LUBRIZOL LIFE SCIENCE

HEALTH

Betamethasone Dipropionate Clear Hydroalcoholic Gel

The gel contains **Betamethasone dipropionate micronized, 0.06% w/w (Equivalent to 0.05% betamethasone)**. This anti-inflammatory gel features **Carbopol® 980 NF polymer** which imparts viscosity and clarity to the hydroalcoholic formulation. The gel is used to relieve inflammatory manifestations of resistant or severe psoriasis and corticosteroid-responsive dermatoses.

Number	Ingredients	% w/w
	Part A:	
1.	**Carbopol® 980 NF polymer**	0.50
2.	Deionized water	58.00
	Part B:	
3.	Betamethasone dipropionate micronized, (Equivalent to 0.05% betamethasone)	0.06
4.	Propylene glycol	20.00
5.	Isopropyl alcohol	20.00
	Part C:	
6.	Triethanolamine	q.s to pH 5.6
7.	Deionized water	q.s to 100.00
	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® 980 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 attained.

2. **Part B:** Disperse betamethasone dipropionate in isopropyl alcohol and propylene glycol.

3. Add Part B ingredients to Part A ingredients and mix thoroughly.

4. **Part C:** Adjust the above mixture slowly with triethanolamine to pH 5.6 and add the remaining deionized water. Mix with paddle or S/U-shaped low-shear impeller to avoid the air entrapment and obtain a clear, viscous gel.

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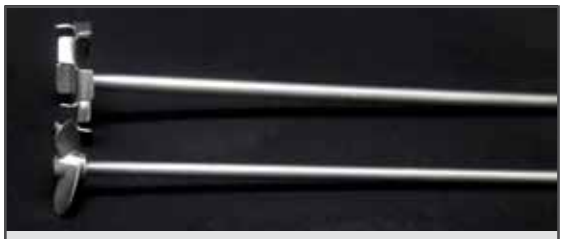
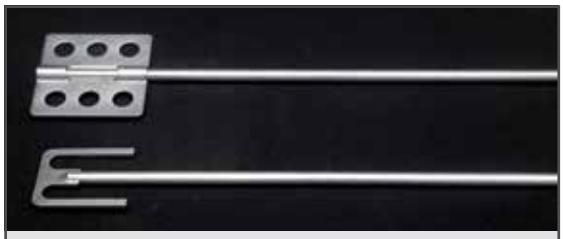
Product Properties	Stability
Appearance: Clear Gel	Passed 3 freeze/thaw cycles
pH: 5.6	Stable for a minimum of 6 months when stored under the following ICH conditions: Long term (25 ± 2°C / 60 ± 5% relative humidity)
Viscosity (cP)*: 32,2550 • *Brookfield RVT @25°C, 20 rpm, Spindle #6, measured at 24 hours	Accelerated (40 ± 2°C / 75 ± 5% relative humidity)

Design of mixing elements:



Propeller or dissolver for dispersing Carbopol® polymers.



Paddle or U-shaped low-shear impeller for neutralization.

Summary:

Carbopol® polymers have demonstrated to be useful and highly efficient as rheology modifiers for clear hydroalcoholic system.

An alternative Lubrizol product to use in this formulation is Carbopol® Ultrez 10 NF polymer which allows for versatility in formulating and processing because it is easy to disperse in water.

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.

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