

CLAIMS

1. A pharmaceutical formulation comprising:
- 5 0.1-8% wt. % of nicotine;
at least 65 wt.% water; and
one or more of flavouring agents, co-solubilisers and solubilisers;
wherein the nicotine is the form of a nicotine salt of nicotine and an acid; and
wherein the pharmaceutical formulation has an acidic pH.
- 10 2. A pharmaceutical formulation as claimed in claim 1, wherein the acid is selected
from acetic acid, acetylsalicylic acid, alginic acid, 2-aminoethanesulfonic acid
(taurine), aminomethylphosphonic acid, arachidic acid, ascorbic acid, aspartic acid,
azelaic acid, barbituric acid, benzylic acid, benzoic acid, butanoic acid, butyric acid,
15 capric acid, caproic acid, caprylic acid, carbonic acid, chloroplatinic acid, cinnamic
acid, citric acid, decanoic acid, dodecanoic acid, enanthic acid, ethanoic acid, folic
acid, formic acid, fumaric acid, gallic acid, gentisic acid, gluconic acid, glutamic acid,
glutaric acid, heptanoic acid, hexanoic acid, hydrochloric acid, icosanoic acid,
ketobutyric acid, lactic acid, lauric acid, levulinic acid, malic acid, maleic acid, malonic
20 acid, margaric acid, methanoic acid, 2-methylbutyric acid, 3-methylbutyric acid, 2-
methylpropanoic acid; 3,7-dimethyl-6-octenoic acid, myristic acid, nonadecylic acid,
nonadecanoic acid, ocatadecanoic acid, octanoic acid, oleic acid, oxalic acid, 2-
oxobutyric acid, palmitic acid, pectic acid, pelargonic acid, pentadecanoic acid,
pentadecylic acid, pentanoic acid, phthalic acid, phenylacetic acid, picric acid,
25 propanoic acid, propiolic acid, propionic acid, pyruvic acid, quinic acid, rosolic acid,
salicyclic acid, silicotungstic acid, sorbic acid, stearic acid, succinic acid, sulfosalicylic
acid, tannic acid, tartaric acid, tetradecanoic acid, p-toluenesulfonic acid, tridecanoic
acid, tridecylic acid, trifluoroacetic acid, trifluoromethanesulfonic acid, undecanoic
acid, undecylic acid, uric acid and valeric acid.

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3. A pharmaceutical formulation as claimed in claim 2, wherein the acid is selected from lactic acid, 2-methylpropanoic acid, acetylsalicylic acid, 2-aminoethanesulfonic acid (taurine), aminomethylphosphonic acid, arachidic acid, ascorbic acid, azelaic acid, barbituric acid, benzylic acid, butanoic acid, capric acid, caproic acid, caprylic acid, carbonic acid, cinnamic acid, decanoic acid, dodecanoic acid, enanthic acid, ethanoic acid, folic acid, fumaric acid, gluconic acid, glutaric acid, heptanoic acid, hexanoic acid, icosanoic acid, ketobutyric acid, levulinic acid, maleic acid, malonic acid, margaric acid, methanoic acid, 3,7-dimethyl-6-octenoic acid, myristic acid, nonadecanoic acid, nonadecylic acid, ocatadecanoic acid, octanoic acid, oleic acid, 2-oxobutyric acid, pelargonic acid, pentadecanoic acid, pentadecylic acid, pentanoic acid, propanoic acid, propiolic acid, quinic acid, rosolic acid, sorbic acid, stearic acid and succinic acid, tetradecanoic acid, p-toluenesulfonic acid, tridecanoic acid, tridecylic acid, trifluoroacetic acid, trifluoromethanesulfonic acid, undecanoic acid, undecylic acid and uric acid; preferably wherein the acid is lactic acid.
4. A pharmaceutical formulation as claimed in any preceding claim, comprising at least 75% water.
5. A pharmaceutical formulation as claimed in any preceding claim wherein the formulation is a liquid formulation.
6. A pharmaceutical formulation as claimed in any preceding claim, wherein the formulation is in the form of aerosolised droplets.
7. A pharmaceutical formulation as claimed in any preceding claim wherein the pH of the formulation is from 5.0 to 6.5, preferably wherein the pH of the formulation is from 4.5 to 5.9.
8. A pharmaceutical formulation as claimed in any preceding claim wherein:
- (i) the formulation comprises a flavouring agent, optionally wherein the flavouring

agent is a tobacco, mint or fruit flavouring; and/or

(ii) wherein the formulation additionally comprises a sweetener.

9. A pharmaceutical formulation as claimed in any preceding claim, wherein
 - 5 (i) the formulation comprises a co-solubiliser, optionally wherein the co-solubiliser is selected from propylene glycol, polyethylene glycol, glycerine, polyethylene glycol/polypropylene glycol co-polymers, polyvinylpyrrolidone, 1,2-hexanediol, 1,2-pentanediol, diethylene glycol mono ethyl ether, dimethyl isosorbide, ethanol, n-Butanol n-Pentanol, and mixtures thereof; preferably wherein the co-solubiliser is
 - 10 propylene glycol, glycerine, or a mixture thereof; and/or
 - (ii) wherein the formulation comprises a solubiliser, optionally wherein the solubiliser is selected from polyoxyethylene (40) castor oil, poloxamer 407 TM (poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol), polyoxyl (35) castor oil, polyoxyl (40) castor oil, polyoxyl (40) castor oil in admixture
 - 15 with PPG-1-PEG 9 lauryl glycol ether, PPG-1-PEG 9 lauryl glycol ether, polyoxyethylated 12-hydroxystearic acid, PEG 300, PEG 400, dioleic acid PEG 600 ester, heptyl glucoside, isostearic acid monoisopropanolamide, coconut fatty acid diethanolamide, coconut fatty acid glycol ester, coconut fatty acid monoethanolamide, coconut fatty acid PEG200 ester, coconut fatty acid PEG600
 - 20 ester, oleic acid PEG600 ester, oleic acid C12-C14 alkylester, oleic acid diethanolamide, oleic acid monoisopropanolamide, oleic acid PEG1000 ester, oleic acid PEG200 ester, rape seed oil diethanolamide, tall oil fatty acid diethanolamide, tall oil fatty acid monoisopropanolamide, tall oil PEG200 ester, tall oil PEG600 ester, polysorbate 20, polysorbate 40 (polyoxyethylene sorbitan monopalmitate/Tween TM
 - 25 40), polysorbate 60, polysorbate 65, polysorbate 80 (Tween TM 80), polysorbate 85, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan monooleate, sorbitan monoisostearate, sorbitan tristearate, CosmacolTM N119 (C12-C13 Pareth 9) and mixtures thereof.
 - 30 10. A pharmaceutical formulation as claimed in any preceding claim, the formulation comprising:
 - from 75 to 85 wt.% water;

from 0.1 to 8 wt.% nicotine;
from 0.1 to 15 wt.% co-solubiliser;
from 0.5 to 1.5 wt.% sweetener;
from 0.05 to 1.5 wt.% of flavouring.

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11. An inhalable pharmaceutical formulation as claimed in any preceding claim.
12. A method of delivering nicotine to a subject, comprising:
providing an aerosolised formulation comprising 0.1-8% wt.% of nicotine and
10 at least 65 wt% water; and
administering the aerosolised formulation via inhalation.
13. A method of delivering nicotine to a subject as claimed in claim 12, wherein the
method further comprises providing a liquid formulation comprising 0.1-8% wt.% of
15 nicotine and at least 65 wt.% water; and nebulising the liquid formulation to form
the aerosolised formulation; optionally
wherein the liquid formulation is nebulised via the application of oxygen,
compressed air or ultrasonic power to form the aerosolised formulation.
- 20 14. A cartridge for use with an e-cigarette, wherein the cartridge comprises the
formulation according to any of claims 1 to 12.
15. An e-cigarette comprising a cartridge as claimed in claim 15.