Claims

1. An inhalation device for delivering a nebulised aerosol to a patient, comprising:

(a) an aerosol generator with a vibratable mesh;

(b) a reservoir for a liquid to be nebulised, said reservoir being in fluid connection with the vibratable mesh;

(c) a gas inlet opening shaped as a tube fitting;

(d) a face mask, having

- a casing,
- an aerosol inlet opening,
- a patient contacting surface, and
- a one-way exhalation valve or a two-way inhalation/exhalation valve in the casing having an exhalation overpressure resistance selected in the range from 0.5 to 5 mbar; and

(e) a flow channel extending from the gas inlet opening to the aerosol inlet opening of the face mask, the flow channel having

- a lateral opening through which the aerosol generator is at least partially inserted into the flow channel,
- a constant flow resistance between the gas inlet opening and the aerosol inlet opening of the face mask at a flow rate of 1 to 20 L/min,

wherein the flow channel upstream of the lateral opening is shaped such as to effect a laminar flow when a gas is conducted through the flow channel at a flow rate of 1 to 20 L/min.

2. The inhalation device of claim 1, wherein the flow channel is sized and shaped to achieve, at a position immediately upstream of the lateral opening, an average gas velocity of at least 4 m/s at a flow rate of 2 L/min.

3. The inhalation device of any preceding claim, wherein the flow channel exhibits no further inlet opening for receiving a gas.

4. The inhalation device of any preceding claim, wherein the aerosol generator is oriented such as to emit nebulised aerosol into the flow channel at an angle of approx. 90° to the longitudinal axis of the flow channel, and wherein the inhalation device preferably comprises a switch for starting and stopping the operation of the

aerosol generator, wherein the operation of the aerosol generator comprises the continuous vibration of the vibratable mesh.

5. The inhalation device of any preceding claim, wherein the face mask has a nominal internal volume of not more than 90 mL, or of not more than 70 mL, or of not more than about 50 mL; or wherein the nominal internal volume is smaller than the average tidal volume of the patient.

6. The inhalation device of any preceding claim, wherein the face mask has a two-way inhalation- and exhalation valve having a resistance of not more than 3 mbar in either direction, and wherein the nominal internal volume of the face mask is not more than about 50 mL.

7. The inhalation device of any preceding claim, wherein the interior volume of the flow channel between the lateral opening and the aerosol inlet opening of the face mask is not more than 30 mL.

8. An assembly comprising the inhalation device of any preceding claim and a gas source providing a gas at a constant flow rate in the range from 1 to 5 L/min , wherein the gas source is connected to the inhalation device such that the gas enters the flow channel through the gas inlet opening, and wherein the gas is selected from oxygen, air, oxygen-enriched air, a mixture of oxygen and nitrogen, and a mixture of helium and oxygen.

9. A combination or kit comprising (a) the inhalation device of claims 1 to 7 or the assembly of claim 8, and (b) a pharmaceutical composition for inhalation use.

10. The combination or kit of claim 9, wherein the pharmaceutical composition comprises an active agent selected from antibiotics, antiviral agents, bronchodilators, anticholinergics, corticosteroids, hypertonic saline, antibodies, antibody fragments, and immunoglobulin single variable domains.

11. The combination or kit of claim 10, wherein the active agent is an anti-RSV agent, and wherein the anti-RSV agent is optionally a polypeptide comprising or essentially consisting of one or more anti-RSV immunoglobulin single variable domains.

12. The combination or kit of claim 11, wherein

(a) the anti-RSV immunoglobulin single variable domain comprises a CDR1 having the amino acid sequence of SEQ ID NO: 46, a CDR2 having the amino acid sequence of one of SEQ ID NOs: 49-50, and a CDR3 having the amino acid sequence of SEQ ID NO: 61;

(b) the anti-RSV immunoglobulin single variable domain is selected from one of the amino acid sequences of SEQ ID NOs: 1-34; and/or

(c) the polypeptide is selected from one of the amino acid sequences of SEQ ID NOs: 65-85.

13. The inhalation device of claims 1 to 7, the assembly of claim 8, or the kit or combination of claims 9 to 12 for use in the treatment of a patient suffering from a disease affecting the respiratory system.

14. The inhalation device, assembly, kit or combination for the use of claim 13, wherein the patient is

(a) a paediatric patient, such as a neonate, an infant, a toddler, or a school child;

(b) an adult patient for whom controlled oral inhalation is not possible or considerably impeded; and/or

(c) a patient suffering from a respiratory infection, and wherein the respiratory infection is optionally an RSV infection, such as an RSV lower respiratory tract infection.

15. The inhalation device of any of claims 1 to 7, further comprising a flow restrictor capable of restricting the flow of gas through the flow channel to a constant flow rate in the range from 1 to 5 L/min when connecting the gas inlet opening with a pressurised gas source.

16. The inhalation device of any of claims 1 to 7 or 15, comprising

- a base unit, comprising
  - an electronic controller for controlling the aerosol generator, and
  - an upstream portion of the flow channel including the gas inlet opening; and
- a mixing channel unit, comprising
  - a downstream portion of the flow channel including the lateral opening,

wherein the downstream portion comprises a segment where the flow channel widens in the downstream direction, said segment being positioned downstream of the lateral opening.

17. The combination or kit of claims 9 to 12, wherein the patient is a paediatric patient, and preferably of not more than 2 years of age.

18. The combination or kit of claims 11, 12 or 17, wherein the combination or kit comprises instructions to administer the anti-RSV agent at daily doses of about 1 to 2 mg/kg body weight.

19. The combination or kit of any of claims 11, 12, 17, or 18, further comprising a bronchodilator, preferably

wherein the bronchodilator belongs to the class of beta2-mimetics, or

wherein the bronchodilator belongs to the class of anticholinergics.