EFFECT OF AMBIENT TEMPERATURE AND HUMIDITY ON THE IN VITRO REGIONAL LUNG DEPOSITION OF SOLUTION AND SUSPENSION MDIS

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The effect of ambient conditions on *in vitro* mouth-throat and lung deposition was investigated for the following pressurised metered dose inhaler (pMDI) formulations: 1) beclomethasone dipropionate (BDP) solution in 13% w/w ethanol, 1.3% w/w glycerol and HFA 134a propellant solution ("BDP HFA 134a"); 2) BDP solution in 13% w/w ethanol and HFA 227 propellant solution ("BDP HFA 227"); 3) Flixotide Evohaler™ (fluticasone propionate 250μg/dose suspension in HFA 134a). The testing apparatus was an Alberta Idealised Throat connected to an inline filter and a vacuum pump. The apparatus, and the pMDIs prior to discharge, were kept within an environmental chamber. Single doses (3 replicates) from each pMDI formulation were collected in the apparatus according to an experimental matrix, containing the following variables: relative humidity (RH) (0%, 35%, 80%); temperature (20°C, 40°C); air flow rate (28.3, 60, 90 L/min). The results suggest that delivered lung dose fractions from the formulations are affected by relative humidity, while air flow rate and temperature have a limited and inconsistent effect. For the solution formulations, an increase in RH from 30 to 80% had a general decreasing trend in fractional delivered lung dose (35% decrease the worst case). Flixotide™ suspension exhibits different behaviour, with lung dose fraction falling sequentially (50% decrease the overall worst case), as RH is increased from 0% to 30% to 80%. The *in vitro* lung delivery of pMDI formulations is affected by ambient conditions, implicating variability in inhaler performance when used in different climates, or when used outside of air conditioned rooms.