

The invention relates to an apparatus for increasing the reliability of metering in the therapeutic use of suspension-based aerosol preparations.

Suspensions of extremely finely ground pharmaceutical preparations in the pressurised liquid phase of the propellants (e.g. fluorochlorohydrocarbons) are of major importance particularly in the treatment of asthma. The suspensions are packed into pressurised containers with metering valves. By means of the metering valve it is possible to release a specific volume of suspension which is converted by spontaneous evaporation of the propellant into an inhalable aerosol.

For therapeutic reasons it is necessary for the quantity of active substance released on each actuation of the metering valve to fluctuate as little as possible. The prerequisite for this is a uniform distribution of the particles of active substance in the liquid phase.

Active substances the density of which are greater than that of the liquefied propellants settle when left to stand for lengthy periods. If the aerosol container is in the position of use (with the valve downwards) there is an increase in the concentration of active substance in the region of the inlet opening of the metering valve. Depending on the particular circumstances the increase in concentration, which depends inter alia on the difference in density between the propellant and the pharmaceutical preparation and the length of time it has been left, may be considerable. A homogeneous suspension can generally easily be reconstituted by shaking, tapping, tilting and also by the vibrations which occur during travel and when the aerosol is carried. If, contrary

to the instructions for use for suspension metering aerosols of this kind, the aerosol is not shaken before use and none of the other movements mentioned above takes place, a greatly increased dosage of active substance may enter the metering valve. Consequently in the most serious case, the quantity of active substance released on a single actuation of the aerosol may be several times the intended therapeutic dose.

References to the problems of metering in suspension metering aerosols are contained, for example, in AEROSOL AGE, vol. 27, pp. 36 - 40, New Jersey, USA; R.E. SCHARMACH; however, the full significance of these problems, not least as a function of the density of the liquefied propellant gas used, has clearly not yet been recognised.

The aim of the invention is to eliminate the danger of overdosing in suspension metering aerosols containing active substances with a tendency to sedimentation, by preventing as far as possible any increase in the concentration of active substance in the region of the inlet opening of the metering valve by certain means.

This is achieved according to the invention by means of constructional elements which are incorporated in the metering aerosol container either individually or in any desired combination.

The construction elements are:

1. a funnel shaped element which encloses the valve and is open at the top (in the position of use of the container) and leaves only one opening, e.g. an annular slot, in the region of the container wall;

2. a cover plate below the funnel which surrounds the valve housing in an annular configuration and substantially fills the internal width of the container;
3. an annular element below the coverplate, which substantially reduces the volume in the region of the inlet opening of the valve.

Figure 1 shows a preferred embodiment of the invention, which will serve as an example. It will be understood that the construction elements may also be used in other conventional metering valves, suitably adapted if necessary.

In Figure 1, reference numeral 1 denotes the aerosol container, 2 the flange closure cap to which the valve 3 is secured. The valve has an inlet opening 4 for the suspension.

The construction elements according to the invention are a funnel-shaped part 5 below which is mounted the cover plate 6 with a raised edge 7, whilst the volume in the constricted part of the closure cap 2 is partly filled by the element 8.

Between the elements 5, 6 and 8 and the wall of the container or the closure cap there is sufficient space to ensure that operation of the valve is not impaired and sufficient quantities of the suspension can travel past these elements to reach the inlet opening 4.

In the case of the valve type shown in Figures 1 and 3, the preliminary tank (outer valve portion) is fixed to the valve stem and therefore moves with it.

In the case of valves in which the valve member does not move, the construction elements may be shaped so that they abut on the walls of the container and have, as their openings, small openings (e.g. channels, grooves) in the region of the wall.

An embodiment of this kind is shown in Figure 2. Here, the funnel shaped part 5 and the volume-reducing part 8 are combined to form an element 5a, dispensing with the cover plate 6. The opening provided for the suspension consists of grooves 9, since the part 5 abuts on the walls of the aerosol container in the upper region and on the wall of the closure cap in the lower region and tightly encloses the valve housing.

Another embodiment of the invention is shown in Figure 3, in which the elements 5 and 6 have also been combined (somewhat differently) to form the element 5a.

The elements 5, 6 and 8 may be made from materials which are inert with regard to the suspension, e.g. plastics, stainless steel, aluminium. The elements are constructed, for example, so that they may be secured to the valve housing in a suitable manner or may form part thereof.



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Claims

1. Apparatus for improved metering of suspension-based aerosol preparations containing active substances with a tendency to settle, from conventional aerosol containers with a metering valve, characterised in that about the valve housing (3) in the operating position above the inlet opening (4) are mounted

- a) a funnel shaped construction element (5) which is open at the top,
- b) an annular, volume-reducing element (8) in the region of the inlet opening of the valve, and possibly, between them,
- c) an annular cover plate (6) with a raised outer edge tightly enclosing the valve housing,

whilst the elements mentioned in a) to c) substantially close off the space between the interior of the wall of the aerosol container and the valve housing, apart from an opening which consists of an annular slot or small openings near the container wall.

2. Apparatus as claimed in claim 1, characterised in that the elements according to 1a), 1b) and optionally 1c) are in one piece.

3. Apparatus as claimed in claim 1 or 2, characterised in that the elements according to 1a), 1b) and/or 1c) form a unit with the outer valve parts (3) projecting into the container.



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4. Apparatus as claimed in claim 1, 2 or 3, characterised in that the funnel-shaped element according to 1a) and the volume reducing element according to 1b) are combined to form an element (5a), thus dispensing with the cover plate according to 1c).