LUBRIZOL LIFE SCIENCE

HEALTH

Oxyclozanide Veterinary Suspension

The suspension contains **Oxyclozanide 3.4% w/v**. This oral suspension features **Carbopol® 974P NF polymer** which is used as a suspending agent in the formulation. The formulation does not show any sedimentation tendency because of high yield value – high suspending ability- of Carbopol® 974P NF polymer at low inclusion level.

Number	Ingredients	% w/w
	Part A (Carbopol® polymer dispersion phase):	
1.	**Carbopol® 974P NF polymer**	0.20
2.	Methyl paraben	0.20
3.	Propyl paraben	0.02
4.	Disodium EDTA	0.05
5.	Deionized water	50.00
	Part B:	
6.	Sodium hydroxide solution (10% w/w)	q.s to pH 6.40
	Part C (drug phase):	
7.	Polysorbate 80	0.05
8.	Deionized water	30.00
9.	Oxyclozanide	3.40
	Part D:	
10.	Avicel® PH 101 (Microcrystalline Cellulose)	2.0
11.	Deionized water	q.s to 100.00

Lab batch size – 1000 mL

Process:

1. **Part A (Carbopol polymer dispersion phase):** Dissolve methyl paraben and propyl paraben in deionized water that has been heated to 90 - 95°C. Cool the solution to 60°C, add disodium EDTA and mix until it dissolves. Add Deionized water in a vessel equipped with dispersing type or propeller type impeller. Dissolve disodium EDTA and sodium saccharine in this 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 a lump-free dispersion is attained.

2. **Part B:** Neutralize the above mixture with the 10% sodium hydroxide solution to pH ~5.8 and mix for 30 minutes using a U or paddle shaped low-shear mixer.

3. **Part C (Drug phase):** Dissolve polysorbate 80 in Deionized water. Add oxyclozanide and homogenize using suitable homogenizer to obtain a smooth, white dispersion.

4. Add Part C to Part B and mix for 15 minutes.

5. **Part D:** Disperse Avicel PH 101 in Deionized water and add it to the dispersion from step 4. Mix well and adjust the volume to 100 ml with Deionized water. Continue mixing for 15 minutes using U or paddle shaped low-shear mixer. 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
Appearance: Smooth, cream colored suspension	Stable for a minimum of 3 month when stored under the following ICH conditions:
pH: 6.40	Long term (25 ± 2°C / 60 ± 5% relative humidity)
Viscosity (cP)*: 2,740 • *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 suspension stabilizer making them a first choice when formulating liquid oral suspensions.

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
- 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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