BIOPHARMACEUTICAL RESEARCH OF SUPPOSITORY BASE INFLUENCE AND METHOD OF SUPPOSITORIES PREPARATION ON RELEASE OF ZINC SULFATE HEPTAHYDRATE

Tolochko K. V., Yarnych T. G., Chushenko V. M.
National University of Pharmacy, Kharkiv, Ukraine

Suppository bases have certain physicochemical properties and cause a significant effect on the bioavailability of medicinal substances in their composition, therapeutic effect, uniformity of the ingredients distribution, precision of dosing, etc. Also, they provide a certain structural and mechanical or rheological properties.

Cocoa butter has long been used in the pharmaceutical practice of medicines preparation. This base has the following positive qualities: releases well the introduced medicinal substances; has pronounced melting temperature (32.0–34.0 °C); has good plasticity; mixes well with different medicinal substances. It is known that when overheating cocoa butter changes its allotropic modification that results in decreasing the melting temperature. In this connection, this base is recommended for hand-rolling of suppositories. However, the US Pharmacopoeia (USP, 2008, Section 9, p. 1096-1101) offers the casting method of preparing suppositories based on cocoa butter. This method is based on the observance of strict temperature regime of cocoa butter melting, of the active ingredients introduction and cooling of suppositories.

The aim of our work is to investigate the influence of the type of suppository base on the release rate of the active ingredients on the example of zinc sulfate heptahydrate.

The first stage of the work was to study the properties of the suppositories based on cocoa butter prepared by different methods. For the experiment there were prepared 2 series of suppositories with zinc sulfate heptahydrate. Samples of the 1st series were prepared by the rolling method and samples of the 2nd series – by the casting method. Zinc sulfate heptahydrate was introduced by the type of emulsion.

It was found that both series of suppositories meet the requirements of the State Pharmacopoeia of Ukraine (SPU) (see table). Suppositories of the 2nd series have the same melting point as the 1st series of suppositories, indicating the absence of the phenomenon of polymorphism. Also, suppositories of the 2nd series surpass suppositories of the 1st series by the indicator resistance to destruction.

Table

Properties of suppositories with zinc sulfate heptahydrate

Indicator	Results		
	Series 1	Series 2	Requirements of SPU
Homogeneity	Homogeneous	Homogeneous	There should be no inclusions on the cut.
Average weight, g	2.15±0.11 (±5%)	2.01±0.08 (±4%)	±5%.
Melting temperature, °C	31.9±1.0	34.3±1.0	not more than 37.0
Resistance to destruction, kg	2.8	3.0	-

Thus, it can be argued that at the precise observance of temperature regime (32.0–34.0 °C) preparation of the suppositories based on cocoa butter by the casting method ensures their proper quality, which contributes to the optimization of the production process in the pharmacy as hand-rolling method is time consuming.