



Approved by:

Dean

Date.....

SOFIA UNIVERSITY "ST. KLIMENT OHRIDSKI"

Faculty: Chemistry and Pharmacy

Subject area: (code and name)

C	H	L	3	8	2	4	1	3
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Pharmacy

Master Program: (code and name)

C	H	L	3	8	2	4	1	3
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Pharmacy

SYLLABUS

Course:

C	4	1	8
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(code and name)

Pharmaceutical Analysis 2

Lecturers: Prof. DSc Sonia Ilieva, Prof. PhD Todor Dudev

Teaching assistants: Senior Ass. Prof. PhD Valia Nikolova, Senior Ass. Prof. PhD Diana Cheshmedzhieva

Academic work	Type	Acad. hours
In-class work	Lectures	45
	Seminars	
	Practical classes (teaching assistance)	75
Total in-class work		120
Out-of-class work	Topical writing / Course paper	
	Presentation	10
	Scientific essay	
	Course project	
	Field trip	70
	Independent literature research	
	Student teaching	
Total out-of-class work		80
TOTAL ACADEMIC WORK		200
ECTS credits in-class work		4.8
ECTS credits out-of-class work		3.2
TOTAL ECTS CREDITS		8

Nº	Grade components ¹	% of the grade
1.	Workshops (search of information and group discussions of presentations and topical writings)	
2.	Participation in topical discussions during the classes	
3.	Demonstrations in class	
4.	Field trip attendance	
5.	Portfolio	
6.	Quizzes throughout the semester	
7.	Case studies	
8.	Homeworks/mid-term test	40
9.		
10.		
11.		
12.	Final exam	60

Outline of the course:

The main objective of **Pharmaceutical Analysis 2** is to provide students with comprehensive knowledge about the methodology and specific approaches in characterizing large groups of drug substances of synthetic or natural origin. A plethora of state-of-the-art analytical techniques are studied and their capacity and specific features for performing quantitative and/or qualitative analysis of drug substances, impurities, metabolites and degradation products are discussed and meticulously assessed. The analytical methodologies taught are in line with the Pharmacopoeia requirements. The students gain knowledge enabling them to choose the most appropriate analytical method for characterizing a given analyte, as well as practical skills for its implementation. Furthermore, the course offers valuable information about the contemporary analytical documentation such as pharmacopoeias and standardization files as well as validation of the analytical methods employed.

Preliminary requirements:

The students must have successfully completed the courses of Inorganic, Organic and Analytical Chemistry, as well as Pharmaceutical Analysis 1, where the physical principles and experimental techniques of the respective analytical methods had been taught.

Key competences acquired:

As a result of successful completion of the course of **Pharmaceutical Analysis 2** the students are expected to acquire theoretical knowledge and practical skills in applying various analytical techniques for Pharmacopoeia analysis of drugs. The students will be trained to choose an appropriate and reliable analytical method/methodology for performing the drug analysis, as well as to be able to critically interpret and assess the analytical data obtained. The knowledge and skills gained would be beneficial for the students working in pharmaceutical laboratories, research, forensic and medical centers.

¹ Depending on the course specificity and on the requirements of the teacher, other types of activity can be added or the unnecessary ones can be removed.

Lessons plan

№	Topic	Acad. hours
	Lectures	45
<i>Analysis of drugs, intermediates and reactants based on functional groups</i>		
1.	Halogenated derivatives of aliphatic and aromatic hydrocarbons: Halothan (Narcotan), Riodoxol, Cyclophosphamide (Cytosan), Chlorambucil (Leuceran), Melphalan (Alkeran).	1
2.	Alkenes and alkynes – Ethacrynic acid (Uregyt), Ascorbic acid (Vitamin C), Retinol acetate (Vitamin A).	1
3.	Hydroxyl derivatives	
	3.1. Alcohols: Menthol, Propylene glycol, Glycerol, Sorbitol, Mannitol, Ethanol.	1
	3.2. Phenols: Phenol, Thymol, Chlorthymol, Resorcinol, Diethylstilbestrol propionate, Dienestrol (Synestrol), Paracetamol.	1
4.	Ethers: Clemastin fumarate (Tavegyl), Aether, Diphenhydramin maleate (Benadril N), Propranolol (Obsidan), Pindolol (Visken).	1
5.	Aldehydes and ketones: Formaldehyde, Haloperidol, Droperidol, Glucose, Acetone.	1
6.	Carboxylic acids and their derivatives.	
	6.1. Carboxylic acids and their salts: Maleinic acid, Citric acid, Panthotenic acid, Calcium gluconate, Undecylenic acid, Methotrexate, Salicylic acid, Acetylsalicylic acid.	2
	6.2. Esters: Bisacodyl (Bisalax), Tocopheryl acetate (vitamin E acetate), Pethidine (Lydol), Valoron (Tilidin), Nitrolong, Isosorbide mononitrate (Monisid), Procaine hydrochloride, Atropine sulphate, Methylatropine, Scopolamin, Homatropine, Cocaine.	2
	6.3. Lactones: Erythromycin (Erythran), Nystatin, Warfarin (Coumadin), Santonine, Ascorbic acid.	1
	6.4. Amides, imides, hydrazides: Bromisoval (bromvalerylurea), Glutethimide, Lidocaine, Piracetam (Pyramem), Isoniazid (Rimicid), Phenitoin (Diphenin), Mephentoin (Sacerno), Trimethadion (Trimedal), Ethosuximide (Suxilep), Morsuximide (Morfolep).	2
	6.5. β - lactam derivatives: Benzylpenicillin sodium (Penicillin G), Phenoxymethylpenicillin, Amoxycillin (Amopen, Ospamox), Ampicillin sodium, Amoxycillin + Clavulanic acid (Augmentin, Amoxyclav, Curam), Ampicillin + Sulbactam (Unasyn, Ampisulcillin).	2
7.	Drugs containing nitro-group: Chloramphenicol (Chlornitromycin, Laevomycetin), Thiamphenicol, Nifedipin (Corinfar, Adalat), Nitrendipin,	1

	Metronidazol (Flagyl), Nitrazepam (Radedorm).	
8.	Amines: Cinnarizin (Stugeron), Methadon, Piperazine hexahydrate (Helmicid), Propranolol (Obsidan), Verapamil (Isoptin), Astoren, Lidocaine, Paracetamol (Acetophen), Benzocain (Anaesthesin), Procaine hydrochloride (Gericain), Tetracaine hydrochloride (Dicain), Sulfathiazole sodium (Norsulfazol), Sulfadimetoxine, Co-Trimoxazol, Sufacetamide sodium, Sulfaguanidine.	2
9.	Sulfur-containing drugs: Captopril (Alkadil), Cimetidine (Tagamet), Ranitidine hydrochloride, Dimercaprol, Thioproperazin (Majeptil), Furosemide, Piroxicam, Indapamid (Tertensif), Tinidazol, Saccharin sodium.	1
10.	Amino-saccharides and their derivatives: Dona, Lincomycin hydrochloride, Amikacin hydrochloride, Gentamycin sulfate, Streptomycin sulfate, Kanamycin sulfate.	2
Analysis of drugs with heterocyclic structure		
11.	Pyrazole derivatives: Phenazon (Antipirin), Propyphenazone, Methamizol sodium (Analgin), Phenylbutazon (Butadion), Aminophenazon (Amidophen).	2
12.	Imidazole derivatives: Histamin phosphate, Pylocaprine hydrochloride, Naphazoline hydrochloride (Naphazolin), Clonidine hydrochloride (Chlophazolin), Xylomethazoline (Olynth, Otrivin, Xylopharm), Oxymetazolin hydrochloride, Clotrimazol, Miconazole, Droperidol.	2
13.	Pyridine derivatives: Nicotinic acid, Pyridoxine hydrochloride (Vitamin B6), Nicotinamide, Isoniazid, Disopyramide.	2
14.	Pyrimidine derivatives: Thiamine, Trimetoprim.	1
15.	Uracils: Fluorouracil, Idoxuridine, Orotic acid Methylthiouracil, Propylthiouracil.	1
16.	Piperidine derivatives: Promedol, Fentanil, Thenaldine (Sandosten), Droperidol.	1
17.	Derivatives of barbituric and thiobarbituric acid: Barbital (Veronal), Phenobarbital, Cyclobarbitol calcium (Hexodorm calcium), Hexobarbital, Hexetidine, Trimetoprim, Thiopental sodium (Thiopental).	2
18.	Furan derivatives: Nitrofurazone (Furaciline), Furazolidone (Nifolidon).	1
19.	Indole derivatives: Indomethacin (Metindol), Ergotamine tartrate (Ergotamin), Ergometrine maleate (Ergometrin), Nicergolin (Sermion), Dihydroergotoxin methansulfonate (Redergin), Vincristine, Vinblastine.	2
20.	Phenothiazine derivatives: Chlorpromazine hydrochloride (Chlorazin), Thioridazin hydrochloride (Melleril), Promazin, Fluphenazine.	2
21.	Thioxanthenes: Chlorprothixene.	1
22.	Acridine derivatives: Ethacridine lactate (Rivanol).	1
23.	Quinoline and Isoquinoline derivatives: Chloroquine phosphate (Artrochin, Rezorchin), Nitroxolin (5-Nitrox), Quinidine sulphate, Hydroxyquinoline,	1

	Chlorquinaldol, Papaverine, Dextromethorphan, Noscapine.	
24.	Purine derivatives: Adenine, Adenosine, Allopurinol (Milurit), Pentoxiphylline (Agapurin, Trental), Xanthinol nicotinate (Sadamin).	1
25.	Benzodiazepine and dibenzazepine derivatives: Medazepam (Rudotel), Diazepam (Relanium), Oxazepam, Carbamazepine (Tegretol), Imipramine (Psihoforin), Nitrazepam (Radedorm), Midazolam (Dormicum), Amitriptyline (Tridep).	1
26.	Xanthines : Caffeine, Theophylline, Etophylline, Proxyphylline, Diprophylline.	1
27.	Tetracyclines: Tetracycline hydrochloride, Doxycycline (Vibramycin), Methacycline hydrochloride (Rondomycin).	1
28.	Steroids: Steroids with aromatic ring: Estradiol (Dermestril), Ethnylaestradiol (Microfolin forte). Keto- steroids and α - ketol steroids: Testosteron propionate, Progesteron, Cortison acetate, Prednisolon (Decortin), Methylprednisolon (Urbason). Steroids with unsaturated 5-membered lactone ring at C ₁₇ : Digoxin, Digitoxin (Digitalin), Lanatosid (Ceglunat).	1
	Seminars/Practical Classes	75
1.	Good laboratory practice (GLP). Analytical documentation. Pharmacopoeias and standardizing documents. Quality control of drugs: pharmacopoeia methods for testing the substance purity, contaminants and additives.	5
2.	Pharmacopoeia tests for drug identity. Physical and physicochemical methods. Determination of physicochemical constants. Pharmacopoeia reactions for ions identity.	5
3.	Analytical approaches for quantitative spectrometric analysis of multicomponent solutions. Difference spectroscopy, application for quantitative analysis of a substance in a tablet.	5
4.	Application of the UV/VIS spectroscopy in determining the partition coefficient and solubility of a drug; monitoring the process of active substance release from the drug form.	5
5.	Application of the near-IR spectroscopy for pharmacopoeia analysis: determining particle size, homogeneity of a tablet, active substance in a polycomponent drug form, quantitative analysis of antibiotics.	5
6.	Pharmacopoeia analysis of drugs: halogenated derivatives of aliphatic and aromatic hydrocarbons, alkenes and alkynes.	5
7.	Pharmacopoeia analysis of drugs: hydroxyl derivatives (alcohols and phenols).	5
8.	Pharmacopoeia analysis of drugs: ethers, aldehydes and ketones.	5
9.	Pharmacopoeia analysis of drugs: carboxylic acids and their derivatives (salts, esters, lactone, lactams, amides, imides, hydrazides).	5
10.	Pharmacopoeia analysis of drugs: amines, nitro- and sulfur-containing drugs.	5

11.	Analysis of sedative drugs: bromides, barbiturates (Barbital, Cyclobarbitol, Phenobarbital), benzodiazepine derivatives (Nitrazepam, Midazolam, Flunitrazepam), dioxopiperidines (Glutethimide), and others (Chloral Hydrate, Methaqualone).	5
12.	Analysis of neuroleptics: derivatives of 1,4-benzodiazepine (Diazepam, Oxazepam, Medazepam), triazolobenzodiazepin (Alprazolam), derivatives of phenothiazine (Chlorpromazine, Levomepromazine, Thioridazine), thioxanthene derivatives (Chlorprothixene, Flupentixol), butiropenones (Haloperidol, Droperidol), diphenylpiperidines (Pimozide, Fluspirilene, Penfluridol).	5
13.	Analysis of antidepressant drugs: (Imipramine, Desipramine, Opipramol), (Amitriptyline, Nortriptyline), (Maprotiline), (Fluvoxamine).	5
14.	Analysis of narcotic and non-narcotic analgetics: morphine group (Morphine, Codeine, Dextromethorphan), piperidine derivatives (Pethidine), diphenylpropylamine (Methadone, Piritramide), salicylic acid derivatives (Acetylsalicylic acid), aniline derivatives (Paracetamol).	5
15.	Analysis of non-steroidal anti-inflammatory drugs: aromatic and arylaromatic acids, oxicams and their derivatives (Diclofenac sodium, Indomethacin, Ketoprofen, Ibuprofen, Chloroquine, Piroxicam, Tenoxicam), derivatives of 5-pyrazolon (Phenazone, Aminophenazone, Propyphenazone, Noramidopyrine Methanesulfonate sodium), derivatives of 3,5-pyrazolidinedione (Phenylbutazone).	5

Bibliography

Main sources:

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2. European Pharmacopoeia, Sixth edition, Vol. 2, European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe, Strasbourg, 2008.
3. M. Dekker, Handbook of Pharmaceutical Analysis, Ed. L. Ohannessian, A. Streeter, Marcel, Inc. New York Basel, 2002.

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