

# Nimesulide, Methyl Salicylate and Menthol Cream

The cream contains **Nimesulide 1%, Methyl Salicylate 10% and Menthol 5% w/w**. This cream features **Pemulen™ TR-1 NF polymer** as an emulsifying agent and **Carbopol® 980 NF polymer** for rheology modification. Both polymers provide robust formulation at low inclusion level.

Number	Ingredients	% w/w
<b>Part A (oil Phase):</b>		
1.	Methyl salicylate	10.00
2.	Menthol	5.00
3.	Cetostearyl alcohol	5.00
4.	Polysorbate 80 (tween 80)	0.30
5.	<b>Pemulen™ TR-1 NF polymer</b>	0.30
6.	<b>Carbopol® 980 NF polymer</b>	0.30
<b>Part B (aqueous phase):</b>		
7.	Nimesulide	1.00
8.	Methyl paraben	0.20
9.	Propyl paraben	0.02
10.	Glycerin	10.00
11.	Deionized water	65.88
<b>Part C:</b>		
12.	Triethanolamine	q.s. to ~ pH 4.75
<b>TOTAL:</b>		<b>100.00</b>

Lab batch size - 1,000 gm

## Process:

- Part A (Oil Phase):** Dissolve menthol, cetostearyl alcohol and polysorbate 80 in methyl salicylate by warming to 40-45°C. Disperse **Pemulen™ TR-1 NF** and **Carbopol®980 NF polymers** into the oil mixture using propeller stirrer at low RPM.
- Part B (Aqueous Phase):** Mix glycerin in water and heated to 75°C. Dissolve methyl paraben and propyl paraben in the solution and allow it to cool to 45°C. Add Nimesulide and homogenize to form a smooth dispersion.
- Add the **oil phase** to the **aqueous phase** (both maintained at 40 to 45°C) and homogenize to form a smooth, white emulsion. Cool to room temperature.
- Part C:** Dissolve disodium EDTA and sodium parabens in water and add this salt solution into the Part A + B mixture.
- Part D:** Neutralize the above mixture with triethanolamine to achieve pH 4.75 (desired range 4.5 to 5.0). Use anchor paddle or U-shaped low-shear mixer during neutralization to minimize the air entrapment. Add water to the specified batch size. Continue mixing for at least 30 minutes until achieved uniform pH and viscosity.

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Product Properties	Stability
<b>Appearance:</b> White, smooth cream	Stable for a minimum of 3 month when stored under the following ICH conditions:
<b>pH:</b> 4.75	Long term ( $25 \pm 2^\circ\text{C}$ / $60 \pm 5\%$ relative humidity)
<b>Viscosity (cP)*:</b> 41,500 • *Brookfield RVT @25 °C, 20 rpm, Spindle #6, measured at 24 hours	Accelerated ( $40 \pm 2^\circ\text{C}$ / $75 \pm 5\%$ relative humidity)

## Design of mixing elements:



## Summary:

Carbopol® and Pemulen™ polymers have demonstrated to be useful and highly efficient as rheology modifiers and emulsion stabilizer to provide a stable o/w cream with nice sensory.

The Lubrizol Life Science Health website <https://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.**

