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BIOPHARMACEUTICAL RESEARCH AN INFLUENCE OF TECHNOLOGICAL FACTORS ON SOLUBILITY OF SUPPOSUTORIES

Annotation. We have conducted the research of solubility of rectal suppositories of different manufacturers. The research demonstrated an influence of technological factors on dissolution rate of suppositories

Keywords: Biopharmaceutics, suppository, dissolution.

Introduction. The term “biopharmaceutics” appeared in the 60’s of XX century, but many experimental data obtained long before. Well known empirical observations of ancient doctors, such as Avicenna, who noticed the effect of additives honey and some herbal remedies on the level of action of drugs. In the XXI century foreign and domestic scientists experimentally established dependence of the absorption and effectiveness of the drug from the way its administration; proved surfactants impact on the process of absorption of drug. It has become apparent inability of previous methods for assessing drugs that were limited mainly to their commodity specifications and standards for quantitative content of active ingredients. However, these facts passed unnoticed due to lack of scientific evidence.

Teaching Biopharmaceutics as a scientific discipline introduced in 70’s of XX century. Today, in many countries in pharmaceutical universities are Biopharmaceutics Department. There is the Institute of Pharmaceutical Technology and Biopharmaceutics in Vienna, Austria.

Biopharmaceutics based on knowledge of mathematics, physics, inorganic and organic chemistry, pharmaceutical chemistry, physiology, anatomy, biochemistry, pharmacology, drug technology, so its terminology commonly used pharmacological, technological, pharmaceutical chemistry terms.

Unlike pharmacology, biopharmaceutics doesn't study mechanisms of action and practical point of drug or excipient. It explores the impact extremely variable factors on pharmacokinetics and pharmacodynamics of drugs.

Due to the fact that the therapeutic effectiveness of drugs is determined by the processes of absorption, distribution and elimination of macroorganism, biopharmaceutics focuses on the study of these processes, as well as exposure to physical and chemical properties of drugs.

Therefore, all formulations studied, now covered in biopharmaceutical aspects.

The main purpose of Biopharmaceutics as a science is theoretical and experimental study of new drugs and improve existing considering increasing their therapeutic effect and reducing side effects on the body.

In addressing these tasks are important studies to assess the bioavailability of drugs. This means that pharmaceutical complex knowledge, where previously the physical and chemical constancies were the main criteria; introduce new provisions that are purely biological, medical justification [2, 4].

One of pharmaceutical factors that create a significant impact on the therapeutic activity of drugs is a technological process. The effectiveness of drugs depends not only on the nature and dose of the drug, but also on technological stages of its production and equipment.

The process determines the choice of excipients to provide certain properties of drugs. It is also associated with the dosage form. It is therefore necessary to consider these factors in relationship to each other [3, 5].

The object of the study were suppositories with metamizole sodium manufactured by "Monpharm", "Lekhim" and "Nizhpharm".

Disintegration test performed on the device for determining the disintegration of suppositories company PHARMA TEST. The device (State Pharmacopoeia of Ukraine art.2.9.2, p.152) is made of transparent glass or plastic hollow cylinder of appropriate wall thickness, which is in the middle with three holders of fixed metal devices. Device occurs two perforated discs of stainless steel, mounted approximately 30 mm apart. The diameter of the discs is almost equal to the inner diameter of the cylinder, and each disc has 39 holes with a diameter of 4 mm.

Research methodology. We studied three samples suppositories. Each sample placed on the bottom of disc; the device installed and fixed in the cylinder. We put the device in a tank of water heated to 37°C and the test started. Automatic overturned every 10 minutes at 180°. After the time we studied samples.

Disintegration test allows to determine soften or breaking of the samples of suppositories within the set time if they are placed in a liquid medium in experimental conditions.

It considered that the samples disintegrated when:

- There is complete dissolution;
- Components of suppositories divided: fat melted material gathered on the surface of the liquid, insoluble particles settled on the bottom and soluble components dissolved;

- Softening sample accompanied by appreciable change in shape without separation of components or complete lack of suppositories solid core that creates pressure resistance glass rod.

Results and discussion. As the object of the study of the influence of the technological process on pharmacotherapy were selected suppositories, which currently is a popular dosage form. Their effectiveness depends on technology. Advanced multistage manufacturing process of suppositories accompanied by various technological operations that can change the dissolution rate and completeness of the release of active ingredients. Pharmaco-technological research adopted to the State Pharmacopoeia of Ukraine, close to requirements of Pharmacopoeia USP / EP / DAB / JAP. They regulate the suppository test of disintegration and dissolution [1, 6].

As examples of metamozole sodium suppositories made of hydrophobic basis, the requirements of the SPU decompose such suppositories should not be longer than 30 minutes.

Table

Name of drug / manufacturer	*Time of softening, min*		
	1-st sample	*2-nd sample*	*3-th sample*
"Analdim" / "Monpharm"	12,50	15,00	15,25
"Analgin" / "Lekhim-Kharkiv"	20,25	18,75	20,00
"Analgin" / "Nizhpharm"	12,25	11,25	12,50

As seen from the results of the experiment, all samples match requirements of the SPU. For the time specified in the table, suppositories had divided: melted fat components assembled on the surface of the water, soluble components dissolved. Thus, samples of studied suppositories withstand disintegration test.

Conclusions. The research has shown that the investigated suppositories withstand disintegration test, but technological factors have an influence on the time of disintegration of suppositories of different manufacturers.

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