

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

APPROVED

Vice-rector on educational
and pedagogical work,
member of National Academy of
Medical Sciences of Ukraine
M.R. Gzhegotsky



2021

EDUCATIONAL PROGRAM

**on elective discipline «World pharmaceutical industry»
for training specialists of the second (master's) degree of higher education of
knowledge branch of 22 «Health care»
of speciality 226 «Pharmacy, industrial pharmacy»
for the third-year students of Pharmacy Faculty**

Approved
at the meeting of Department of
Drug Technology and Biopharmaceutics
«14» 08 2021
Minutes No.1
Head of the Department
C. Bilous assoc. prof. S.B. Bilous

Approved
by the Methodological Committee on
Pharmaceutical Disciplines
«14» 08 2021
Minutes No.3
Head of the Committee
C. Bilous assoc. prof. S.B. Bilous

2021

Educational program on elective discipline «World pharmaceutical industry» was developed by staff members of the Drug Technology and Biopharmaceutics Department:


Head of the Department, PhD, associate professor **S.B. Bilous**

PhD, associate professor **K.F. Vashchenko**

PhD, assistant professor **O.O. Vashchenko**

PhD, associate professor **O.V. Yakymiv**

PhD, associate professor **O.I. Yezerska**



Reviewed by: PhD, associate professor of Department of Management and Economy of Pharmacy of Danylo Halytsky Lviv National Medical University, O.R. Levytska

INTRODUCTION

Educational program of the elective discipline

“World Pharmaceutical Industry”

according to the Higher Education Standard of second (master’s) degree of knowledge

branch of knowledge 22 «*Healthcare*»

specialty 226 "Pharmacy, Industrial Pharmacy"

educational program of *Master of pharmacy*

Description of the elective discipline (abstract)

The elective discipline "World Pharmaceutical Industry" belongs to the cycle of disciplines of the professionally-oriented training of specialists in the specialty "Pharmacy, Industrial Pharmacy" and consists of 1 content module.

The educational program on elective discipline «World pharmaceutical industry» is structured in accordance with The Standard of Higher Education of Ukraine for speciality "Pharmacy, Industrial Pharmacy".

The elective discipline «World pharmaceutical industry» is designed for higher full-time education graduates and provides theoretical knowledge about the basic stages of the formation and development of pharmaceutical technology in Ukraine and the world, the current trends of the pharmaceutical industry development, and the general requirements for the manufacturing of various pharmaceutical groups of drugs.

Structure of educational discipline	Number of credits, hours, including			Year of study / semester	Types of control	
	Total	Class hours				Self-education
		Lectures	Seminar classes			
World pharmaceutical industry	2 credit ECTS / 60 hours	10	20	60	3 course, V semester	Credit

The subject of the study of the elective discipline is the main statements and trends of the pharmaceutical industry development in Ukraine and other countries of the world; mastering of modern principles of the manufacturing of medicinal products in various dosage forms.

Interdisciplinary connections include:

- the discipline is based on the study of the history of pharmacy and medicine, pharmaceutical informatics and statistics;

- discipline is the basis for the study of pharmaceutical technology, good practices in pharmacy, management and marketing in pharmacy, which foresees the integration of teaching with the aforementioned disciplines in the formation of skills to apply knowledge in the process of further education and professional activities;

- the discipline sets the basis for the professional training of a future specialist, promotes the formation of pharmaceutical and technical thinking;

- along with other pharmaceutical disciplines and social sciences, this elective discipline plays an important role in providing special technological training for carrying out professional activities.

1. Goal and objectives of the elective discipline

1.1. The aim of the elective discipline “World pharmaceutical industry” is gaining the theoretical bases of the pharmaceutical industry formation in Ukraine and in the world, the stages of the development of new drug products, organization of medicines production in pharmaceutical enterprises with considerations of the requirements of good manufacturing practice; gaining the knowledge of characteristics, classification and assortment of dosage forms, which gives the opportunity to realize more the scientific and creative potential of futur specialists.

1.2. The main objectives of learning the elective discipline "World Pharmaceutical Industry" are:

- familiarization with stages of the pharmaceutical industry development in Ukraine and in the world;
- gaining the basic knowledge about the characteristics and classification of drug products, main stages of the development and standardization;
- acquisition with the requirements of current normative documents regulating the organization of manufacturing in pharmaceutical enterprises;
- acquisition with the organization of manufacture of drug products in accordance with the requirements of Good Manufacturing Practice (GMP);
- using laws and other normative documents regulating the manufacture of drug products in the professional activity.

1.3. Competencies and learning outcomes, the formation of which the discipline facilitates (the relationship with the normative content of the training of higher education graduates, formulated in terms of the results of training in the Standard).

The elective discipline ensures acquiring of the following **competencies** by students according to the requirements of the Standard:

- *Integrative competencies:*

- the ability to solve typical and complex specialized tasks and practical issues in the professional pharmaceutical practice using statements, theories and methods of fundamental, chemical, technological, biomedical and social-economic sciences;
- ability to integrate knowledge and solve complex issues, to formulate judgments in case of insufficient or limited information;
- to present clearly and unambiguously conclusions and knowledge, justifying in a wise way to the professional and non-professional audience.

- *General competencies:*

GC 1. The ability to act in socially and civil responsible manner.

GC 2. The ability to use knowledge in practical situations.

GC 3. The desire to maintain the environment.

GC 4. The ability for abstract thinking, analysis and synthesis, ability to study and to be modernly trained.

GC 5. The ability to show initiative and entrepreneurship.

GC 6. The knowing and understanding of subject field and the understanding of profession.

GC 7. The ability to adapt and act in a new situation.

GC 8. The ability to communicate in the native language in both spoken and written ways. The ability to communicate in other language that provides an effective professional activity.

GC 9. The ability to use information and communication technologies.

GC 10. The ability to choose communication strategy, to work in team and with experts from other fields of knowledge / types of economic activity.

GC 11. The ability to evaluate and ensure quality of performed work.

GC 12. The ability to conduct investigations on an appropriate level.

• *Specific (professional, objective) competencies:*

CS 1. The ability to use knowledge of laws and regulations and the recommendations of good pharmaceutical practices in the professional activities.

CS 2. The ability to develop and form documents on manufacture of drug preparations in accordance with the recommendations of Good practices.

The specification of the competencies according to the descriptors of the NRC in the form of "Matrix of competencies" is shown below.

Matrix of competencies

No.	Competency	Knowledge	Abilities	Communication	Autonomy and responsibility
<i>Integrative competency</i>					
the ability to solve typical and complex specialized tasks and practical problems in the professional pharmaceutical practice using statements, theories and methods of fundamental, chemical, technological, biomedical and social-economic sciences; ability to integrate knowledge and solve complex issues, to formulate judgments in case of insufficient or limited information; to present clearly and unambiguously conclusions and knowledge, justifying in a wise way to the professional and non-professional audience.					
<i>General competencies</i>					
GC 1	The ability to act in socially and civil responsible manner.	To know social and civil rights and obligations	To form civil consciousness and to act according to it	Ability to present social and civil position	To be responsible for civil position and activity
GC 2	The ability to use knowledge in practical situations	To know methods of knowledge implementation in solving practical issues	To be able to use professional knowledge for solving practical issues	To establish contacts with entities of practical activities	To be responsible for making decisions in time
GC 4	The ability for abstract thinking, analysis and synthesis, ability to study and to be modernly trained	To know current development trends of the pharmaceutical branch and to analyze them	To be able to analyze professional information, make justified decisions, acquire modern knowledge	To establish appropriate contacts for achieving the goals	To be responsible for acquisition of modern knowledge in time
GC 6	The knowing and understanding of	To know structure and	To be able to carry out professional	To form communication	To be responsible for

	subject field and the understanding of profession	features of professional activities	activities that requires updating and integration of knowledge	strategy in the professional activities	professional development with high level of autonomy
GC 7	The ability to be adapted and act in a new situation	To know elements of manufacture and social adaptation, factors of successful adaptation to a new environment	To be able to form an effective strategy of personal adaptation to new circumstances	To communicate with public (colleagues, management, professionals of other branches) in case of appearance of new situations with unpredictable elements	To be responsible for making decisions
CG 9	Skills of usage of information and communication technologies.	To have a deep knowledge in the information and communication technologies which are used in the professional activities	To be able to use the information and communication technologies in the professional activities that requires updating and integrating the knowledge	To use the information and communication technologies in the professional activities	To be responsible for the development of professional knowledge and skills
CG 11	The ability to evaluate and ensure quality of performed work	To know methods for evaluation of a work quality	To be able to ensure competent performance of professional activities	To establish contacts for assurance of a competent performance of activities	To be responsible for a qualitative performance of activities
CG 12	The ability to conduct investigations on an appropriate level	To know elements of the health care system, planning and evaluation of a scientific research	To search scientific sources of information; to carry out a choice of methods of scientific research; to use methods of mathematical analysis and modeling, theoretical and experimental investigations in pharmacy	To use information from scientific sources	To be responsible for the development and implementation of planned projects
<i>Specific (professional, objective) competencies</i>					
CS 1	The ability to use knowledge of Ukrainian laws, regulations and the recommendations of	To know general principles of pharmaceutical provision of the	To use regulations that regulate pharmaceutical activity in Ukraine and abroad; to	To formulate conclusions and normative documents in a professional	To be responsible for competent and usage of normative

	guidelines of Good practices in pharmaceuticals in professional activities	population, the basic mechanisms of state regulation of pharmaceutical activity	provide the information on the material and technical resources of pharmacy	manner	documents in professional activities
CS 2	The ability to develop and form documents on manufacture of drug preparations in accordance with the recommendations of Good practices	To know the requirements of normative documents (orders, guides etc.) for the development of drug products and the forming production documents, to know the rules for the development of production documentation	To perform investigation on the development of drug product; to make the process schemes and the instructions for compounding drug preparations “as a reserve”; to create technological documentation for manufacture of drug products in industrial conditions	To develop and form production documentation	To be responsible for a good development and forming of documents

Learning outcomes:

Integrative final programmatic learning outcomes, the formation of which the elective discipline facilitates:

- Identification of future professional activities as a socially significant for human health.
- Realization of professional activity on the basis of general knowledge of the main stages of formation and development of the pharmaceutical industry in Ukraine and other countries, practical approaches to the organization of the supplying of the public and healthcare establishments with medicinal products.
 - Argumentation of making decisions in standard professional situations.
 - Formation of basic knowledge and acquisition of practical skills for the further study of professional training disciplines.

Learning outcomes for discipline:

- To conduct professional activities in social interaction based on humanistic and ethical principles; to identify future professional activities as a socially significant for human health.
 - Apply knowledge on general and professional disciplines in professional activities.
 - Use the results of independent search, analysis and synthesis of information from various sources to solve typical professional tasks.
 - To explain information for making decisions, to be responsible for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activities.

- Carry out professional activities using creative methods and approaches.
- To carry out professional activities using reference scientific literature, information technologies, information databases, navigation systems, Internet resources, software and other information and communication technologies.
 - To use methods for assessing quality indicators of activity; to identify reserves for improving labor productivity.
 - To analyze, generalize, systematize and use the information obtained as a result of scientific research, in professional activity.
 - To plan and realize the professional activities based on Ukrainian regulatory documents and Guidelines of Good Practices.
 - To acquire skills in the organization of the production in the pharmaceutical industry.
 - Objectively use the best foreign experience of pharmaceutical manufacturers.
 - To know the requirements of GMP, GPP, other Good Practices and regulatory documents (orders, guidelines, etc.) for the development and manufacture of drug products.

2. Information volume of the elective discipline

There are 2 credits ECTS – 90 hours.

Content module 1. World pharmaceutical industry. 3rd educational year – 2 credits, 90 h.

Topic 1. Historical aspects of pharmaceutical industry formation.

Topic 2. Current state of the world pharmaceutical industry. Trends and prospects of the development of world pharmaceutical market.

Topic 3. Organization of pharmaceutical manufacture. Regulatory technical documentation for the manufacture of medicinal products.

Topic 4. Classification of drug products.

Topic 5. Preclinical and clinical studies of drug products.

Topic 6. Pharmaceutical development. Basic stages of the development of new drug products.

Topic 7. Trends of the development of pharmaceutical industry in different countries.

Topic 8. Social and geographic aspects of the development of the world pharmaceutical industry.

Topic 9. Implementation of innovative drug products.

Topic 10. Specific of the world market of pharmaceuticals.

3. Structure of the elective discipline “World pharmaceutical industry”

Topic	Lessons	Seminar classes	Self-education	Individual work
Content module 1. World pharmaceutical industry				
Topic 1. Historical aspects of pharmaceutical industry formation	2	2	-	-
Topic 2. Current state of the world pharmaceutical industry. Trends and prospects for the development of the world pharmaceutical market	2	2	6	-
Topic 3. Organization of drug manufacturing. Regulatory technical documentation for the drug production.	2	4	12	-
Topic 4. Classification of drug products	2	4	6	-

Topic 5. Pharmaceutical development. Basic stages in the development of new drug products	2	2	6	-
Topic 6. Preclinical and clinical studies of drug products	-	4	6	
Topic 7. Trends of the development of pharmaceutical industry in countries in the world	-	-	6	
Topic 8. Social and geographic aspects of the development of world pharmaceutical industry	-	-	6	
Topic 9. Implementation of innovative drug products	-	2	6	
Topic 10. Specific of the world market of pharmaceuticals	-	-	6	
Total Hours for Discipline 90/2 credits ECTS	10	20	90	
Final control				Credit

4. Thematic plan of lectures

No.	Topic	Number of hours
Content module 1. World pharmaceutical industry		
1	Topic 1. Historical aspects of pharmaceutical industry formation	2
2	Topic 2. Current state of the world pharmaceutical industry and factors influencing pharmaceutical industry development	2
3	Topic 3. Organization of pharmaceutical manufacture, normative and technical documents regulating pharmaceutical production	2
4	Topic 4. Classification of drug products. Basic stages in the development of new drug products	2
5	Topic 5. Preclinical and clinical studies of new drug products	2
Total		10

5. Thematic plan of seminar classes

No.	Topic	Number of hours
Content module 1. World pharmaceutical industry		
1	Pharmaceutical industry. Basic terms and concepts	2
2	Stages of pharmaceutical industry development	2
3	Current state and development trends of pharmaceutical industry	2
4	Social and geographic aspects of the development of world pharmaceutical industry	2
5-6	Pharmacopoeia as a main legislative document of the manufacture and quality control of drug products	4
7	Pharmaceutical development. Regulatory documents	2
8	Preclinical and clinical studies of new drug products	2
9	Development of new drug products	2
10	The European vector for the Ukrainian pharmaceutical industry	2
Total:		20

6. Thematic plan for self-education

No.	Topic	Number of hours	Type of control
Content module 1. World pharmaceutical industry			
1.	Common principles of organization of pharmaceutical manufacture	6	Current control in seminar classes – “ –
2.	Concepts of good practices in pharmaceutical industry	6	
3.	Normative regulation of quality assurance of drug products	6	
4.	Role and functions of the International Pharmacopoeia	6	
5.	Brand and generic drugs. Characteristics and registration features	6	
6.	Biosimilars – clinical and regulatory aspects	6	
7.	Postmarket studies of medicines	6	
8.	Specific features of the world market of pharmaceutical products	6	
9.	Trends in the development of pharmaceutical industry in the world	6	
10.	The influence of epidemics on the pharmaceutical industry	6	
Total		60	

7. Individual tasks

It is not provided by the academic curriculum.

8. Teaching methods: explanatory-illustrated (multimedia lectures with elements of discussion communication with higher education students), reproductive, research, part-search (independent work of search character, work with scientific and reference literature).

The following teaching methods are used:

- *verbal* – narrative, explanation, conversation, instruction, lecture, discussion;
- *visual* – demonstration of films, illustrations, materials;
- *inductive methods* - generalization of the results of observations and experiments.

On seminar classes students discuss issues of the topic, and indicate in the protocol the purpose of class, main issues according to tasks, provide conclusions.

Self-education includes necessary sections of the program that are studied during the educational process of other disciplines, as well as basic stages in the development of the world pharmaceutical industry, normative documents regulating manufacture of pharmaceutical preparations.

Plan and organizational structure of seminar classes on the elective discipline “World pharmaceutical industry”

No.	Main stages of seminar classes, their functions	Methods of control and training	Materials for methodological support (control, visualization etc.)	Time, min.
1. The preparatory stage				
1.	The organization of class			3-5
2.	Formulation of learning objectives		Topicality of the topic The aim of the class	10-15
2. The main stage				
3.	Control of initial level of knowledge, skills and abilities	Frontal oral examination Individual oral examination	Control questions	25-30

4.	Formation of professional abilities and skills	Constant practical use of normative documentation and Internet resources Professional training for practical tasks	State Pharmacopoeia of Ukraine Guidelines Internet resources Typical exercises in the form of situation tasks	20-30
3. The final stage				
5.	Summing up of seminar class			3-5
6.	Homework: theme, literature		Oriented algorithms for self-education work with literature	3-5

9. Forms of control

Forms of control include current and final semester control.

According to the curriculum, the form of the final control on the elective discipline is a credit.

10. Current control is carried out during seminar classes and aims to checking mastering of material by students.

Current control: oral questioning. Current control is performed on every seminar class according to the specific objectives.

The form of assessment of current educational activity is standardized and includes control of theoretical training.

Control of theoretical training is conducted by questioning and performing the situational tasks. Practical skills are assessed by the ability to interpret the results.

Self-education is assessed during the current control of theme on the appropriate seminar class.

For student who has missed classes is allowed to work out academic debt before the deadline according to the schedule.

11. Final control is carried out to assess results of learning at a particular educational qualification level and at the completed stages according to the national scale and ECTS scale. Final control includes semester control.

Semester control is carried out in the form of semester credit and includes educational material defined by working program and is carried out in the terms established by educational working plan and an individual educational plan of student.

Semester credit is a form of final control of mastering by a student of theoretical and practical material on the educational subject on the base of the results of current control.

12. Scheme of obtaining and distribution of scores received by students

Each student is assessed on each class for four-points system.

The results of the current control are an indicator of the level of mastering by students of the curriculum and performance of independent work.

The highest number of points which can be obtained by a student for the current educational activity is equal to 200 points.

Minimum sum of points which student can get for current educational activity is equal to 120 points.

Calculation of the number of points is conducted on base of marks received by a student according to the traditional scale during the study of discipline by means of multiplying mean value (MV), rounded to second decimal mark, by 40:

$$X = \frac{MV \times 200}{5}$$

Recalculation of the average mark for current activity into multi-point scale for elective discipline which is finished by a credit is given in Table 1.

Table 1

Recalculation of the average mark for current activity into multi-point scale for elective discipline which is finished by a credit

4-pointed scale	200-pointed scale		4-pointed scale	200-pointed scale		4-pointed scale	200-pointed scale		4-pointed scale	200-pointed scale
5	200		4.45	178		3.92	157		3.37	135
4.97	199		4.42	177		3.89	156		3.35	134
4.95	198		4.4	176		3.87	155		3.32	133
4.92	197		4.37	175		3.84	154		3.3	132
4.9	196		4.35	174		3.82	153		3.27	131
4.87	195		4.32	173		3.79	152		3.25	130
4.85	194		4.3	172		3.77	151		3.22	129
4.82	193		4.27	171		3.74	150		3.2	128
4.8	192		4.24	170		3.72	149		3.17	127
4.77	191		4.22	169		3.7	148		3.15	126
4.75	190		4.19	168		3.67	147		3.12	125
4.72	189		4.17	167		3.65	146		3.1	124
4.7	188		4.14	166		3.62	145		3.07	123
4.67	187		4.12	165		3.57	143		3.02	121
4.65	186		4.09	164		3.55	142		3	120
4.62	185		4.07	163		3.52	141		Less than 3	Not enough
4.6	184		4.04	162		3.5	140			
4.57	183		4.02	161		3.47	139			
4.52	181		3.99	160		3.45	138			
4.5	180		3.97	159		3.42	137			
4.47	179		3.94	158		3.4	136			

Points for the discipline are converted regardless both in ECTS scale and four-point scale. Points from ECTS-scale are not converted to four-point scale and conversely.

Points of the students studying in the same specialty are ranged on ECTS-scale as follows:

ECTS mark	Statistical index
A	The best 10% students
B	Next 25 % students
C	Next 30 % students
D	Next 25 % students
E	Last 10 % students

Points of discipline for students, who successfully performed the program, are converted into traditional four-pointed scale for the absolute criteria listed in the table below:

Points from discipline	Mark according to the four-pointed scale
From 170 to 200 балів	5
From 140 to 169 балів	4
From 139 points to minimal amount of points which a student should obtain	3
Less than minimal amount of points which a student should obtain	2

ECTS mark is not converted into traditional scale because ECTS scale and four-pointed scale are independent.

Objectivity of evaluation of student's educational activities is checked by statistical methods (coefficient of correlation between ECTS assessment and mark according to the national scale).

13. Methodological support:

- Lectures materials (multimedia presentations, texts of lectures, thematic plan of lectures)
- Thematic plans of seminar classes
- Questions for seminar classes and self-education
- Videofilms
- Internet-resources

14. REFERENCES

Basic literature

1. Биофармація: Учебн. для студ. фармац. вузов и фак. / Тихонов А.И., Ярных Т.Г., Зупанец И.А. и др. / Под ред. Тихонова А.И. – Х.: Изд-во НФаУ; Золотые страницы, 2003. – 240 с.
2. Богатирьова Є. В. Історія фармації України / Є.В. Богатирьова, Ю.П. Сніжанко, В.П. Черних та ін. – Х., 1999. – 322 с.
3. Державна Фармакопея України. – Х.: РІРЕГ, 2001. – 556 с.; Доповнення 1, 2004. – 520 с.; Доповнення 2, 2008. – 617 с.; Доповнення 3, 2009. – 280 с.; Доповнення 4, 2011. – 540 с.
4. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т.1. – 1128 с.
5. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т.2. – 724 с.
6. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т.3. – 732 с.
7. Про лікарські засоби: закон України від 4.04.96 № 123/96 // Відомості Верховної Ради України. – 1996. – № 123.
8. Промислова технологія лікарських засобів : навч. посіб. для самостійної роботи студентів / О.А. Рубан, В.Д. Рибачук, Л.М. Хохлова та ін. – Х. : НФАУ, 2015. – 120 с.

9. Сучасні фармацевтичні технології: навч. посіб. до лабораторних занять магістрантів денної, вечірньої та заочної форми навчання спеціальності 8.110201 «Фармація» / під ред. О.А. Рубан. – Х. : Вид-во НФаУ, 2016. – 256 с.
10. Сятиня М.Л. Історія фармації: Навчальний посібник для вищих навчальних закладів / М.Л.Сятиня. – Львів, 2002. – 660 с.
11. Технологія лікарських препаратів промислового виробництва: навч. посіб./ за ред. проф. Д.І. Дмитрієвського. – Вінниця: Нова книга, 2008. – 280 с.
12. Технологія ліків промислового виробництва: підруч. для студентів вищ. навч. закл. : в 2-х ч. / В.І. Чуєшов, Є.В. Гладух, І.В. Сайко та ін. – 2-е вид., перероб. і доп. – Х. : НФаУ : Оригінал, 2012. – Ч. 1. – 694 с.
13. Технологія ліків промислового виробництва : підруч. для студентів вищ. навч. закл. : в 2-х ч. / В.І. Чуєшов, Є.В. Гладух, І.В. Сайко та ін. – 2-е вид., перероб. і доп. – Х. : НФаУ : Оригінал, 2013. – Ч. 2. – 638 с.

Additional literature

1. Гавриленко Н.І. Тенденції та перспективи розвитку фармацевтичного ринку/ Н.І. Гавриленко, Я.В. Кулич // Проблеми і перспективи економіки та управління. – 2015. – №1. – Режим доступу: <http://ppeu.stu.cn.ua/index.pl?task=arcls&id=10>.
2. Глумсков В. Мировой фармацевтический рынок: состояние и тенденции // Эксперт. – 2007. – № 20. – С. 10-32.
3. Головенко М.Я. «Філософія» фармацевтичних інновацій / М.Я. Головенко // Вісн. НАН України. – 2012. – № 3. – Режим доступу: <file:///C:/Users/DiscipleDX/Documents/індустрія/фарм%20%20інд.pdf>.
4. Жилінська О.І. Фармацевтичний ринок: Україна в контексті світових тенденцій / О.І. Жилінська // Теоретичні та прикладні питання економіки. – 2012. – вип. 27. – Т. 1. – С. 252-259.
5. Клунок Н.С. Вплив глобалізаційних процесів на тенденції розвитку світового фармацевтичного ринку / Н.С. Клунок // Економіка. Менеджмент. Підприємництво. – 2012. – № 24(1). – С. 39-45.
6. Лідери та аутсайди світового фармринку [Електронний ресурс]. Режим доступу: http://www.aptekaGal.com.ua/show_article.php?year=2011&month=3&num=12.
7. Лин А.А. Фармацевтический рынок: фундаментальные особенности / А.А. Лин, С.В. Соколова // Проблемы современной экономики. – 2012. – № 2 (42) [Електронний ресурс]. – Режим доступу: <http://www.m-economy.ru/art.php?nArtId=41182>.
8. Миронишина О.В. Глобалізація фармацевтичної індустрії: наслідки впливу для української економіки / О.В. Миронишина // Вісник Донецького університету. – 2007. – № 2. – С. 1593-168.
9. Наказ МОЗ № 944 від 14.12.2009 р. Про затвердження Порядку проведення до клінічного вивчення лікарських засобів та експертизи матеріалів доклінічного вивчення лікарських засобів.
10. Належні практики у фармації: практикум для студ. вищих мед. навч. закладів / Н.І. Гудзь, С.Б. Білоус, Т.Г. Калинюк, К.І. Сметаніна; за ред. Т.Г. Калинюка.- Вінниця: Нова книга, 2013.– 368 с.
11. Настанова 42-01-2003. Лікарські засоби. Технологічний процес. Документація. – Київ, 2003. – 48 с.
12. Настанова 42-3.1:2004 «Настанови з якості. Лікарські засоби. Фармацевтична розробка».- Київ, МОЗ України, 2004. – 15 с.
13. Настанова 42-3.4:2004. Настанови з якості. Лікарські засоби. Виробництво готових лікарських засобів. – Київ, 2004. – 18 с.
14. Настанова 42-7.1:2005. Настанови з клінічних досліджень. Лікарські засоби. Дослідження біодоступності та біоеквівалентності. - Київ, 2005. – 18 с.
15. Настанова «Лікарські засоби. Фармацевтична розробка (ICH Q8). СТ-Н МОЗУ 42-3.0:2011».- Київ, МОЗ України, 2011. – 33 с.

16. Настанова «Лікарські засоби. Належна виробнича практика СТ-Н МОЗУ 42-4.0:2015». Режим доступу від 27 серпня 2015 р. <http://www.diklz.gov.ua/control/main/uk/publish/article/746296>.
17. Новий світовий порядок на фармацевтичному ринку [Електронний ресурс]. Режим доступу: <http://www.apteka.ua/article/16320>.
18. Овчаров Е.Г. Мировая фармацевтическая промышленность: современное состояние и тенденции развития в условиях глобализации // Автореф. дис. на соиск. ученой степени канд. экон. Наук / Е.Г. Овчаров, 2005. – 24 с.
19. Пашков В. Глобалізація фармацевтичного ринку як загроза економічного суверенітету України / В.Пашкрв // Еженедельник аптека. – 2013. - № 24. – Режим доступу: <https://www.apteka.ua/article/235037>.
20. Пешко А. Процеси глобалізації та їх вплив на національні економіки / А. Пешко// Вісник Національної Академії державного управління при Президентові України. – 2006. – № 2. – С. 133–138.
21. Родионова И.А. Фармацевтическая промышленность мира (основные направления развития) / Родионова И.А., Овчаров Е.Г // Депонировано ИНИОН РАН №55815 от 17.07.2000, 36 с.
22. Солодковський Ю.Перспективи трансформації сучасної моделі світового фармацевтичного ринку // Ю. Солодковський, О. Довженко // Міжнародна економічна політика. – 2012. – № 1-2 (16—17). – С. 147-152. – Режим доступу: http://iejjournal.com/journals/16-/2012_6_yuri_solodkovsky_olga_dovzhenko.pdf.
23. Тищенко А.Н. Социально–экономическое значение и характерные черты фармации / А.Н. Тищенко, А.В. Доровский // Світова економіка та міжнародні відносини. – 2013. – № 3. – С. 13 -20.
24. Фармацевтична енциклопедія / Голова ред. ради та автор передмови В. П. Черних. – 3-тє вид., переробл. і доповн. – К.: «МОРІОН», 2016. – 1952 с.
25. Фармацевтичні та медико-біологічні аспекти ліків. Навчальний посібник /За ред. І.М. Перцева - Вінниця: НОВА КНИГА, 2007. – 728 с.
26. Фармацевтическая промышленность и глобальное здравоохранение: факты и цифры [Електронний ресурс] – точка доступу: http://www.aipm.org/netcat_files/458/359/h_a3aa4d524d29da146c9a3493f2639ce.
27. Яковлева Л.В. Оцінка медичних технологій - позиція держав Європейського Союзу / Л.В. Яковлева, О.Я. Міщенко // Раціональна фармакотерапія. - 2013. - № 1. - С. 25–28.
28. Nigel MacLennan «Brand Planning for the Pharmaceutical Industry» — P.: Gover House, 2004.
29. Pharma 2020: The Vision — Which Path Will You Take? by PriceWaterhouse Coopers [Електронний ресурс]. Режим доступу: <http://www.pwc.com/gx/en/pharma-life-sciences/pharma2020/pharma-2020-vision-path.jhtml>.
30. World pharmaceutical market 2010 [Електронний ресурс]. Режим доступу: <http://www.publicagenda.org/chats/world-pharmaceuticalmarket>.

15. Information resources

1. Офіційний сайт Міністерства охорони здоров'я України: www.moz.gov.ua.
2. Журнал «Фармацевт практик»: fp.com.ua.
3. Журнал «Провізор»: www.provisor.com.ua.
4. Компендиум: лекарственные препараты: – [Електронний ресурс]. – Режим доступу: <http://compendium.com.ua/>.
5. Державний реєстр лікарських засобів України. – [Електронний ресурс]. – Режим доступу: <http://www.drlz.com.ua/>.
6. Еженедельник Аптека: <https://www.apteka.ua/>.