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Short communication

Rheological characterization of cetostearyl alcohol–cetomacrogol 1000 paraffin-based oil-in-water creams

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Introduction

Topical creams stabilized by surfactant–fatty-alcohol mixed emulsifiers should be viewed as structured semisolid systems, not simple oil-in-water dispersions. In liquid-paraffin emulsions containing cetomacrogol and cetostearyl alcohol, Barry and Saunders (1972) showed that consistency and flow were governed mainly by a structured gel phase in the continuous aqueous phase, rather than by droplet-size distribution. This self-bodying network, formed through surfactant–fatty alcohol–water interactions, was associated with non-Newtonian flow, hysteresis, and shear-induced structural breakdown. Thus, emulsification temperature, homogenization speed and time during the emulsification process, cooling rate, and post-emulsification restructuring can strongly affect viscosity, microstructure, thixotropy, viscoelasticity, and physical stability. Within the EMA framework for locally applied cutaneous products, Q1 denotes qualitative similarity, Q2 quantitative similarity, and Q3 physicochemical/structural similarity, including rheological and microstructural attributes relevant to drug release, local availability, and equivalence. Accordingly, the aim of this study was to evaluate how formulation and process-related variables affect the rheological attributes of O/W cream systems. The generated rheological data may therefore support rational selection of critical material and process parameters for development of pharmaceutically equivalent semisolid products.

Materials and methods

An oil-in-water cream containing cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, liquid paraffin, and purified water was prepared as a smooth, homogeneous semisolid using an Olsa MiniLab 2G mixer/homogenizer. Rheological measurements (flow curve/thixotropy, amplitude sweep, frequency sweep) were performed at 25 °C using an Anton Paar MCR 92 rheometer equipped with parallel-plate geometry (PP35) with a 1 mm gap. Emulsification conditions were varied as follows: F1: emulsification time 15-min., T 65 °C, at 2500 rpm, cetostearyl alcohol grade 70:30; F2: emulsification time 15-min., T 65 °C, at 2500 rpm; F3: emulsification time 5-min., T 75 °C, at 2500 rpm; F4: emulsification time 15-min, T 75 °C, at 2700 rpm, with a 10% relative reduction in cetostearyl alcohol. All other formulation components and process parameters were kept unchanged. Cetostearyl alcohol grade 50:50 was used in all trials except F1.

Results and discussion

In line with Realdon et al. (2002), the rheological behavior of the oil-in-water creams was sensitive to

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emulsification conditions, particularly emulsification temperature and mechanical energy input. Because the F1–F4 trials also differed in cetostearyl-alcohol grade or level, the observed differences were interpreted as formulation–process trends rather than independent main effects. The discriminative rheological outputs for F1–F4, respectively, were: $\eta 0.1$ = 424.88, 500.74, 618.86, 511.34 Pa·s; $\eta 100$ = 1.149, 1.326, 1.903, 1.155 Pa·s; $\eta 0.1/\eta 100$ = 370, 378, 325, 443; thixotropic loop area = 1.526, 1.451, 1.698, 1.425 $\times 10^3$ Pa·s^{-1}; LVR G* = 848, 1034, 1048, 840 Pa; 10% G′-drop stress = 8.4, 13.7, 17.7, 14.4 Pa; and weak-gel strength, S = 956, 1092, 1183, 934 Pa. When comparing F2 (T 65 °C; 15 min. emulsification time) to F3 (T 75 °C; 5 min. emulsification time), F3 showed higher low- and high-shear viscosity, higher thixotropic loop area, higher 10% G′-drop stress and higher weak-gel strength S, suggesting a stronger and more deformation-resistant viscoelastic network. This may reflect improved fatty alcohol–surfactant–paraffin mobility at the higher emulsification temperature and more favorable lamellar gel-network formation during cooling, despite the shorter emulsification time. In contrast, F2 likely combined lower thermal mobility with prolonged shear, leading to a more mechanically reorganized or less connected network with lower viscosity and moduli. For the comparison of F1 to F2, composition and process were unchanged except for cetostearyl-alcohol grade; F2 gave higher viscosity and G′/G″ than F1, indicating a stronger lamellar gel-network structure. This is consistent with fatty alcohol–surfactant o/w creams, where cetyl/stearyl alcohol mixtures act as co-emulsifying consistency factors and form liquid-crystalline lamellar networks whose rheology depends strongly on C16/C18 ratio and packing; here, cetostearyl alcohol 50:50 likely promoted a more effectively connected cetomacrogol–fatty-alcohol lamellar network than the 70:30 cetostearyl-alcohol grade under the same processing conditions. F4 showed a lower thixotropic loop area than F3, but still differed rheologically by showing lower high-shear viscosity and reduced viscoelastic strength, indicating weaker structural resistance under deformation. Because F3 differed from F4 not only in cetostearyl-alcohol level but also in emulsification history, specifically emulsification speed and time, this effect should be interpreted as a combined formulation–process effect rather than an isolated composition effect. Compared with F4, F3 and F2 showed stronger network formation, suggesting that the higher cetostearyl-alcohol level may have contributed to the structure-building capacity of the cream, although this cannot be separated from the different processing history in the F3–F4 comparison. F4 differed mainly by behaving as a weaker, less stress-resistant network: its LVR G′, G″ and G* were lower, its 10% G′-drop stress was lower than F3, while remaining comparable to F2, and its frequency-sweep weak-gel strength S was reduced, while tan δ and the frequency exponent remained similar. Thus, F4 did not represent a different rheological type, but a less connected cetomacrogol–cetostearyl alcohol lamellar gel network. The viscosity curve supports this interpretation partially: F4 was not uniformly less viscous at low shear, but it showed lower high-shear viscosity and lower viscoelastic strength, indicating weaker structural resistance under deformation.

Conclusion

The investigated cetomacrogol–cetostearyl alcohol paraffin oil-in-water creams showed strongly process-dependent, non-Newtonian and viscoelastic behavior governed by lamellar gel-network formation. Emulsification temperature, mixing energy/time and cetostearyl-alcohol grade or level altered viscosity, thixotropy and stress resistance, with F3 forming the strongest network and F4 behaving as a weaker, less deformation-resistant system. Overall, the rheological behavior reflected combined formulation–process control of semisolid microstructure rather than composition alone.

References

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