

Development of a new method to determine water content in hydrated matrix tablets of sodium alginate

Ewelina Juszczyk¹, Przemysław Dorożyński¹, Piotr Kulinowski², Encarna García Montoya³, Josep M. Suñé Negre³, Pilar Pérez Lozano³, Montse Miñarro³, Josep Ramon Ticó³

¹ Department of Pharmaceutical Technology and Biopharmaceutics, Jagiellonian University Medical College, Cracow, Poland

² Institute of Technology, Pedagogical University of Cracow, Cracow, Poland

³ Department of Pharmacy and Pharmaceutical Technology, University of Barcelona, Barcelona, Spain

Introduction

One of the methods used to measure a water content in a sample is Karl-Fischer titration. In this work we have used this method to measure the water content of particular matrix tablet's layers, after hydration. The tablets contained sodium alginate, which is a natural polymer that swells in water creating a matrix that is able to prolong a drug release. This characteristic is used in pharmacy to prepare modified-release drugs.

Materials and equipment

Materials

AQUAMETRIC Composite 5 for volumetric analysis (Panreac AppliChem, Spain)

Methanol according to Karl Fischer (Panreac AppliChem, Spain)

Methanol for UHPLC (Panreac AppliChem, Spain)

All other reagents were of analytical grade.

Equipment

Karl-Fischer titration equipment (Metrohm, USA)

Analytical weight (Sartorius, Germany)
Home-made device for tablet hydrating and cutting layers

Methods

In order to prepare the samples, a special device (that allows hydrating and cutting the layers) has been invented (Fig. 1A). The device contains a holder and a micrometric screw which allows moving up the tablet in the holder to the required height. The device with a tablet is placed in a beaker filled with water heated up to 37°C (Fig. 1B). After reaching a required timepoint (1, 2, 3 or 4 hours), the device is removed from the beaker. Each layer is cut with a spatula (slice of 1 mm) and weighted on analytical scale. After cutting a layer, a tablet is moved 1 mm up with a micrometric screw. In such a way 5 layers (of 1 mm each) are obtained. The samples are put into flasks and filled with methanol. Water content of the samples is determined by Karl-Fischer method.

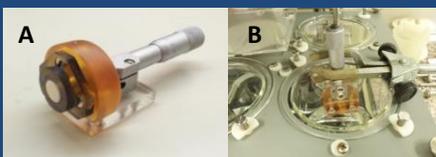


Fig. 1. A – A home-made device for tablet hydrating and cutting layers, B – Way of installation for hydration

Results and discussion

The results show that water migrates into the tablet during hydration (Fig.2 and 3), as it was detected both in external and internal layers at each timepoint. What is more, water content decreases at each timepoint according to the distance from the tablet surface (the deeper layer, the less water content) (Fig.3). Additionally, each layer (besides the external one) gets more water upon longer hydration (the longer hydration, the more water is detected in particular layer). It is in agreement with other works that used different methods to study water migration inside the matrix tablets.

Conclusion

The presented method is the first that allows determination of water content in any layer of the hydrated matrix tablet.

References

1. Kulinowski P, Młynarczyk A, Dorożyński P, Jachowicz R, Jasiński K, Gruwel MLH, Tomanek B, Węglarz WP. *Pharm Res* 2012; 29(12): 3420-3433.
2. Kojima M, Nakagami H. *Chem Pharm Bull* 2002; 50(12): 1621-1624.

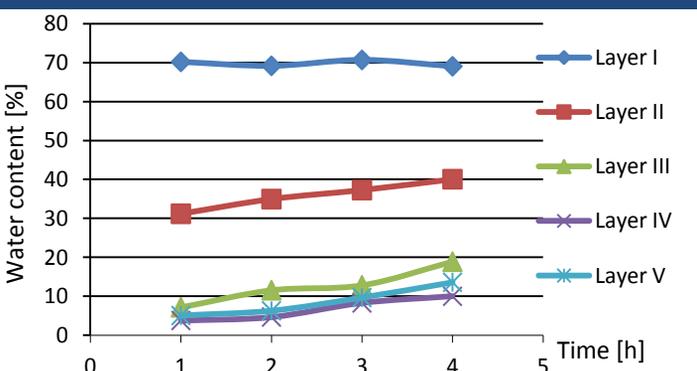


Fig.2. Water content (%) of each layer upon time.

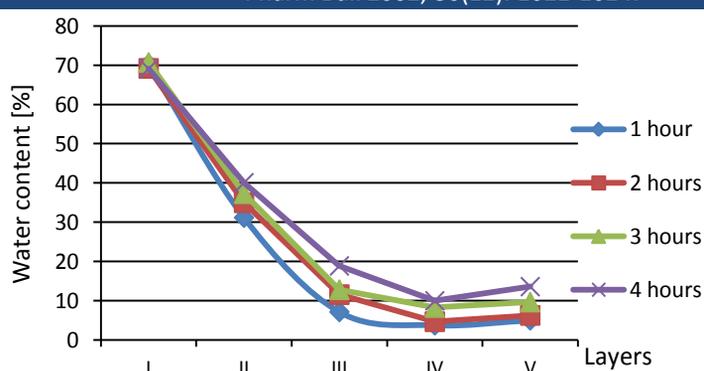


Fig.3. Water content change according to the distance from the tablet surface (I – most external layer, V – most internal layer).