

VOLGOGRAD STATE MEDICAL UNIVERSITY

DEPARTMENT OF PHARMACOLOGY AND BIOINFORMATICS

Methodological recommendations for students for practical classes in the discipline:
" Immunobiological and gene therapy drugs"

Subject block: Gene therapy drugs

Topic of the lesson:

Gene therapy drugs. Nomenclature (gene therapy drugs, cell therapy drugs, cell-based gene therapy drugs and virus-based therapy drugs..

Faculty of Pharmacy

1. OBJECTIVES OF THE LESSON

- teach students the general principles of classification of gene therapy drugs and cell products in the Russian Federation ;
- to familiarize students with the fundamental approach to the composition of gene therapy and cell drugs;
- to familiarize students with approaches to nomenclature names of gene therapy and cell drugs.

2.TASKS

- Learn:
 - concepts and fundamental composition of gene therapy drugs;
 - fundamental groups of biomedical cell products and their differences from each other ;
- To study the development features and nomenclature names for gene therapy and cell drugs.

3. THE FOLLOWING PRACTICAL SKILLS AND ABILITIES ARE PRACTISED IN THE LESSON

- ability to classify gene therapy and cell drugs;
- ability to analyze nomenclature names of gene therapy and cell drugs .

4. ORDER OF CONDUCTING CLASSES:

Venue: classroom of the Department of Pharmacology and Bioinformatics.

Time of the event: part 1 -2 AC

Competencies to be developed: UK-1.1.3, UK-1.2.1, UK-1.2.2, UK-1.2.3., UK-1.3.1, UK-1.3.2., UK-6.1.1., UK-6.2.1, UK-6.2.2, UK-6.3.1, UK-6.3.2, UK-6.3.3, UK-6.3.4, 1.1.1 ., OPK-1.2.1, OPK-1.2.2., OPK-1.3.1, OPK-6.1.1, OPK-6.2.1, OPK-6.3.1, PC-7.1.1, PC-7.2.1, PC-7.3.1.

4.1 Technological map of the lesson

Part	No.	Stage of the lesson	Time
1	1	Checking the number of students present at the lesson, the lesson schedule, and the lesson topic.	5 min
	2	Checking the initial level of students' knowledge (written survey).	10 min
	3	Survey on the topic of the lesson.	45 min
	4	Independent work of students (on prescriptions with analysis of the most complex prescriptions (if any in the topic), analysis of errors in medical prescriptions written by students; work with synonyms).	15 min
	5	Checking independent work	5 min

	6	Summing up the lesson. Assignment for the next lesson.	5 min
	7	Cleaning of workplaces.	5 min

4.2 Demonstrations

1. Demonstration of advertising brochures on this topic during a survey on the topic of the lesson.

4.3 Lesson plan

4.3.1 The lesson begins with an introductory speech by the teacher, a statement of the purpose of the lesson, and answers to students' questions.

In the opening remarks, the teacher should draw students' attention to the growing role and number of emerging new approaches to gene therapy using gene therapy agents.

Pay attention to the fundamental transition from experimental preclinical and clinical developments of gene therapy methods at the turn of the 2000s-2010s to the increasingly widespread implementation of the results of gene therapy methods in clinical practice with the development of specific methods and algorithms of therapy, the development of new end products for gene therapy (gene therapy drugs).

It should be noted separately that the algorithms for treatment with gene therapy drugs can be so-called protocols developed according to the principles of gene therapy *ex vivo*, i.e. using modified cells. These approaches formed the basis for the development of a separate direction of therapy with genetically modified cells, which together with other cell preparations (for example, without gene modification) are currently generalized under the name of biomedical cell products.

Both of these groups of drugs are expanding very dynamically both for systemic clinical use and for solving problems of personalized therapy for a specific patient.

4.3.2 Checking the initial level of students' knowledge (written survey).

4.3.3 Analysis of theoretical material

Plan for analyzing theoretical material

1. Understand the concept of a gene therapy drug.
2. Understand the concept of a biomedical cell product
 - Somatic cell-based LP
 - BMCP (biomedical cell product)
 - Autologous BMCP
 - Allogeneic BMCP
 - Combined BMCP
3. To analyze the main approaches to the nomenclature naming of a gene therapy drug and a cellular product (lecture, Appendix 2).

Complete independent work.

4.3.4 Independent work of students:

1. Using nomenclature principles (lecture material), come up with and propose names for 2 gene therapy and 2 cell drugs. Provide explanations and explanations of the structural components of the proposed drugs.

- 4.3.5 Checking the completion of students' independent work.**
- 4.3.6 Summing up the lesson. Answers to students' questions.**
- 4.3.7 Final words from the teacher.**

Compiled by,
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List of recommended literature, including electronic educational publications:

1. Kharkevich D. A. Pharmacology: textbook / Kharkevich D. A. - 11th ed., revised. and additional - M.: GEOTAR-Media, 2015. - 755, [5] p. : ill. - Text: immediate.
2. Kharkevich, D. A. Pharmacology: textbook / D. A. Kharkevich. - 13th ed. , processed - Moscow: GEOTAR-Media, 2022. - 752 p. : ill. - ISBN 978-5-9704-6820-3. - Text: electronic // EBS "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970468203.html>
3. Pharmacology: textbook / ed. R. N. Alyautdina. - 6th ed. , processed and additional - Moscow: GEOTAR-Media, 2022. - 1104 p. - ISBN 978-5-9704-6819-7. - Text: electronic // EBS "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970468197.html>
4. Maisky, V. V. Pharmacology with a general formulation: a textbook / V. V. Maisky, R. N. Alyautdin. - 3rd ed., supplemented and revised. - Moscow: GEOTAR-Media, 2017. - 240 p. . - ISBN 978-5-9704-4132-9. - Text: electronic // Electronic Library System "Student Consultant": [site]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970441329.html>
5. Alyautdin, R. N. Pharmacology. Ultra light: textbook. allowance / R. N. Alyautdin. - Moscow: GEOTAR-Media, 2012. - 584 p. - ISBN 978-5-9704-1985-4. - Text: electronic // EBS "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970419854.html>
6. Oncology: textbook / M. I. Davydov, Sh. Kh. Gantsev [etc.]. - Moscow: GEOTAR Media, 2020. - 920 p. : ill. - ISBN 978-5-9704-5616-3. - Text: electronic // EBS "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970456163.html>
7. Oncology: textbook / ed. S. B. Peterson. - 2nd ed. , processed and additional - Moscow: GEOTARMEDIA, 2018. - 288 p. : ill. - ISBN 978-5-9704-4704-8. - Text: electronic // EBS "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970447048.html>
8. Oncology / ed. Chissova V.I., Davydova M.I. - Moscow: GEOTAR-Media, 2014. - 1072 p. - ISBN 978-5-9704-3284-6. - Text: electronic // EBS "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970432846.html>
9. Medical microbiology, virology and immunology: V. 1: textbook / edited by Zverev V. V., Boychenko M. N. - Moscow: GEOTAR-Media, 2020. - 448 p. - ISBN 978-5-9704-5835-8. - Text: electronic // Electronic Library System "Student Consultant": [site]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970458358.html>
10. Medical microbiology, virology and immunology: V. 2: textbook / edited by Zverev V. V., Boychenko M. N. - Moscow: GEOTAR-Media, 2021. - 472 p. - ISBN 978-5-9704-5836-5. - Text: electronic // Electronic Library System "Student Consultant": [site]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970458365.html>
11. Etiotropic therapy of acute viral infections in children: a textbook for specialists. 06010365 "Pediatrics" / Kramar L. V., Arova A. A., Zheludkov Yu. A. et al. - Volgograd: Publishing house of Volgograd State Medical University, 2012. - 156 p. - Text: direct.
12. Ioannidi E. A. Chronic viral hepatitis B, D and C: etiopathogenesis, epidemiology, clinical picture, treatment and prevention: textbook / Ioannidi E. A., Bozhko V. G., Belikova E. A., Aleksandrov O. V.; VolGMU of the Ministry of Health of the Russian Federation. - Volgograd: Publishing house of VolGMU, 2016. - 71, [1] p.: table. - Text: electronic // EBS VolGMU: electronic library system. - URL: http://library.volgmed.ru/Marc/MObjectDown.asp?MacroName=%D5%F0%EE%ED%E8%F7_%E2%E8%F0%F3%F1_%E3%E5%EF%E0%F2%E8%F2%FB_2016&MacroAcc=A&DbVal=47
13. Kharkevitch DA, Pharmacology / Kharkevitch DA - M.: GEOTAR-Media, 2008. - 672 p. - ISBN 5-9704-0264-8 - Text: electronic // Electronic Library System "Student Consultant": [site]. - URL: <http://www.studentlibrary.ru/book/ISBN5970402648.html> (date accessed: 02/28/2020). - Access mode: by subscription.

List of professional databases, information reference systems, electronic educational resources recommended for preparation:

1. <http://vrachirf.ru/> - Information portal Doctors of Russia
2. <https://pharmarf.ru> – information portal of Pharma of Russia
3. <https://www.rlsnet.ru/> - RLS (register of medicines of Russia) (information reference system)
4. <http://www.drugs.com> - Information base on medicinal preparations (information reference system)
5. <https://grls.pharm-portal.ru/> - state register of medicines.
6. <http://elibrary.ru> – Electronic database of electronic versions of periodicals on the Elibrary.ru platform (professional database)
7. <http://www.consultant.ru/> – Reference and legal system “Consultant-Plus” (professional database)

Two-word naming scheme for plasmid, viral vector and bacterial gene therapy agents			
	Prefix	Infix	Suffix
WORD 1 (genetic component)	Arbitrary for obtaining a harmonious sound and distinctive name	To indicate the gene used , if available existing infixes for biologicals are used drugs or similar infixes as for a protein that is encoded by a gene, for example:	-(vowel)gen/-(g.b.) gene For example, -(o)gene/-(o)gene
		-cyma-/ -cima -cytosine deaminase	
		-ermin-/ -ermin- growth factor	
		-kin-/ -kin- interleukin	
		-lim-/ -lim- immunomodulator	
		-lip-/ - lip - human lipoprotein lipase	
		-mul-/ -mul- multiple gene	
		-stim-/ -stim- colony-stimulating factor	
		-tima-/ -tima- thymidine kinase	
		-tisu-/ -tisu- tumor suppression	
WORD 2 (cellular component)	Arbitrary for obtaining a harmonious sound and distinctive name	To indicate the type of viral vector , for example:	-century/- vec (non-replicating viral vector)
		-adeno-/ -adeno- adenovirus	
		-cana-/ - cana - canarypox virus	
		-foli-/ - foli - fowlpox virus	
		-erpa-/ -erpa- herpes virus	
		-lenti-/ -lenti- lentivirus	
		-morbilli-/ -morbilli- measles paramyxovirus	
		-parvo-/ - parvo - adeno-associated virus	
		-retro-/ - retro - another retrovirus	
		-vacchi-/ - vaci- vaccine virus	
		To indicate the type of bacterial vector , for example:	-tank/- bac (bacterial vector)
		-lis-/ -lis- Listeria monocytogenes	
			-plasmid/ -plasmid (plasmid vector)

Naming scheme for genetically modified cell-based gene therapy drugs				
	Prefix	Infix		Suffix
WORD 1 (genetic component)	Arbitrary for obtaining a harmonious sound and distinctive name	To indicate the gene used , if available existing infixes for biologicals are used drugs, for example:		-(vowel) gen/ -(g.b.) gene For example -(o)gen/ -(o) gene
		-cyma/- cima - cytosine deaminase		
		-ermin/- ermin - growth factor		
		-kin/- kin - interleukin		
		-lim/-lim- immunomodulator		
		-lip/- lip - human lipoprotein lipase		
		-mul/-mul- multiple gene		
		-stim/-stim- colony-stimulating factor		
		-tima/-tima- thymidine kinase		
		-tisu/-tisu- tumor suppression		
WORD 2 (vector component)	Arbitrary for obtaining a harmonious and distinctive name	Infix 1: Processing To indicate, if applicable, the type processing which cells were subjected to use where it is possibly existing infixes to handle, For example: -fus/- fus -cell fusion	Infix 2: Cell type To indicate the main cell type using where it is possibly existing infixes for types cells	-cel (cell)

Examples of nomenclature names of drugs for gene therapy

Trade name	INN	Developer
IMLYGIC	Talimogenelaherparepvec	Talimogenelaherparepvec is a genetically modified herpes virus (oncolytic herpes virus). Two genes have been removed – one that turns off an individual cell's defenses and one that helps the virus evade the immune system – and a gene for human GM-CSF has been added. The drug works by replicating in cancer cells and causing them to die; it has also been designed to stimulate the patient's immune response to the cancer, which has been demonstrated by numerous data, including regression of tumors that were not treated with talimogene laherparepvec.
KYMRIAH	Tisagenlecleucel	Tisagenlecleucel is a CAR T-cell drug for the treatment of B-cell acute lymphoblastic leukemia that uses the body's own T cells to fight cancer (adoptable cell transfer)