A Dispersible Salbutamol Sulphate Tablet for an Environmentally Sustainable HFC 152a Propellant

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Introduction The switch from hydrofluoroalkanes HFA 134a and 227 to environmentally sustainable HFC 152a presents ongoing challenges for those involved in the manufacture of pressurised metered dose inhalers (pMDIs). Respitab is a propellant dispersible tablet technology designed to overcome manufacturing and formulation challenges such as drug loss and suspension homogeneity and delivered dose uniformity respectively.

Research Hypothesis Respitab pMDI technology is effectual for salbutamol sulphate (SS) in HFC 152a.

Methods A powder mixture containing micronized SS with excipients menthol and lactose was blended by low shear mixing, followed by analysis of SS for content uniformity. 100 mg tablets, each sufficient for delivering 200 doses of SS were manufactured using a single punch tablet machine and dispensed into plain 19 mL canisters. After crimping with pMDI valves, HFC 152a was pressure filled. Standard testing of pMDI hardware and pharmaceutical characteristics were conducted and assessed over a period of months at accelerated stability storage conditions to determine quality aspects of the aerosol characteristics.

Results and Discussion Data collected on Respitab SS pMDI using HFC 152a generated efficient aerosols during characterisation assessment, highlighted with high aerosol characteristics of fine particle fraction (FPF, %<5.0 µm) and uniformity of delivered dose. The use of standard hardware components showed limited effect on the physical stability of the pMDI formulation. Furthermore, aerosol assessment showed possible *in-vitro* bioequivalence to marketed product with non-optimised active pharmaceutical ingredient and excipients.

Conclusion Respitab SS produces a consistent, uniform and high quality aerosol to assist with the switch to HFC 152a pMDIs.