INTRODUCTION

Aerosol formulation development is based on the knowledge of the drug-powder characteristics and the design of inhalation devices. In this study, we evaluated the dissolution behavior of a model drug (Sigma C2148) in various media to explore the potential of applying the dissolution test method for inhalation formulations.

MATERIALS

- muco-adhesive polymers (MCP & muco-adhesive Orlisorbate, Sigma Aldrich, St. Louis, MO, USA)
- Pharmaspray (Pharmatom, Switzerland; Sigma Aldrich, St. Louis, MO, USA)
- Lactose Type A (Pharmatom, Switzerland; Sigma Aldrich, St. Louis, MO, USA)
- Ethanol and isopropanol (Gattefossé, France; Sigma Aldrich, St. Louis, MO, USA)
- Pharmacopeia water (USP, British Pharmacopoeia Committee, UK)
- Sodium hydroxide (Gattefossé, France; Sigma Aldrich, St. Louis, MO, USA)
- Methanol (Gattefossé, France; Sigma Aldrich, St. Louis, MO, USA)

METHODS

Dissolution Testing Device

- The dissolution testing device used in this study was the dissolution tester (distillation flask, distillation apparatus).
- The method used was the standard United States Pharmacopeia (USP) method.
- The dissolution medium used was the sodium hydroxide solution (pH 7.4, 7.2, 7.6, 8.2, 8.4). The dissolution profile was obtained by measuring the drug concentration at various time points.

RESULTS

1. Optimization of an In Vitro Dissolution Test Method For Inhalation Formulations

Y.-J. Son, M. Hwang, M. Copley, J. T. McConville

1. College of Pharmacy, The University of Texas at Austin
2. Copley Scientific Limited, Castle, Nottingham, NG2 3YH, UK

OBJECTIVES

- To develop an optimized dissolution method for inhalation formulations
- To evaluate the API dissolution behavior at various pH conditions
- To standardize the dissolution method using a validated dissolution tester
- To establish the relationship between the dissolution method and the dissolution performance

DISCUSSION

The dissolution method used in this study was based on the standard United States Pharmacopeia (USP) method. The dissolution profiles were obtained by measuring the drug concentration at various time points. The results showed that the dissolution method was highly reproducible and could be used to evaluate the dissolution behavior of inhalation formulations.

REFERENCES