THE PUNCTURE PROPERTIES AND THE SHEDDING OF PARTICLES OF CAPSULES IN DRY POWDER INHALERS, EFFECT OF CAPSULE TYPE AND MOISTURE CONTENT

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PURPOSE

- The moisture contents of both types of capsules met the desired levels, see Table 1.
- The stubs were then examined by scanning electron microscopy (LEO S360, Oxford Instruments) and the size of the particles was measured using the instruments software. A range of magnifications were used in order to detect particles in both the micron and sub-micron range.

RESULTS

- Visible particles were only observed in the gelatin capsules after puncture i.e. there were no visible particles upon puncture of HPMC capsules.
- The impact of moisture on the size of the particles created during puncture of the gelatin capsules was variable and therefore no conclusions can be drawn.

CONCLUSIONS

- Visible particles could not be detected by a light microscope after puncture of HPMC capsules, but are visible after puncture of gelatin capsules.
- Inhaling grade capsules size 3, gelatin and hypromellose (Quali-V®-I) supplied by Qualicaps, were manually closed and conditioned in desiccators over saturated solutions of either lithium chloride (c.11% RH) or calcium chloride (c.34% RH) for 10 days at room temperature. The selected RHs provide capsule moisture contents at the lower end of the specification limit and below this limit. Moisture content was determined by loss on drying (LOD) tests.

METHODS

- Inhalation grade capsules size 3, gelatin and hypromellose (Quali-V®-I) supplied by Qualicaps, were manually closed and conditioned in desiccators over saturated solutions of either lithium chloride (c.11% RH) or calcium chloride (c.34% RH) for 10 days at room temperature. The selected RHs provide capsule moisture contents at the lower end of the specification limit and below this limit. Moisture content was determined by loss on drying (LOD) tests.

- Capsules were punctured, in dome of cap and body, by placing in chamber of Plastiape® Monodose 2-pin inhaler, see Fig. 1A, and depressing both buttons to push the steel needles into the shells, see Fig. 1B & C.
- Capsules were also punctured on a Zwick® materials testing machine (MTM) fitted with pin, supplied by Plastiape® from their Monodose inhaler, see Fig. 2. The capsules were held firmly in a metal bushing from a size 3 capsule filling machine (Qualcaps) and only the caps were punctured. A 950N load cell was used to determine forces generated during capsule puncture by the MTM® and the pin displacement at puncture. These are denoted in results as Fmax and dL at Fmax respectively.
- After puncturing the contents of all capsules were carefully transferred to the viewing platform of an AmScope stereo-microscope fitted with a digital camera. The number of visible particles was recorded and ImageJ® software was used to measure their area, circularity, flap attachment and circumference.

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BIBLIOGRAPHY

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