LUBRIZOL LIFE SCIENCE

HEALTH

Ibuprofen and Paracetamol Suspension

The suspension contains **Ibuprofen 100 mg and Paracetamol 162.5 mg per 5 ml**. This oral suspension features **Carbopol® 971P NF polymer** which is used as a suspending agent. The formulation does not show any sedimentation because of high yield value – high suspending ability of Carbopol® 971P NF polymer at low inclusion level.

Number	Ingredients	% w/v
	Part A (Carbopol® polymer dispersion phase):	
1.	**Carbopol® 971P NF polymer**	0.30
2.	Disodium EDTA	0.05
3.	Sodium saccharine	0.15
4.	Deionized water	13.00
	Part B (sugar syrup phase):	
5.	Methyl paraben	0.20
6.	Propyl paraben	0.02
7.	Sucrose	37.50
8.	Sorbitol solution (70%)	12.50
9.	Deionized water	35.00
	Part C:	
10.	Sodium hydroxide solution (10% w/w)	q.s to ~pH 5.0
	Part D (drug phase):	
11.	Kolliphor® RH 40 (PEG 40 Hydrogenated Castor Oil)	0.75
12.	Deionized water	12.00
13.	Paracetamol	3.25
14.	Ibuprofen	2.00
	Part E:	
15.	Orange RSWL Flavor	0.60
16.	Deionized water	q.s to 100.00

Lab batch size – 1000 mL

Process:

1. **Part A (Carbopol® polymer dispersion phase):** Add deionized water in a vessel equipped with dispersing type or propeller type impeller. Dissolve disodium EDTA and sodium saccharine in water. Disperse Carbopol® 971P NF 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 of 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 uniform dispersion is attained.
2. **Part B (sugar syrup phase):** Dissolve methyl paraben and propyl paraben in deionized water that has been heated to 95°C. Add sucrose and maintain the temperature at 75°C to dissolve the sugar. Filter the sugar solution through a 100-mesh nylon filter while hot. Add the sorbitol solution and mix well. Cool the syrup to room temperature.

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3. Add the Carbopol® polymer dispersion phase (Part A) to the cooled syrup phase (Part B) and mix for 15 minutes.

4. Part C: Neutralize the above mixture with the 10% sodium hydroxide solution to pH 5.0 (desired range 4.7 – 5.1) and mix for 30 minutes using a U or paddle shaped low-shear mixer.

5. Part D (drug phase): Disperse hydrogenated castor oil in deionized water. Add paracetamol and ibuprofen and homogenize to obtain a smooth, white dispersion

6. Add Part D to Part C and mix for 15 minutes using U or paddle shaped stirrer.

7. Part E: Add the color and flavor and continue mixing for 15 minutes using U or paddle shaped low-shear mixer. Add water to the specified volume. Continue mixing for at least 30 minutes to achieved uniform pH and viscosity.

Product Properties	Stability
Appearance: Smooth, orange suspension	Stable for a minimum of 3 month when stored under the following ICH conditions:
pH: 4.75	Long term (25 ± 2°C / 60 ± 5% relative humidity)
Viscosity (cP)*: 785 • *Brookfield RVT @25°C, 20 rpm, Spindle #3, measured at 24 hours	Accelerated (40 ± 2°C / 75 ± 5% relative humidity)

Design of mixing elements:

Propeller or dissolver for dispersing Carbopol polymers.

Homogenizer for preparing drug phase.

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

Summary:

Carbopol® polymers have demonstrated to be useful and highly efficient as rheology modifiers and stabilizer for formulating permanent suspension.

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

- Bulletin 04 - Dispersion Techniques; Bulletin 07 - Flow and Suspension Properties; Bulletin 22 - Oral Suspensions
- Dispersion and neutralization videos from 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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