Ear cleanser and fluid bigel as complementary formulations of an otic care platform for pets

VIII ABCF CONGRESS | ABCF ASSOCIAÇÃO BRASILEIRA DE CIÊNCIAS FARMACÊUTICAS

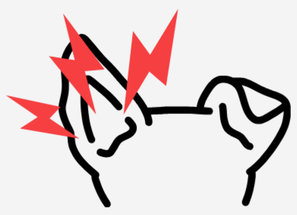
ID 1108

Paulo Henrique Corrêa Dutra da Cunha[1], Kelly Bueno[1]

[1] Gattefossé do Brasil, Barueri, São Paulo, Brazil

Presenting author's email: pcunha@gattefosse.com.br

01 INTRODUCTION



In pets with otitis externa, effective otic care requires both removal of obstructive cerumen and adequate delivery of topical drugs using safe and non-irritating formulations.

1 – CLEAN:
emulsifying cleanser → cerumen dispersion

2 – TREAT:
fluid bigel → otic spreading

02 OBJECTIVES

To develop and preliminarily characterize an **emulsifying ear cleanser** and a **drug-loaded fluid bigel** as **complementary formulations for veterinary otic care**.

03 METHODOLOGY

Ear cleanser

	L (%)	TP (%)	Glycerol (%)	Vehicle q.s. to 100%
Labrasol® (L) screening	1–20	–	1	Phosphate buffer
Transcutol® P (TP) screening	–	1–20	1	
Combination screening	5	0–20	1	

The study compared the formulations with a marketed reference (R) containing polysorbate 20.

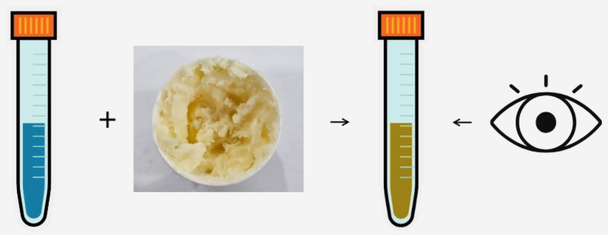


Figure 1. Artificial cerumen emulsification scheme

100 mg of artificial cerumen + 1 mL of formulation

→ *37 °C, 10 min*
→ *Mixing, 10 min*
→ ***Visual turbidity assessment***

Otic Bigel

Ingredient	Function	Concentration
Betamethasone valerate	Drug	0.12%
Clotrimazole	Drug	1.00%
Transcutol® P	Solubilizer	10.00%
Emulfree® Duo	Oily-phase stabilizer	2.00%
Labrafac™ Lipophile WL 1349	Oily phase	10.00%
Xanthan gum	Aqueous gelling agent	0.25%
Glycerol	Humectant /co-solvent	5.00%
Purified water	Aqueous vehicle	q.s. to 100%

Characterization:

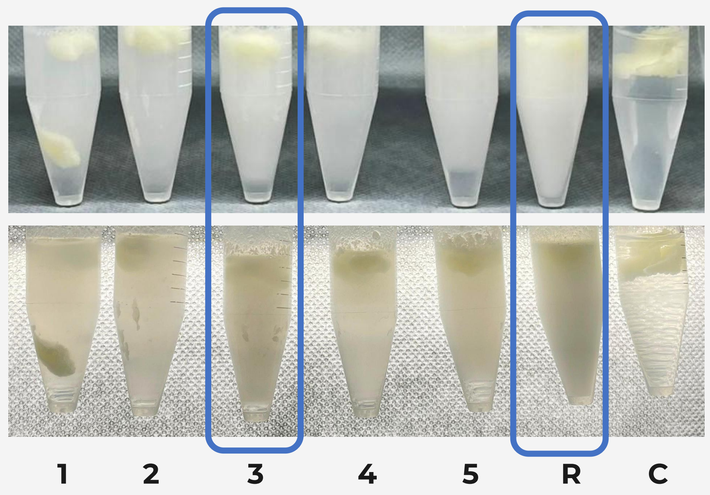
→ *Visual appearance*
→ *pH*
→ *Viscosity*
→ ***Spreadability using glass slides***

The spreadability test compared the formulation with a marketed gel (G).

04 RESULTS AND DISCUSSION

Ear cleanser

5% **L** was the lowest tested concentration to produce visual cerumen emulsification comparable to **R**. **TP** alone did not produce relevant cerumen emulsification. Adding 10% **TP** to 5% **L** preserved its performance, suggesting compatibility with the cleanser under the tested conditions.



Tube	Formulation
1	5% L + 0% TP
2	5% L + 5% TP
3	5% L + 10% TP
4	5% L + 15% TP
5	5% L + 20% TP
R	Marketed reference
C	Negative control

Figure 2. Artificial cerumen emulsification test results

Otic Bigel

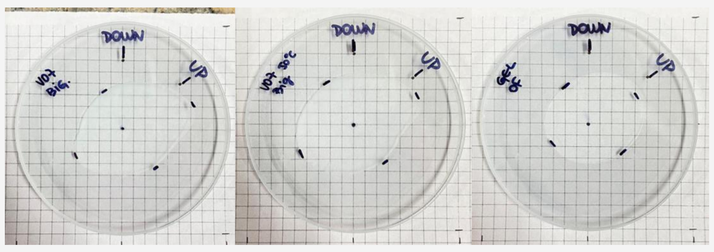
Physical stability

The formulation remained white and homogeneous, without visible phase separation or color change under the preliminary stability conditions. The small changes in pH and viscosity support preliminary physical stability.

Condition	Appearance	pH	Viscosity (mPa.s) Mean ± SD
T0	White, homogeneous	5.57	246.4 ± 0.8
40°C, 30 days	White, homogeneous	5.48	246.9 ± 3.6
50°C, 10 days	White, homogeneous	5.40	251.2 ± 2.9

Spreadability

Bigel showed the same spreading area at T0 and after 10 days at 50°C: 21.2 cm², approximately 1.4 times that of the marketed gel reference (G, 14.8 cm²).



Glass slide	Sample	Condition	Area
1	Bigel	25°C, T0	**21.2 cm²**
2	Bigel	50°C, 10 days	**21.2 cm²**
3	G	25°C, T0	**14.8 cm²**

Figure 3. Spreadability test

Discussion

- Labrasol® demonstrated promising performance as a surfactant for an otic cleanser for pets, providing apparent cerumen emulsification and representing a suitable excipient choice for mucosal administration due to its favorable tolerability profile.
- Transcutol® enabled the incorporation of poorly water-soluble drugs into a fluid bigel. Enhanced spreadability may favor distribution within the ear canal, although in vivo performance remains to be demonstrated.

05 CONCLUSIONS

The proposed “clean-and-treat” otic platform demonstrated promising preliminary performance. Labrasol® showed effective apparent cerumen emulsification, while the medicated fluid bigel combined drug solubilization, physical stability, and enhanced spreadability compared with the marketed reference. Further physicochemical and in vivo studies are needed to confirm the platform’s suitability for veterinary otic care

06 REFERENCES

1. **Nielloud F et al**. J Drug Deliv Sci Technol. 2004;14(3):235-238.
2. **Bajwa J**. Can Vet J. 2019;60(1):97-99.
3. **Song Y et al**. Pharmaceutics. 2025;17:1332.

07 ACKNOWLEDGMENTS

Gattefossé SAS