Health website www.lubrizol.com/Health provides additional information:

- Bulletin 04 Dispersion Techniques; Bulletin 07 Flow and Suspension Properties; Bulletin 08 -Emulsification Properties; Bulletin 21 - Formulating Semisolid Products
- Dispersion and neutralization videos under video gallery
- Technical Data Sheets, Test Procedures, Certificates, and other Formulations

Please contact your Lubrizol representative to get samples, quotations or further technical assistance.





9911 Brecksville Road J LIFE SCIENCE Cleveland, OH 44141-3201 USA

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