THE 67TH INTERNATIONAL

OPEN READINGS

CONFERENCE FOR STUDENTS OF PHYSICS AND NATURAL SCIENCES

BOOK OF ABSTRACTS | 2024

Vilnius University

VILNIUS UNIVERSITY PRESS

Editors:

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Cover and Interior Design:

Goda Grybauskaitė

Vilnius University Press
9 Saulėtekio Av., III Building, LT-10222 Vilnius
info@leidykla.vu.lt, www.leidykla.vu.lt/en/
www.knygynas.vu.lt, www.journals.vu.lt

Bibliographic information is available
on the Lithuanian Integral Library Information System (LIBIS) portal www.ibiblioteka.lt
ISBN 978-609-07-1051-7 (PDF)

P2: Chemistry and Chemical physics; Nanomaterials and Nanotechnologies

OPTIMIZATION OF THE COMPOSITION OF A SOLID DISPERSED SYSTEM OF NIMESULIDE OBTAINED BY CENTRIFUGAL FIBER FORMATION

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For many years, nimesulide-based nonsteroidal anti-inflammatory drugs have been among the most well-known drugs for relieving acute toothache and many different inflammatory diseases. However, the widespread use of these drugs is limited by the low solubility of the active pharmaceutical ingredient (API) in water (0.01 g/l) [1]. This leads to the use of high doses of nimesulide and the occurrence of undesirable side effects. Therefore, research aimed at increasing the solubility of nimesulide is very important.

The analysis of literature sources shows that in recent years the technology of solid disperse systems (SDS) has shown promising results in increasing the solubility of a significant number of water-insoluble anti-inflammatory drugs.

In this study, we used an innovative centrifugal fiber forming technology to produce solid dispersed nimesulide systems. SDS of nimesulide were prepared by fusing API, polymer, and excipient in the working area of the centrifugal fiber forming machine. The resulting melt was then moved through the filter by centrifugal force and solidified into fibers in the air flow. Polyvinylpyrrolidone K-17 (PVP K-17), a pharmaceutically acceptable polymer carrier, was selected. To increase the yield of the fibers formed, sucrose was used, the addition of which to the composition allows the melting point of the mixture to be reduced.

It was found that the design of a solid dispersed system based on nimesulide and PVP K-17 in a percentage ratio of 5:95 can improve the solubility of APIs by 2.85 times. On the other hand, when 5 % of PVP K-17 was replaced by sucrose, the degree of solubility increase was increased to 3.12 times. With a further increase in sucrose in the composition of SDS to 10 % and 20 %, it was possible to increase the degree of increase in the solubility of nimesulide by 3.63 times and 4.88 times, respectively. Subsequently, an increase in the sucrose concentration in the composition had the opposite effect, which led to a decrease in the solubility of nimesulide.

It is worth noting that sucrose affects not only the solubility of nimesulide but also the yield of the resulting SDS fibers. It was found that the solid dispersion of nimesulide, which was formed only from K-17 without the addition of sucrose, has a yield of 55.72 %. At the same time, when 5 % sucrose is added to the system, the fiber yield increases to 69.64 %, and when 20 % sucrose is added, the yield of SDS was increased to 71.40 %.

For the first time, a new method for increasing the solubility of nimesulide was developed based on the centrifugal formation of SDS fibers. It has been established that the optimal content of components for preparing polymeric SDS of nimesulide by the method of centrifugal fiber formation is a ratio of PVP K-17, sucrose, and nimesulide in a proportion of 75:20:5. This composition increases the solubility of the API by 4.88 times and has a high yield of fibers at 71.40 %.

[1] K. D. Rainsford, Consensus Report Group on Nimesulide. Nimesulide–a multifactorial approach to inflammation and pain: scientific and clinical consensus, Current medical research and opinion, 22(6), 1161-1170 (2006). https://doi.org/10.1185/030079906X104849