have primarily been used in topical biomaterials for the sustained release of active pharmaceutical agents. Sustained release of such drugs helps to maintain therapeutic drug concentrations over a longer period-of-time and helps to decrease dosage intervals, thereby increasing patient compliance.

[0009] There has been extensive research into poloxamers, which has resulted in various patent filings incuding, but not limited to U.S. Patent 7,879,320, U.S. Patent No. 4,188,373, U.S. Patent No. 6,482,435, EP Publication No. 1982696, U.S. Patent Application Publication No. 2016/0144038, U.S. Patent Application Publication No. 2009/0017120, U.S. Patent Application Publication No. 2012/0277199, U.S. Patent Application Publication No. 2015/0071864, PCT Publication No. WO2014/027006, U.S. Patent No. 8,829,053, and EP Patent Publication No. 2490722.

SUMMARY

[0009a] In one aspect, provided herein is a poloxamer gel composition comprising: 0.05 to 5 wt. % hydrophobic vicinal diol component; and 10 to 65 wt. % of a poloxamer component, 0.5 wt. % or less of a water soluble polymer other than poloxamer, wherein the hydrophobic vicinal diol component is 6-carbon to 16-carbon length monoalkyl glycols, monoalkyl glycerols, monoacyl glycerols, or a combination thereof, and wherein the hydrophobic vicinal diol component depresses a sol-gel temperature of the aqueous poloxamer equivalent by at least 1°C.

[0009b] In one aspect, provided herein is a method of lowering the sol-gel temperature of a poloxamer gel composition by at least 3°C, comprising: adding 0.1 to 1.8 wt. % of a hydrophobic vicinal diol component to the aqueous poloxamer gel composition, wherein the poloxamer gel composition comprises 17 to 46 wt. % of a poloxamer component, wherein the poloxamer component is selected from the group consisting of Poloxamer 407, Poloxamer 188, and a combination thereof, and wherein the hydrophobic vicinal diol component comprises monoalkyl glycols, monoalkyl glycerols, or a combination thereof.

[0010] In various embodiments, a method of lowering the sol-gel temperature of an aqueous poloxamer gel composition by up to 12 °C is provided. The method includes adding 0.1

to 1.8 wt. % hydrophobic vicinal diols to the aqueous poloxamer gel composition, wherein the hydrophobic vicinal diols are 6-carbon to 16-carbon length monoalkyl glycols, monoalkyl glycerols, monoacyl glycerols, or a combination thereof.

[0011] Additional features and advantages will be set forth in the detailed description which follows, and in part will be readily apparent to those skilled in the art from that description or recognized by practicing the embodiments as described herein, including the detailed description which follows, the claims, as well as the appended drawings.

[0012] It is to be understood that both the foregoing general description and the following detailed description are merely exemplary, and are intended to provide an overview or framework to understanding the nature and character of the claims. The accompanying drawings are included to provide a further understanding, and are incorporated in and constitute a part of this specification. The drawings illustrate one or more embodiment(s), and together with the description serve to explain principles and operation of the various embodiments.

CLAIMS

1. A poloxamer gel composition comprising:

0.05 to 5 wt. % hydrophobic vicinal diol component; and

10 to 65 wt. % of a poloxamer component,

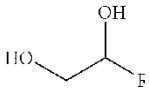
0.5 wt. % or less of a water soluble polymer other than poloxamer,

wherein the hydrophobic vicinal diol component is 6-carbon to 16-carbon length monoalkyl glycols, monoalkyl glycerols, monoacyl glycerols, or a combination thereof, and

wherein the hydrophobic vicinal diol component depresses a sol-gel temperature of the aqueous poloxamer equivalent by at least 1°C.

2. The poloxamer gel composition of claim 1, wherein the poloxamer component comprises a poloxamer selected from the group consisting of Poloxamer 108, Poloxamer 124, Poloxamer 188, Poloxamer 127, Poloxamer 237, Poloxamer 238, Poloxamer 288, Poloxamer 335, Poloxamer 338, Poloxamer 407, or combinations thereof.

3. The poloxamer gel composition of claim 1, wherein the hydrophobic vicinal diol component comprises a hydrophobic monoalkyl glycol having a structure of formula 1:

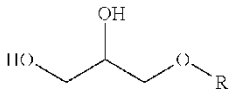


formula 1,

wherein R = C_6–C_{16} branched or unbranched alkyl group or alkylene group.

4. The poloxamer gel composition of claim 3, wherein the hydrophobic monoalkyl glycol is selected from the group consisting of 1,2-hexanediol, 1,2-octanediol, 1,2-nonanediol, 1,2-decanediol, 1,2-undecanediol, 1,2-dodecanediol, 1,2-tridecanediol, 1,2-tetradecanediol, 1,2-pentadecanediol, 1,2-hexadecanediol, and combinations thereof.

5. The poloxamer gel composition of claim 1, wherein the hydrophobic vicinal diol component comprises a hydrophobic monoalkyl glycerol having a structure of formula 2:

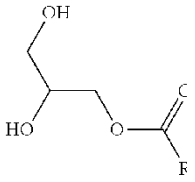


formula 2,

wherein R = C_6–C_{16} branched or unbranched alkyl group or alkylene group.

6. The poloxamer gel composition of claim 5, wherein the hydrophobic monoalkyl glycol is selected from the group consisting of glycerol 1-hexyl ether, glycerol 1-heptyl ether, glycerol 1-octyl ether, glycerol 1-(2-ethylhexyl)ether (also known as octoxyglycerin, 2-ethylhexyl glycerin, 3-(2-ethylhexyloxy)propane-1,2-diol, and Sensiva® SC SC 50), glycerol 1-nonyl ether, glycerol 1-decyl ether, glyceryl 1-undecyl ether, glycerol 1-dodecyl ether, glycerol 1-tridecyl ether, glycerol 1-tetradecyl ether, glycerol 1-pentadecyl ether, and glycerol 1-hexadecyl ether, and combinations thereof.

7. The poloxamer gel composition of claim 1, wherein the hydrophobic vicinal diol component comprises a hydrophobic monoacyl glycerol having a structure of formula 3:



formula 3,

wherein R = C_6–C_{16} branched or unbranched alkyl group or alkylene group.

8. The poloxamer gel composition of claim 7, wherein the hydrophobic monoacyl glycerol is selected from the group consisting of glycerol monohexanoate, glycerol monooctanoate, glycerol monononanoate, glycerol monodecanoate, glycerol monoundecanoate, glycerol monododecanoate, glycerol monotridecanoate, glycerol monotetradecanoate, glycerol monopentadecanoate, glycerol monohexadecanoate, and combinations thereof.

9. The poloxamer gel composition of claim 1, wherein the composition is aqueous.

10. The poloxamer gel composition of claim 1, wherein the hydrophobic vicinal diol component depresses a sol-gel temperature of the aqueous poloxamer equivalent by at least 3°C.

11. The poloxamer gel composition of claim 10, wherein the sol-gel temperature of the aqueous poloxamer equivalent is at least 26.5°C.

12. The poloxamer gel composition of claim 1, wherein the aqueous poloxamer gel composition further comprises a solubilized or suspended silver salt, silver nanoparticle, zinc nanoparticle, zinc salt, calcium salt, gold salt, gold nanoparticle, magnesium nanoparticle salt, titanium nanoparticle salt, phosphorous compound, siloxy compound, iodine compound, barium salt, cerium compound, cobalt compound, copper compound, iron compound, manganese compound, nickel compound, strontium compound, or combination thereof.

13. The poloxamer gel composition of claim 1, wherein the poloxamer gel composition further comprises a biologically active agent, solubilized or suspended, the biologically active agent being an antibiotic, antimicrobial agent, antifungal agent, antiviral agent, antibacterial agent, anti-acne agent, anti-allergenic, psoriasis agent, analgesic, anesthetic, anticlotting agent, antihistamine, anti-protozoan agent, antiparasitic agent, anti-pruritic agent, arthritis agent, astringent, anorectal, anti-inflammatory agent, antimitotic, antiperspirant, chelating agent, deodorant, essential oil, eczema agent, antiseborrheic agent, cancer treatment agent, canker sore treatment agent, cold sore treatment agent, corticosteroid, cytokine, dental agent, depigmenting agent, diaper rash treatment agent, endocrine hormone, enzyme, glycolipid, immunological response modifier, keratolytic agent, joint pain agent, hair growth stimulant, heat shock protein, glycoprotein, growth factor, growth hormone, hemostatic, lipid, moisturizer, nasal active, non-steroidal anti-inflammatory drug (NSAID), protein, peptide, pediculicide, periodontal treatment agent, nucleic acid, protease inhibitor, photosensitizing active, polysaccharide, retinoid, rosacea agent, skin protectant/barrier agent, skin treatment agent, saccharide, scabicide, steroid, sunburn treatment agent, sunscreen, thermal and radiation burn treatment agent, transdermal active, vaginal active, vasoconstrictor, vasodilator, vitamin, wart treatment agent, wart removal agent, wound debriding agent, wound treatment agent, wound healing agent, wound antimicrobial agent, or combination thereof.

14. The poloxamer gel composition of claim 1, wherein the poloxamer gel composition further comprises a water-soluble polymer selected from the group consisting of aloe vera, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose, polyquaternium-1, polyquaternium-6,

polyquaternium-10, guar, hydroxypropylguar, hydroxypropylmethylguar, cationic guar, carboxymethylguar, maltodextrin, hydroxymethylchitosan, hydroxypropylchitosan, carboxymethylchitosan, N-[(2-hydroxy-3-trimethylammonium)propyl]chitosan chloride, water-soluble chitosan, hyaluronic acid and its salts, chondroitin sulfate, heparin, dermatan sulfate, amylose, amylopectin, pectin, locust bean gum, alginate, dextran, carrageenan, xanthan gum, gellan gum, scleroglucan, schizophyllan, gum arabic, gum ghatti, gum karaya, gum tragacanth, pectins, starch and its derivatives, tamarind gum, poly(vinyl alcohol), poly(ethylene oxide), poly(ethylene glycol), poly(methyl vinyl ether), polyacrylamide, poly(N,N-dimethylacrylamide), poly(N-vinylacetamide), poly(N-vinylformamide), poly(2-hydroxyethyl methacrylate), poly(glyceryl methacrylate), poly(N-vinylpyrrolidone), poly(dimethylaminoethyl methacrylate), poly(dimethylaminopropyl acrylamide), polyvinylamine, poly(diallyldimethyammonium chloride), poly(N-isopropylacrylamide), poly(N-vinylcaprolactam), and combinations thereof,

provided that gel formation is maintained.

15. The poloxamer gel composition of claim 1, wherein the poloxamer gel composition further comprises an antimicrobial agent, the antimicrobial agent being a chlorhexidine salt, alexidine salt, poly(hexamethylenebiguanide) salt, benzalkonium salt, benzethonium salt, cetyltrimethylammonium salt, cetylpyridinium salt, didodecyldimethylammonium salt, N-heptyl-N-dodecylpiperidinium bromide, N-hexyl-N-dodecylpiperidinium bromide, glyceryl monolaurate, sorbic acid, or combinations thereof.

16. A method of lowering the sol-gel temperature of a poloxamer gel composition by at least 3°C, comprising:

adding 0.1 to 1.8 wt. % of a hydrophobic vicinal diol component to the aqueous poloxamer gel composition,

wherein the poloxamer gel composition comprises 17 to 46 wt. % of a poloxamer component,

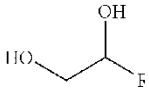
wherein the poloxamer component is selected from the group consisting of Poloxamer 407, Poloxamer 188, and a combination thereof, and

wherein the hydrophobic vicinal diol component comprises monoalkyl glycols, monoalkyl glycerols, or a combination thereof.

17. The method according to claim 16, wherein the hydrophobic vicinal diol component comprise hydrophobic monoalkyl glycols, monoalkyl glycerols, and monoacyl glycerols, and

wherein the hydrophobic substituents are aliphatic, linear or branched, and saturated or unsaturated.

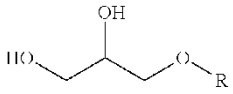
18. The method according to claim 16, wherein the hydrophobic vicinal diol component comprise a hydrophobic monoalkyl glycol having a structure of formula 1:



formula 1,

wherein R = C_6–C_{16} branched or unbranched alkyl group or alkylene group.

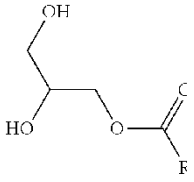
19. The method according to claim 16, wherein the hydrophobic vicinal diol component comprise a hydrophobic monoalkyl glycerol having a structure of formula 2:



formula 2,

wherein R = C_6–C_{16} branched or unbranched alkyl group or alkylene group.

20. The method according to claim 16, wherein the hydrophobic vicinal diol component comprise a hydrophobic monoacyl glycerol having a structure of formula 3:



formula 3, wherein R = C_6–C_{16} branched or unbranched alkyl group or alkylene group.

21. The composition according to claim 1, wherein the poloxamer gel composition further comprises an active ingredient selected from the group consisting of at least 0.4% EDTA, at least 0.4% guar, at least 2% avobenzene, at least 2.5% lidocaine, 0.1% to 1% PHMB, at least 10% zinc oxide, at least 1% miconazole nitrate, at least 0.4% terbinafine, at least 0.5% acetylsalicylic acid, at least 5% Medihoney, at least 0.5% silver sulfadiazine, at least 0.5% amylase, and combinations thereof.