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Olena WELCHINSKA

Features of the content of test tasks in the discipline «Standardization of Medicines»

OLENA WELCHINSKA. **Features of the content of test tasks in the discipline «Standardization of Medicines».** *Testing has long taken a firm place in the training system. Using testing, we use the method of researching the level of student's knowledge, abilities and skills. Standardized tasks, namely tests (tasks related to each other), are solved using the basic knowledge available after studying the discipline and logical approaches. «Standardization of medicines» is discipline that studies the development of medicines (drugs) quality standards that ensure an appropriate level of quality of medicines. It is based on the material of pharmaceutical chemistry and is the logical conclusion of the study of a complex of chemical pharmaceutical sciences. A feature of the test tasks in «Standardization of medicines» is the use of pharmaceutical chemistry and pharmaceutical analysis data.*

Key words: *standardization, medicines, test, pharmaceutical analysis.*

The pharmaceutical sector in Ukraine is in its infancy, so the basic principles of EU legislation in the field of licensing and control of medicinal products are of particular relevance to Ukraine. Experiment EU

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countries in developing legislation in the pharmaceutical field for more than 30 years. Using the principles of the EU in the practice of government regulation of the pharmaceutical sector will help accelerate the integration of Ukraine into the European market, improve competitiveness and the quality of Ukrainian drugs.

The educational discipline «Standardization of medicines» is studied by students of higher medical and pharmaceutical universities of Ukraine in the 5th year of study.

The main tasks of this discipline is study of the development of quality medications standards that ensure the required level of medications quality and to provide future pharmacists with systemic knowledge about standardization of medicines.

This discipline aims to provide students with knowledge about standardization of substances and dosage forms of industrial pharmaceutical production, taking into account the current state of development of the pharmaceutical field; structure and basic principles of standardization of medicines in the pharmaceutical field according to GMP, GLP, GCP, GXP requirements, state standards of Ukraine; principles and requirements of documentation (pharmacopoeia articles, AND, methods of quality control for substances and medical preparations); use of chemical methods of analysis for identification, purity research, instrumental methods of quantitative analysis of medicines, modern physical and physical-chemical methods that are widely used in standardization of medicines [1, 2].

This discipline studies a wide range of concepts and issues. This is the main sections of standardization of medicines and its field of application, methods for standardization of drugs, validation of analytical methods, basic state regulations in pharmaceutical analysis, safety rules and work in pharmaceutical laboratory analysis, legal regulation of procedures for standardization, a system of quality assurance of pharmaceutical products, general instructional techniques assessing the quality of drugs and dosage forms, theoretical foundations of pharmacopoeia methods for the analysis of drugs and their detection, identification and quantification of using chemical and physical-chemical methods.

«Standardization of medicines» is based on the knowledge of different sciences, such as, inorganic chemistry or physical and colloid chemistry (properties of elements and their compounds, basics of chemical kinetics, theory of thermodynamics, phase equilibria, solutions of electrolytes, ionic equilibrium surface events, how to calculate the chemical equilibrium known initial concentrations and the equilibrium constant, basis extraction

processes), organic chemistry (properties of organic compounds, the nature of chemical bonds and electronic of the structure of organic compounds, reaction mechanisms of organic compounds, methods of analysis in organic chemistry), analytical chemistry (general questions analyzing trace amounts of materials, modern methods of analysis), biological chemistry (basic patterns of metabolism of drugs, biochemical basis of individual variability in metabolism of drugs, mechanism of transport of xenobiotic), pharmaceutical chemistry (properties of medications and methods of its quality analysis), statistics and informatics (statistical analysis of experimental data), technologies drugs (impact of dosage forms the bioavailability of drugs, products of secondary metabolism), pharmacology (pharmacodynamics and pharmacokinetics of bioactive substances, the mechanism of action of biologically active substances, differential diagnosis analysis), toxicological and forensic chemistry (properties of poisonous drugs, methods of its isolation and analysis, toxic dynamics and toxic kinetics of bioactive substances).

The educational discipline «Standardization of medicines» is based on the data of science «Pharmaceutical chemistry» and is the logical conclusion of the study of a complex of chemical pharmaceutical sciences.

«Pharmaceutical chemistry» studies methods of analysis for identification, purity research, instrumental methods of quantitative analysis of medications, pharmaceutical compositions, and biological active substances. At the same time, both pharmacopoeia methods and non-pharmacopoeia methods are used for the pharmaceutical analysis of medication.

Many methods of qualitative and quantitative analysis of medications have been adopted for chemical-toxicological analysis. However, the objects of research in this case are not only medical preparations, but also other toxic substances, as well as the biological material of a poisoned person [3-5].

Thus, only «Standardization of medicines» studies standardized methods of identification, quantitative analysis of medications.

Testing student's knowledge is one of the most important forms of knowledge control. Standardized tasks – tests are solved using the basic knowledge available after studying the discipline and logical approaches.

Testing allows to save time, check the level of knowledge on extensive material, and develop the student's memory. However, testing does not give a complete picture of the level of knowledge of students.

The positive point is that standardized methods of medications analysis have already been studied in the discipline «Pharmaceutical

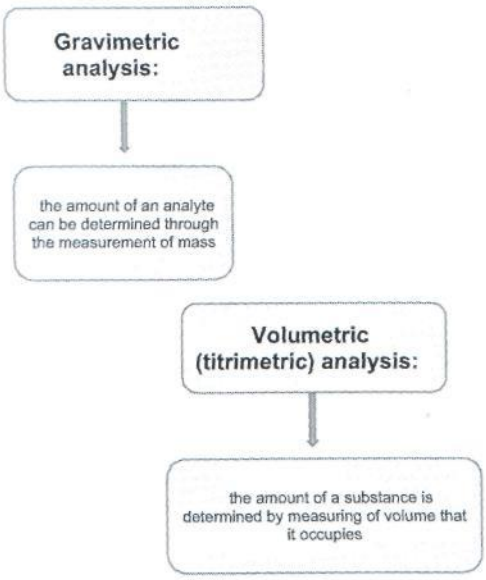
chemistry», which allows students to use the previously acquired knowledge base (tabl.1).

Table 1. Methods of analysis that are studied in disciplines «Standardization of medicines» and «Pharmaceutical chemistry»

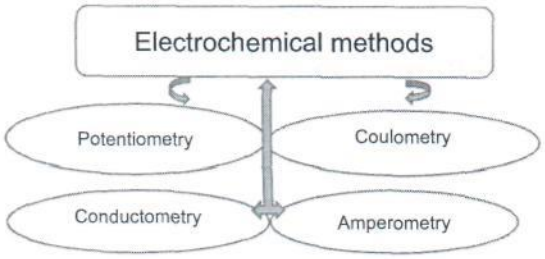
«Standardization of medicines» standardized methods	«Pharmaceutical chemistry» standardized and non-standardized methods
chemical methods	chemical methods
physical and physical-chemical methods (instrumental methods): chromatography (TLC, GC, LC, HPLC), electrochemical methods, spectral methods (UV-, IR-, NMR-, other)	physical and physical-chemical methods (instrumental methods): chromatography (TLC, GC, LC, HPLC), electrochemical methods, spectral methods (UV-, IR-, NMR-, other)

Chemical methods are separations *(precipitation), extraction,* distillation, *qualitative analysis* (colour, smell, melting point, other). There are *two types* of chemical methods in quantitative determination of medicines (scheme 1).

Scheme 1.



There are next electrochemical methods (scheme 2):



The main characteristic of electrochemical method is measu signal (tabl.2).

The main topics of the discipline «Standardization of medicines»

Electrochemical method	Measured signal
Potentiometry	Potential
Coulometry	Amount of electricity (in Coulones)
Conductometry	Conductivity
Voltamperometry	Dependence of electric current (in Amperes) on voltage (in Volts)
Amperometry	Electric current (in Amperes)

- The system of standardization of medicines. Analy documentation for pharmaceutical products: AND, monograp
- Use of chemical methods in the development of qu standards of medicines under sections of pharmacopoeia ar «Identification», «Purity research».
- Use of chemical methods in the development of quality stand of medicines under sections of pharmacopoeia article «Quantit determination».
- Use of physical and physical-chemical methods for identifica purity research and quantitative determination as standardiz of medicines.

- Use of chromatography and electrochemical methods for identification, purity research and quantitative determination as standardization of medicines.

For example, topic «Use of chemical methods in the development of quality standards of medicines under sections of pharmacopoeia article «Identification», «Purity research»». We can use next tests (tabl.2):

Table 2. «Use of chemical methods in the development of quality standards of medicines under sections of pharmacopoeia article «Identification», «Purity research»»

TEST QUESTION 1. Which reagent is used for determination Ca^{2+} in medicines?	a) Potassium iodide b) *Ammonium oxalate c) Sodium hexahydroxistibiate d) Ammonium chloride e) Silver nitrate
TEST QUESTION 2. Which analytical effect will be after adding $FeCl_3$ to benzoate-ion?	a) an orange-yellow spot b) a white precipitate c) a green precipitate d) a violet color e) *a pink-yellow precipitate
TEST QUESTION 3. Which range of colours is used for examination of the colour intensities of liquids?	a) *a brown-yellow-red b) a red-yellow-green c) a yellow-orange-red d) a red-white-black e) a red-green-blue
TEST QUESTION 4. Which laboratory glassware should be used for determination of sensitivity reactions?	a) clean test tubes of the different diameters b) clean dry retorts of the same diameter c) *clean dry test tubes of the same diameter d) clean dry retorts of the different diameters e) none answer is right
TEST QUESTION 5. Which background is used for determination of solution's clarity?	α) a white β) a yellow χ) *a black δ) clary ε) none answer is right
TEST QUESTION 6. What reagent should be added for identification of Al^{3+}?	a) HCl b) *NaOH c) $AgNO_3$ d) $(NH_4)_2C_2O_4$ e) Na_2HPO_4

TEST QUESTION 7. Which colour of precipitate does Br^- give after adding $AgNO_3$?	a) a white **b)** *a pale yellow c) a yellow d) an orange e) a brown
TEST QUESTION 8. Which colour of precipitate does Fe^{3+} give after adding $K_3[Fe(CN)_6]$?	a) a white b) a pale yellow c) a yellow d) an orange **e)** *a blue
TEST QUESTION 9. Which reagent is used for separation of CO_3^{2-} and HCO_3^-?	a) $AgNO_3$ b) Na_2HPO_4 **c)** *$MgSO_4$ d) NaOH e) $K_2Cr_2O_7$
TEST QUESTION 10. Pharmacist-analyst defines a sodium iodide. The presence of heavy metals he will check by forming of:	a) a green fluorescence **b)** *a brown coloration c) a yellow colour d) a white opalescence e) a blue fluorescence
TEST QUESTION 11. The laboratory for quality control of medicines received a mucolytic drug containing Ambroxol hydrochloride. To detect chloride ions in its identification, it is necessary to use a solution:	a) *Argentum nitrate b) Barium sulfate c) Glyoxalhydroxyanil d) Potassium ferrocyanide e) Diphenylamine
TEST QUESTION 12. Dexamethasone is a hormonal agent that contains covalently bound fluorine. This allows after mineralization of the substance to identify F^- with a solution of:	a) *Calcium chloride b) Sodium chloride c) Ammonium oxalate d) Argentum nitrate e) Sodium acetate
TEST QUESTION 13. The pharmacist-analyst identifies the antimicrobial agent "Ciprofloxacin hydrochloride". To detect the chloride ion, it reacts in the presence of sulfuric acid concentrated with the following reagent:	a) *Potassium dichromate b) Sodium hydroxide c) Magnesium sulfate d) Potassium chloride e) Zinc oxide

QUESTION 14. uality control of 0.1% injectable ion of atropine sulfate is d out in the central analytical atory of the pharmaceutical prise. Due to sulfate ions, the substance can be identified nteraction with the following nt:	a) *Barium chloride b) Copper (II) sulfate c) Potassium iodide d) Sodium bicarbonate e) Ammonium chloride
QUESTION 15. aboratory for quality ol of medicines received an ypertensive drug containing line hydrochloride (clonidine). entify it, determine the de ions by reaction with silver e in the environment:	a) *Nitric acid, dil. b) Sulfuric acid, conc. c) Sodium hydroxide d) Diethyl ether e) Formaldehyde
QUESTION 16. g the pharmaceutical analysis e drug substance, a reaction performed with antipyrine azone) in the presence of dilute chloric acid. The appearance en color allows you to identify:	a) *Nitrites b) Sulfates c) Fluorides d) Bromides e) Iodides
QUESTION 17. r the action of acetic acid d like a drug substance, there apid release of gas bubbles, causes turbidity of the barium xide solution. This test allows identify:	a) *Carbonates b) Fluorides c) Nitrites d) Sulfates e) Chlorides
QUESTION 18. boratory for quality control dicines received an antiulcer containing bismuth sub citrate. g the reaction to the bismuth , the formation of a yellowish- e color was observed. What nt was used in this test?	a) *Thiourea b) Glyoxalhydroxyanil c) Hydrochloric acid d) Sodium hydroxide e) Potassium acetate

TEST QUESTION 19. The laboratory for quality control of medicines received a substance of the antibiotic *Ampicillin sodium*. The sodium ion was identified by reaction with a solution of potassium pyroantimonate to form a precipitate of the following color:	a) *a white b) a blue c) a yellow d) a red e) a green
TEST QUESTION 20. As a result of the reaction of the analgesic Metamizole sodium monohydrate with a solution of potassium pyroantimonate, a white precipitate formed. This confirms the presence in the structure of the drug:	a) *sodium ions b) covalently bound sulfur c) methyl groups d) phenyl radical e) keto groups

Thus, these tests can be called standardized, since they can be u test control of student's knowledge, both in the discipline «Standardi of medicines» and in the discipline «Pharmaceutical chemistry».

The development of test material has tremendous possib for example, the creation of thematic complexes of test task combination of test tasks with situational tasks or schemes of ch transformations, and others.

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tracts

ОЛЕНА ВЕЛЬЧИНСЬКА. **Особливості змісту тестових завдань з дисципліни «Стандартизація лікарських засобів».** *Тестування вже давно зайняло міцне місце в системі навчання. Використовуючи тестування, використовуємо метод дослідження рівня знань, умінь і навичок студента. Стандартизовані завдання, а саме тести (завдання, пов'язані між собою), розв'язуються з використанням базових знань, наявних після вивчення дисципліни, та логічних підходів. «Стандартизація лікарських засобів» — дисципліна, що вивчає розробку стандартів якості лікарських засобів (лікарських засобів), які забезпечують належний рівень якості лікарських засобів. Він заснований на матеріалі фармацевтичної хімії і є логічним завершен-*

ням вивчення комплексу хіміко-фармацевтичних наук. Ос
тю тестових завдань із «Стандартизації лікарських засобів»
ристання даних фармацевтичної хімії та фармацевтичного
Ключові слова: *стандартизація, ліки, випробування, фа*
тичний аналіз.

ОЛЕНА ВЕЛЬЧИНСКАЯ. **Особенности содержания**
вых заданий по дисциплине «Стандартизация лека
ных средств». *Тестирование давно заняло прочное место в*
обучения. С помощью тестирования мы используем мето
следования уровня знаний, умений и навыков учащихся. Ста
зированные задачи, а именно тесты (задачи, связанные друг с
решаются с использованием базовых знаний, доступных по
чения дисциплины, и логических подходов. «Стандартизаци
ственных средств» - дисциплина, изучающая разработку
тов качества лекарственных средств (лекарственных средс
спечивающих надлежащий уровень качества лекарственных
Он основан на материале фармацевтической химии и
логическим завершением изучения комплекса химико-фарм
ческих наук. Особенностью тестовых заданий в «Стандар
лекарственных средств» является использование данных ф
тической химии и фармацевтического анализа.
Ключевые слова: *стандартизация, лекарственные средст*
фармацевтический анализ.

OŁENA WELCZYŃSKA. **Cechy treści zadań testo**
dyscyplinie „Standaryzacja środków leczniczych". *Test*
dawna zajmuje ważne miejsce w systemie edukacyjnym. Stos
stosujemy metodę badania poziomu wiedzy, umiejętności
studenta. Zadania standaryzowane, czyli testy (zadania pow
sobą), rozwiązuje się z wykorzystaniem podstawowej wiedzy z
przestudiowaniu dyscypliny i podejść logicznych. „Standaryzac
leczniczych" to dyscyplina zajmująca się opracowywaniem s
jakości środków leczniczych (leków) zapewniających odpowied
jakości środków leczniczych. Opiera się na materiale chemii farma
i jest logicznym zakończeniem uczenia się kompleksu nauk ch
i farmaceutycznych. Cechą zadań testowych „Standaryzac
leczniczych" jest wykorzystanie danych z chemii farmaceutyczn
farmaceutycznej.
Słowa kluczowe: *standaryzacja, leki, testy, analiza farmaceut*