MINISTRY OF PUBLIC HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY

TOPICAL ISSUES OF NEW DRUGS DEVELOPMENT

Vol. 2

April 20, 2017
Kharkiv

Kharkiv
NUPh
2017

УДК 615.1
А43
Редакційна колегія: академік НАН України Черних В. П., проф. Котвіцька А. А., доц. Крутських Т. В., Данильченко С. Ю.
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Актуальні питання створення нових лікарських засобів: тези доповідей XXIV міжнародної науково-практичної конференції молодих вчених та студентів (20 квітня 2017 р.). в 2-х. т., Т. 2. – Х.: Вид-во НФаУ, 2017. – 413 с.

Збірка містить матеріали науково-практичної конференції молодих вчених та студентів «Актуальні питання створення нових лікарських засобів». Матеріали згруповано за провідними напрямками науково-дослідної та навчальної роботи Національного фармацевтичного університету. Розглянуто теоретичні та практичні аспекти синтезу біологічно-активних сполук і створення на їх основі лікарських субстанцій; стандартизації ліків, фармацевтичного та хіміко-технологічного аналізу; вивчення рослинної сировини та створення фітопрепаратів; сучасної технології ліків та екстемпоральної рецептури; біотехнології у фармації; досягнень сучасної фармацевтичної мікробіології та імунології; доклінічних досліджень нових лікарських засобів; фармацевтичної опіки рецептурних та безрецептурних лікарських препаратів; доказової медицини; сучасної фармакотерапії, соціально-економічних досліджень у фармації, маркетингового менеджменту та фармакоекономіки на етапах створення, реалізації та використання лікарських засобів; управління якістю у галузі створення, виробництва і обігу лікарських засобів; інформаційниих технологій у фармації та медицині; основ педагогіки та психології; суспільствознавства; філології. Для широкого кола наукових і практичних працівників фармації та медицини.

УДК 615.1

UDC 615.1
A43
Editorial board: academician of NAS of Ukraine Chernykh V. P, prof. Kotvitska A. A., ass. prof. Krutskyh T. V., Danylchenko S. Yu.
Compilers: Materiienko A. S., Netyosova K. Y., Surikova I. O., Grygoriv G. V., Ravshanov T. B.

Topical issues of new drugs development: Abstracts of XXIV International Scientific And Practical Conference Of Young Scientists And Student (April 20, 2017) in 2 vol., Vol. 2. – Kh.: Publishing Office NUPh, 2017. – 413 P.

Book of Abstracts includes materials of Scientific and Practical Conference of Young Scientists and Students «Actual questions of development of new drugs». Materials are groupped according to the main directions of scientific, research and educational work of the National University of Pharmacy. Teoretical and practical aspects of the synthesis of biologically active compounds and development of medicinal substances on their basis; standardization of drugs, pharmaceutical and chemical-technological analysis, the study of raw materials and herbal remedies development, modern drug technology and extemporal recipe; biotechnology in pharmacy, modern advances in pharmaceutical microbiology and immunology, clinical trials of new drugs, pharmaceutical care for prescription and OTC-drugs, evidence-based medicine, modern pharmacotherapy, socio-economic studies in pharmacy, marketing management and pharmacoeconomics during the development, implementation and use of drugs, quality management in development, production and traffi cking of drugs; information technologies in pharmacy and medicine; basics of pedagogy and psychology; social science; philology are presented. For a wide audience of scientists and pharmaceutaical and medicinal employees.

UDC 615.1

ELECTRONIC SEPARATION OF DRUGS IN THE STATUS OF "QUARANTINE" IN THE PHARMACEUTICAL WAREHOUSE

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Introduction. As stated in the operating license conditions regarding implementation of manufacturing medicines, wholesale and retail trading of drugs, importing drugs (except for active pharmaceutical ingredients), electronic separation of drugs in the status of "quarantine" may be provided on the condition of existence conforming product identification, validation of computerized systems (CS) and upon condition that the system provides equivalent safety. In good distribution practice (GDP), are says that only specifically designated person should perform data entry or changes in the system. In case of system, failure or malfunction should be determined procedures.

Validation of computerized system and program support, that guarantees electronic separation of prohibited for sale drugs from authorized store, is considered extremely important concerning the functioning of the system of quality in modern pharmaceutical distribution companies. Based on validation testing, should be provided determined and documented procedures of process control of behaving with quarantine production and proper actions in case of malfunctioning system.

Validation testing CS and further determination of documented procedures with consideration for validation testing appears to be distributor of drugs matter of interest. In this instance, validation should cover all of the aspects related to CS: starting from system choice and its installation to operation under normal and critical conditions. All of the mentioned aspects are always concerned with risk on quality influence of pharmaceutical production. They have to be determined and estimated during validation process.

Aim. Determination methods of electronic separation of drugs in the status of "quarantine" with the help of relevant CS and PS, in distributing activity of pharmaceutical company.

Materials and methods. In the capacity of research database were used normative documents, which standardize CS functioning and its validation (in particular, GMP/GDP regulations), ISO specialized standards, ICH regulations and other information sources. The comparative analysis method, the method of structural and logical modeling expert method were applied during the research.

Results and discussions. There is properly built and documented process controlling model of quarantine production and the program of CS and program support (PS) validation that provides electronic separation of prohibited for sale drugs with due account for undesirable situations. It allows qualified person of pharmaceutical distributor to guarantee prevention of ingress the quarantine production to permitted for sale store with following statuses:

- Pharmaceutical products that didn`t pass the incoming inspection of quality by qualified person;
- Drugs that are prohibited in accordance with law;
- Drugs that must be utilized (including rejected products);
- Low-quality drugs or those, which under suspicion of quality violation;
- Adulterated drugs or those, which under suspicion of adulteration;
- Drugs that are recalled from the market;
- Returned drugs;
- Drugs that are imported and do not have permission for selling.

When building a functioning system of electronic separation, should be considered, at least, the following:

- The rights for operations performing on quarantine production with the help of CS must be given only to qualified person. Each qualified person should have the necessary access to system authentication and authorization;
- Any operation performed with the help of CS should retain in PS "audit trail" with a history of events and full name of the person, who performed the operation;
- Pre-compiled database a series of drugs that must be blocked by the system in case of such series remains available in authorized selling stock;
- Block activation a series of drugs by program, whose marketing authorization or shelf life soon expires;
- Any returned pharmaceutical production, which is taken on charges and put into the system, must be automatically blocked, until qualified person makes a decision concerned this production;
- Giving an appropriate status for imported drugs, concerning the stages of the formation of the sales permit.

Conclusions. There is properly built and documented process controlling model of quarantine production and the program of CS, whose validation testing is thoroughly organized. In case of malfunctioning, all of the necessary procedures are determined, which are extremely important for obtaining drugs quality guarantee. Our further researches are focused on developing methodology of validation CS.