No suitable method for sterilising a liquid pharmaceutical composition comprising ensifentrine particles has been described. There is a need to develop a process for producing a sterilised ensifentrine suspension.

SUMMARY

The inventors have found that, of all the available sterilisation techniques, dry heat sterilization of particles of active agent followed by aseptic compounding is particularly well-suited to formulation of ensifentrine as a suspension. Other techniques such as terminal sterilisation or dry gamma-ray sterilisation were found to cause degradation of the formulations.

In an aspect, there is provided a process for producing a sterile liquid pharmaceutical composition suitable for administration by inhalation comprising ensifentrine particles, wherein the process comprises: (a) heating ensifentrine particles at a temperature of from 100°C to 220°C to obtain sterile ensifentrine particles; and (b) combining the sterile ensifentrine particles with a sterile liquid vehicle to produce the sterile liquid pharmaceutical composition suitable for administration by inhalation.

In another aspect, there is provided a process for producing an ampule comprising a sterile liquid pharmaceutical composition suitable for administration by inhalation, the process comprising: (i) producing a sterile liquid pharmaceutical composition suitable for administration by inhalation comprising ensifentrine particles by a process as defined above; and (ii) filling an ampule with the sterile liquid pharmaceutical composition suitable for administration by inhalation.

DETAILED DESCRIPTION OF THE INVENTION

The process of the invention produces a sterile liquid pharmaceutical composition. The sterile liquid pharmaceutical composition is suitable for administration by inhalation. The sterile liquid pharmaceutical composition comprises sterile ensifentrine particles.