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Sustainable alternatives to petroleum-derived excipients in pharmaceutical oil-in-water creams

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Purpose

Recently, vast efforts towards sustainability have been made in the pharmaceutical industry. In conventional oil-in-water (O/W) cream formulations, various petroleum-based excipients, namely mineral oil and petrolatum, are commonly used. Natural or synthetic excipients, derived from vegetable sources, were explored as alternatives to petroleum-based excipients in prototype topical creams, with 1% (w/w) lidocaine.

Methods

A conventional cream comprised of petroleum-derived excipients was compared to creams containing sustainable excipients in terms of key quality and performance attributes and physicochemical properties and formulation performance (emulsion droplet size, rheology, melting point, separation index, IVRT, IVPT).

Results

The petrolatum based Control formulation had the highest viscosity at 248.0 Pa, a melting point of 41.5 °C, a low separation index at 25 °C of 0.031, and an IVRT flux of 52.9 µg/cm2/hr. Formulation SUS-4 was the least viscous formulation at 86.9 Pa, the lowest melting point of 33.7 °C, the highest separation index of 0.120 and the highest IVRT flux of 139.4 µg/cm2/hr. Alternatively, SUS-5 had a higher viscosity at 131.3 Pa, a melting point of 43.4 °C, a low separation index of 0.046, and the lowest IVRT flux of 25.2 µg/cm2/hr. The cumulative drug permeation after 12 hours from SUS-4, SUS-5, and the Control were 126.2 µg/cm2, 113.8 µg/cm2, and 108.1 µg/cm2, respectively.

Conclusion

The composition of the oil-in-water creams had influence on physicochemical properties and drug release, however, skin permeation was not impacted. Sustainable natural or synthetic excipients in topical cream formulations were found to be suitable alternatives to petroleum-based excipients with comparable key quality attributes and performance attributes and should be considered during formulation development.

Keywords: Sustainable, topical formulation, semi-solids, rheology, drug release, permeation