and a cartridge containing the same. Also disclosed are use of the aqueous solutions in the manufacture of a medicament for the therapeutic or prophylactic treatment of bacterial infections in the pulmonary system.

In one aspect, disclosed herein is an aqueous solution comprising from 80 mg A/mL to 400 mg A/mL of a sulfomethylated polymyxin, wherein the sulfomethylated polymyxin is colistimethate sodium.

In another aspect, disclosed herein is a cartridge comprising the aqueous solution as defined herein.

In another aspect, disclosed herein is the use of the aqueous solution as defined herein in the manufacture of a medicament for the therapeutic or prophylactic treatment of bacterial infection in the pulmonary system.

Detailed description

Definitions

The phrase "a" or "an" entity as used herein refers to one or more of that entity; for example, a compound refers to one or more compounds or at least one compound. As such, the terms "a" (or "an"), "one or more", and "at least one" can be used interchangeably herein.

Numerals used herein referring to a physicochemical property, time, temperature, concentration, and the like, are understood to represent measured values, and, as such, should not be strictly construed as being absolute, but rather be construed so as to account for experimental error and rounding. For example, a temperature value of 2°C will be understood to have a certain degree of variance based on the instrument used to measure the temperature, e.g., glass thermometer, digital thermometer, etc. Moreover, a measured temperature of 1.6°C, when rounded up, would be equivalent to a temperature value of 2°C.

The term "chromatographic profile," as used herein, means an HPLC chromatogram obtained by a method capable of separating or display at least 50 peaks present in CMS. Such method can be found in WO 2014/195405.

The term "no significant change in the chromatographic profile" is meant to include chromatograms in which the relative peak intensity is relatively stable, for example, varies less than 5%, or more preferably, less than 2%.

The term "physicochemical property," as used herein, means a parameter that is a measure of a physicochemical property, such as, for example, sub-visible particles, number of visible particles, color, clarity, pH, osmolality, turbidity, or viscosity.

CLAIMS

1. An aqueous solution comprising from 80 mg A/mL to 400 mg A/mL of a sulfomethylated polymyxin, wherein the sulfomethylated polymyxin is colistimethate sodium.

2. The aqueous solution according to claim 1, comprising from 80 mg A/mL to 300 mg A/mL of colistimethate sodium.

3. The aqueous solution according to claim 2, comprising from 85 mg A/mL to 150 mg A/mL of colistimethate sodium.

4. The aqueous solution according to claim 3, comprising from 90 mg A/mL to 120 mg A/mL of colistimethate sodium.

5. A cartridge comprising the aqueous solution of any of claim 1-4.

6. The cartridge according to claim 5 which is a glass ampoule, ready-to-use syringe or a blow-fill sealed vessel.

7. The cartridge of claim 5 wherein the aqueous solution comprises from 0% w/v NaCl to 0.9% w/v NaCl.

8. The cartridge of claim 5 wherein the aqueous solution has an osmolality from 500 mOsm/kg to 1300 mOsm/kg.

9. The cartridge of claim 5 wherein the aqueous solution has a pH from 6 to 9.

10. The cartridge of claim 5 wherein the aqueous solution has a pH from 6 to 7.

11. The use of the aqueous solution according to any of the claims 1-4 in the manufacture of a medicament for the therapeutic or prophylactic treatment of bacterial infection in the pulmonary system.