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ANALYSIS OF SPECTRAL LINES FOR STARS VIA SYNTHETIC SPECTRA	201
Dzmitry Viarbitski, Markus Ambrosch	
ACHIEVING LONG-LASTING ROOM TEMPERATURE PHOSPHORESCENCE IN PHENOTHIAZINE CRYSTALS	202
Vilius Stankevičius, Jonas Žurauskas, Paulius Vaickūnas, Steponas Raišys, Edvinas Orentas, Karolis Kazlauskas	
P2: Chemistry and Chemical physics; Nanomaterials and Nanotechnologies	
Functionalization and Properties Investigations of Benzothiophene Derivatives	203
Arnas Kovševič, Indrė Jaglinskaitė, Vilija Kederienė	
HYDROGELS WITH THE ADDITION OF MODIFIED STARCH AND CLAY OF THE MONTMORILLONITE TYPE	204
Anastasiia Godunko, Irina Liashok, Viktoriia Plavan, Olena Ishchenko, Viacheslav Shvets	
PROPELLANT SELECTION FOR ENHANCED DRUG DELIVERY IN WOUND-HEALING TOPICAL AEROSOLS	205
Mariia Popova, Olena Saliy	
OPTIMIZATION OF THE COMPOSITION OF A SOLID DISPERSED SYSTEM OF NIMESULIDE OBTAINED BY CENTRIFUGAL FIBER FORMATION	206
Viktoriia Lyzhniuk, Viktor Kostyuk, Vadym Lisovyi, Andriy Goy, Galina Kuzmina, Volodymyr Bessarabov	
UV TO NIR EMITTING UPCONVERTING NANOPARTICLES FOR APPLICATIONS IN THERANOSTICS	207
Egle Ezerskyte, Greta Butkiene, Arturas Katelnikovas, Vaidas Klimkevicius	
RESISTIVITY AND LOW FREQUENCY NOISE OF HYBRID COMPOSITES WITH CARBON NANOTUBES AND IRON NANOINCLUSIONS	208
Frydrichas Mireckas	
STRUCTURE OF CAPROIC ACID MONOMERS AND HYDROGEN BOND COMPLEXES. MATRIX ISOLATION IR SPECTROSCOPY STUDY	209
Simona Bučinskaitė, Redas Kazlauskas, Jogilė Mačytė	
INVESTIGATION OF SARS-COV-2 OMIKRON SPIKE PROTEIN REAL-TIME INTERACTIONS WITH SPECIFIC MONOCLONAL ANTIBODIES	210
Justina Liesyte, Silvija Juciute, Vincentas Maciulis, Ieva Plikusiene	
INVESTIGATION OF MXENES ADSORPTION POTENTIAL FOR AZURE A AND METHYLENE BLUE DYES pH-RESPONSIVE BEHAVIOR AND ADSORPTION KINETICS	211
Anton Popov, Martynas Talaikis, Germantė Paulikaitė, Simonas Ramanavicius, Gediminas Niaura	
OPTICAL SECOND HARMONIC GENERATION IN GaN WAVEGUIDE STRUCTURE	212
Ignas Dailidėnas, Roland Tomašiūnas	

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>