

E. Therapeutics: Clinical Pharmacology, Pharmacotherapy, and Pharmacokinetics

E1. Pharmacology, Pathophysiology, and Clinical Laboratory Tests

GIO: To understand the process of drug actions based on the knowledge of general diseases and pharmacology.

(1) Pharmacology

GIO: To acquire basic knowledge of pharmacodynamics/kinetics to understand the appropriate use of pharmaceuticals.

① Pharmacology

1. To describe dose-response relationships.
2. To describe agonists (stimulants) and antagonists (blockers, inhibitors) and their mechanisms of action.
3. To describe the mechanism of action of drugs by listing receptors, enzymes, ion-channels, and transporters.
4. To list major receptors and describe physiological reactions when they are stimulated or blocked.
5. To list major intracellular signaling systems related to the onset of the action of drugs and describe physiological reactions when activated or inhibited.
6. To describe the relationships between pharmacokinetics (absorption, distribution, metabolism, excretion) and the onset of pharmacological effects.
7. To describe, in a detailed manner, the factors (age, disease state, pregnancy, etc.) affecting the selection and adjustment of drugs, dosages, or administration methods.
8. To list major drug interactions derived from pharmacological effects and describe their mechanisms.
9. To describe drug dependency and tolerances with examples.

② Animal Experimentation

1. To practice animal experiments in an ethical manner.
2. To handle experimental animals appropriately.
3. To perform representative drug administrations during animal experiments.

③ Japanese Pharmacopoeia

1. To describe the characteristics of biological assays listed in the Japanese Pharmacopoeia.

(2) Pathophysiology and Clinical Laboratory Tests

GIO: To acquire fundamental knowledges of patients' symptoms, conditions, and clinical laboratory tests to diagnose disease.

① Symptoms and Conditions

1. To describe the major diseases causing the following symptoms and conditions, and to give a preliminary patient diagnosis:
shock, high blood pressure, low blood pressure, fever, convulsions, unconsciousness and fainting, cyanosis, dehydration, general malaise, overweight, underweight, jaundice, rash, anemia, bleeding tendencies, lymph node swelling, edema, rapid heartbeat, palpitations, pleural effusion, chest pain,

breathing difficulties, cough and phlegm, hemoptysis, dizziness, headaches, paralysis and involuntary movements, muscle weakness, abdominal pain, nausea and vomiting, swallowing difficulties, anorexia, diarrhea, constipation, hematemesis and melena, abdominal distension (including ascitic fluid retention), proteinuria, hematuria, urine and abnormal urination, menstrual abnormalities, joint swelling and joint pain, back pain, memory impairment, sensory abnormalities including numbness, nerve pain, visual impairment, and hearing impairment.

② Disease Status and Laboratory Tests

1. To list the items examined in urinalysis and stool analysis, to describe the objectives, and to recognize abnormal values in the results.
2. To list the items examined in blood, blood coagulation, and cerebrospinal fluid tests, to describe the objectives, and to recognize abnormal values in the results.
3. To list the items examined in blood and serum chemical tests, to describe the objectives, and to recognize abnormal values in the test results.
4. To list the items examined in immunological tests, to describe the objectives, and to recognize abnormal values in the results.
5. To list the items examined in arterial blood gas, to describe the objectives, and to recognize abnormal values in the results.
6. To list the laboratory tests commonly ordered for major physiological function (heart, kidney, liver, respiratory system, etc.), histopathological, and imaging examinations, and to describe their objectives, and to recognize abnormal values in the results.
7. To list the laboratory tests commonly ordered for microbial examinations, to describe the objectives, and to recognize abnormal values in the results.
8. To list the laboratory tests commonly ordered for physical assessment examinations, to describe the objectives, and to recognize abnormal values in the results.

(3) Common Disease States and an Overview on Making Clinical Decisions

GIO: To acquire the basic knowledge of medical treatment and pharmacotherapy for major diseases to work as part of an interprofessional team.

1. To describe the roles of drug, diet, and non-drug therapies (surgery, etc.) in treating major diseases.
2. To discuss the significance of drug therapy in major diseases based on disease state, pharmacology, and pharmacokinetics.

(4) Medication Safety and Quality Improvement

GIO: To acquire the basic knowledge of adverse events (side effects, interactions), drug-induced injury/damage, and drug abuse to avoid the risks associated with pharmacotherapy.

1. To describe the effects, side effects, and toxicity of drugs and their relationships.
2. To describe the differences between side effects and adverse events.

3. To describe the drugs, physical tests, laboratory tests, and methods to treat major side effects and disease states such as:
blood disorders, electrolyte abnormalities, liver failure, renal failure, digestive disorders, circulatory disorders, mental disorders, skin disorders, respiratory problems, drug allergies (including anaphylactic shock), metabolic disorders, and muscle disorders.
4. To discuss major drug-induced damage/injury and drug abuse issues from the viewpoint of health risk management.

E2. Pharmacology, Pathophysiology, and Pharmacotherapy

GIO: To acquire fundamental knowledge of pharmacology, pathophysiology, and pharmacotherapy to participate in appropriate treatment through the selection of appropriate pharmaceuticals, dosages, and routes of administration while following drug information and safety guidelines.

(1) Drugs Used for the Treatment of Nervous System Disorders

GIO: To acquire fundamental knowledge of pharmacology, pathophysiology, and pharmacotherapy of drugs for the treatment of nervous system disorders and to learn the basics of collecting and analyzing information for the appropriate use of pharmaceuticals.

① Drugs Affecting the Autonomic Nervous System

1. To list the major drugs that affect the sympathetic nervous system by altering the functions of the governing organs and to describe their pharmacology, mechanisms of action, and major side effects.
2. To list the major drugs that affect the parasympathetic nervous system by altering the function of the governing organs and describe their pharmacology, mechanisms of action, and major side effects.
3. To list the major drugs that affect the ganglia and describe their pharmacology, mechanisms of action, and major side effects.
4. To evaluate the efficacy of major drugs that affect the autonomic nervous system in animal experiments.

② Drugs Affecting the Somatic Nervous System and Drugs Used for the Treatment of Muscle Disorders

1. To list the major drugs that affect the sensory nerves and to describe their pharmacological effects, mechanisms of action, and major side effects.
2. To list the major drugs that affect the motor nervous system and to describe their pharmacological effects, mechanisms of action, and major side effects.
3. To evaluate the efficacy of major drugs that affect the sensory and motor nerves in animal experiments.
4. To describe the following diseases:
progressive muscular dystrophy, Guillain-Barre syndrome, and myasthenia gravis.

③ Drugs Used for Treatment of Central Nervous System Disorders

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of general anesthetics and hypnotic drugs.

2. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications (including the WHO three-step analgesic ladder) of narcotic analgesics and non-narcotic analgesics.
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of the central nervous system stimulants.
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of the drugs used to treat schizophrenia as well as disease state (pathophysiology, symptoms, etc.).
5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat major depression, mania, and depressive (bipolar) disorders as well as disease state (pathophysiology, symptoms, etc.).
6. To describe pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat anxiety disorders (panic, general anxiety disorders), psychosomatic disorders, and insomnia as well as disease state (pathophysiology, symptoms, etc.).
7. To describe the pharmacology (pharmacological effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat epilepsy as well as disease state (pathophysiology, symptoms, etc.).
8. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat cerebrovascular diseases (intracerebral hemorrhage, cerebral infarction including thrombosis, embolism, transient cerebral ischemia, and subarachnoid hemorrhage) as well as disease state (pathophysiology, symptoms, etc.).
9. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat Parkinson's disease as well as disease state (pathophysiology, symptoms, etc.).
10. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat dementia (Alzheimer's disease, cerebrovascular dementia) as well as disease state (pathophysiology, symptoms, etc.).
11. To describe pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat migraine as well as disease state (pathophysiology, symptoms, etc.).
12. To evaluate the efficacy of drugs that affect the central nervous system in animal experiments.
13. To discuss central nervous system disorders that may affect social life and the significance of pharmacotherapy.
14. To discuss the following diseases:
encephalitis, meningitis, multiple sclerosis, amyotrophic lateral sclerosis, narcolepsy, drug addiction, and alcoholism.

④ Chemical Structure and Drug Effect

1. To describe briefly the basic chemical structures and effects (pharmacology, pharmacokinetics) of major drugs that affect the nervous system.

(2) Immunosuppressants, Antiinflammatory Agents, Drugs Used for the Treatment of Allergies, and Bone/Joint Disorders

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs for immunosuppressants, antiinflammatory agents, drugs for the treatment of allergies and bone/joint disorders and to collect and analyze information for the appropriate use of pharmaceuticals.

① Antiinflammatory Agents

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of antiinflammatory agents (steroidal, non-steroidal) and anti-pyretic analgesic agents.
2. To describe inflammation based on the mechanism of action of antiinflammatory drugs.
3. To describe the process of wound healing.

② Immunosuppressants, Antiinflammatory Agents, Drugs Used for the Treatment of Allergies

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of drugs used to treat allergies (antihistamines, antiallergic agents, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of immunosuppressants.
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following allergic diseases as well as disease state (pathophysiology, symptoms, etc.):
atopic dermatitis, urticaria, contact dermatitis, allergic rhinitis, allergic conjunctivitis, pollen allergies, digestive allergies, and asthma.
4. To describe the drugs used to treat the following drug-induced allergies as well as disease state (pathophysiology, symptoms, etc.):
Stevens-Johnson syndrome, toxic epidermal necrosis, drug-induced hypersensitivity syndrome, and drug eruption.
5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat anaphylactic shock as well as disease state (pathophysiology, symptoms, etc.).
6. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) for the following diseases:
psoriasis vulgaris, bullous dermatosis, photodermatitis, and Behçet's disease
7. To describe the pharmacology (pharmacological effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following organ-specific autoimmune diseases as well as disease state (pathophysiology, symptoms, etc.):
Grave's disease, Hashimoto's thyroiditis, pernicious anemia, Addison's disease, type 1 diabetes mellitus, myasthenia gravis, multiple sclerosis, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, and Sjogren's syndrome.

8. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following systemic autoimmune diseases as well as disease state (pathophysiology, symptoms, etc.):
systemic lupus erythematosus, scleroderma, polymyositis/dermatomyositis, and rheumatoid arthritis.
9. To describe the disease state (pathophysiology, symptoms, etc.), pharmacotherapy (drug selection, etc.) of rejection and graft-versus-host disease (GVHD) associated with kidney, liver, and bone marrow transplantation and with umbilical cord blood, and blood transfusion.

③ Drugs Used for the Treatment of Bone/Joint and Calcium Metabolism Disorders

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat rheumatoid arthritis as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs to treat osteoporosis as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs to treat osteoporosis as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following calcium metabolism disorders as well as disease state (pathophysiology, symptoms, etc.):
hyper/hypoparathyroidism, osteomalacia (including rickets), and hypercalcemia associated with malignant tumors.

④ Chemical Structure and Drug Effects

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of major drugs such as immunosuppressants, antiinflammatory agents, and drugs for the treatment of allergies.

(3) Drugs Used for the Treatment of Cardiovascular, Hematological, Renal/Urinary Tract, and Reproductive Disorders

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs used to treat cardiovascular, hematological, renal/urinary tract, and reproductive disorders and to collect and analyze information for the appropriate use of pharmaceuticals.

① Drugs Used for the Treatment of Cardiovascular Disease

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following types of cardiac arrhythmia and related conditions as well as disease state (pathophysiology, symptoms, etc.):
supraventricular premature contraction (PAC), premature ventricular contraction (PVC), atrial fibrillation (AF), paroxysmal supraventricular tachycardia (PSVT), WPW syndrome, ventricular tachycardia (VT), ventricular fibrillation (VF), atrioventricular block, and long QT syndrome.

2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat acute and chronic heart failure as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat ischemic heart disease (angina pectoris, myocardial infarction) as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following forms of hypertension as well as disease state (pathophysiology, symptoms, etc.):
essential hypertension and secondary hypertension (including renal vascular hypertension and renal hypertension).
5. To describe arteriosclerosis obliterans (ASO), cardiogenic shock, valvular disease, and congenital heart disease.
6. To evaluate the efficacy of drugs to treat circulatory disorders in animal experiments.

② **Drugs Used for the Treatment of Blood and the Hematopoietic System Disorders**

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of hemostatic drugs.
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of anti-thrombotic drugs, anti-coagulants, and thrombolytic agents.
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following types of anemia as well as disease state (pathophysiology, symptoms, etc.):
iron deficiency anemia, megaloblastic anemia (pernicious anemia, etc.), aplastic anemia, autoimmune hemolytic anemia (AIHA), renal anemia, and sideroblastic anemia.
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat disseminated intravascular coagulation (DIC) as well as disease state (pathophysiology, symptoms, etc.).
5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection etc.) of drugs used to treat the following blood and hematopoietic system disorders as well as disease state (pathophysiology, symptoms, etc.):
hemophilia, thrombotic thrombocytopenic purpura (TTP), leukopenia, thromboembolism, leukemia, and malignant lymphoma.

③ **Drugs Used for the Treatment of Urinary Tract and Reproductive System Disorders**

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of diuretic agents.
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat acute and chronic renal failure as well as disease state (pathophysiology, symptoms, etc.).

3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat nephrotic syndrome as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat overactive/underactive bladder as well as disease state (pathophysiology, symptoms, etc.).
5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following urinary tract disorders as well as disease state (pathophysiology, symptoms, etc.):
chronic kidney disease (CKD), glomerulonephritis, diabetic nephropathy, drug-induced nephropathy, pyelonephritis, cystitis, urinary tract infection and urinary stones.
6. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat prostatic hypertrophy, endometriosis, and uterine fibroids as well as disease state (pathophysiology, symptoms, etc.).
7. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs related to conception, pregnancy, and birth as well as the physical conditions associated with them.
8. To describe the processes of the reproductive system in cases of infertility and during abnormal pregnancy and abnormal delivery.

④ Chemical Structures and Drug Effects

1. To describe the basic structures and effects (pharmacology, pharmacokinetics) of major drugs used to treat cardiovascular, urinary, and reproductive system disorders.

(4) Drugs Used for the Treatment of Respiratory and Digestive Tract Disorders

GIO: To acquire fundamental knowledge of the pathophysiology of respiratory and digestive tract disorders as well as the pharmacology and pharmacotherapy of drugs used to treat them and to collect and analyze information for the appropriate use of pharmaceuticals.

① Drugs Used for the Treatment of Respiratory Tract Disorders

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat bronchial asthma as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat chronic obstructive pulmonary disease (COPD) and tobacco-related diseases (including nicotine dependence) as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat interstitial pneumonia as well as disease state (pathophysiology, symptoms, etc.).

4. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of antitussive, expectorant, and respiratory stimulants.

② **Drugs Used for the Treatment of Digestive Tract Disorders**

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat gastroesophageal reflux (including reflux esophagitis), peptic ulcer, and gastritis as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat inflammatory bowel disease (ulcerative colitis, Crohn's disease, etc.) as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat liver disease (hepatitis, liver cirrhosis including viral cirrhosis, and drug-induced liver damage as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat pancreatitis as well as disease state (pathophysiology, symptoms, etc.).
5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat biliary tract disease (cholelithiasis, cholangitis) as well as disease state (pathophysiology, symptoms, etc.).
6. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat gastrointestinal function disorders, including irritable bowel syndrome, as well as disease state (pathophysiology, symptoms, etc.).
7. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat constipation and diarrhea as well as disease state (pathophysiology, symptoms, etc.).
8. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat nausea and vomiting as well as disease state (pathophysiology, symptoms, etc.).
9. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat hemorrhoids as well as disease state (pathophysiology, symptoms, etc.).

③ **Chemical Structures, Properties, and Activities of Drugs**

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of drugs used to treat respiratory and digestive disorders.

(5) Drugs Used for the Treatment of Metabolic and Endocrine Disorders

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs for the treatment of endocrine and metabolic disorders and to collect and analyze information for the appropriate use of pharmaceuticals.

① Drugs Used for the Treatment of Metabolic Disorders

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat diabetes mellitus and its complications as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat dyslipidemia as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat hyperuricemia and gout as well as disease state (pathophysiology, symptoms, etc.).

② Drugs Used for the Treatment of Endocrine Disorders

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of sex hormone-related drugs used to treat endocrine system disorders as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat Basedow's (Grave's) disease as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat thyroiditis (chronic Hashimoto's thyroiditis and subacute thyroiditis) as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat diabetes insipidus as well as disease state (pathophysiology, symptoms, etc.).
5. To describe the following diseases:
acromegaly, hyperprolactinemia, hypopituitarism, ADH syndrome of inappropriate secretion (SIADH), hyperparathyroidism, hypothyroidism, Cushing's syndrome, aldosteronism, pheochromocytoma, adrenal insufficiency (acute, chronic), endometriosis and Addison's disease.

③ Chemical Structure and Drug Efficacy

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of drugs used for the treatment of metabolic and endocrine system disorders.

(6) Drugs Used for the Treatment of Ophthalmological, Ear/Nose/Throat, and Dermatological Conditions

GIO: To acquire fundamental knowledge of the pathophysiology, pharmacology, mechanisms of action, and side effects of drugs used for the treatment of ophthalmological, ears/nose/throat, and dermatological conditions and to collect and analyze information for the appropriate use of pharmaceuticals.

① Drugs Used for the Treatment of Ophthalmological Conditions

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat glaucoma as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat cataract as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat age-related macular degeneration as well as disease state (pathophysiology, symptoms, etc.).
4. To describe conjunctivitis, retinopathy, uveitis, and retinitis pigmentosa.

② Drugs Used for the Treatment of Ears/Nose/Throat Conditions

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat dizziness, motion, sickness, Meniere's disease, etc. as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the following diseases:
allergic rhinitis, hay fever, sinusitis, otitis media, pharyngitis, tonsillitis, and epiglottitis.

③ Drugs Used for the Treatment of Dermatological Conditions

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat atopic dermatitis as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat fungal diseases of the skin as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat decubitus as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the following diseases:
urticaria, drug eruption, bullous dermatosis, psoriasis, contact dermatitis, and photodermatitis

④ Chemical Structure and Drug Effect

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of drugs used for the treatment of ophthalmological, ears/nose/throat, and dermatological conditions.

(7) Drugs Used for the Treatment of Infectious Diseases and Cancer

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs used for the treatment of infectious diseases and cancers and to collect and analyze information for the appropriate use of pharmaceuticals.

① Antibacterial Agents

1. To describe the pharmacology (effects, mechanisms of action, antibacterial spectrum, major side effects, interactions, tissue absorption) and clinical applications of drugs used for the treatment of infectious diseases, including β -lactams, tetracyclines, macrolides, aminoglycosides, new quinolones, glycopeptide-based, anti-tuberculosis drugs, sulfa drugs (including the ST case agent), and other antibacterial agents.
2. To list the major biological agents (vaccines, etc.) related to bacterial infection and describe their mechanisms of action.

② Antibacterial Drug Resistance

1. To describe the mechanism of resistance acquisition of resistance to major anti-bacterial agents and how to treat patients with drug-resistant bacterial infections.

③ Drugs Used for the Treatment of Bacterial Infections

1. To describe the disease states (pathophysiology, symptoms, etc.), infection route, preventive methods, and pharmacotherapy (drug selections, etc.) in the treatment of the following respiratory tract infections:
upper respiratory infection (common cold syndrome), bronchitis, tonsillitis, bacterial pneumonia, pulmonary tuberculosis, Legionella infection, pertussis, and mycoplasma pneumonia.
2. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following gastrointestinal tract infections:
acute appendicitis, cholecystitis, cholangitis, pathogenic *E. coli* infection, food poisoning, *Helicobacter pylori* infection, dysentery, cholera, typhoid, paratyphoid, and pseudomembranous colitis.
3. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following sensory organ infections:
sinusitis, otitis media, and conjunctivitis.
4. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following urinary tract infections:
pyelonephritis, cystitis, and urethritis.
5. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following sexually transmitted diseases:
syphilis, gonorrhea, and chlamydia.
6. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of encephalitis and meningitis.

7. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following bacterial skin infections:
contagious impetigo, erysipelas, carbuncle, folliculitis, and leprosy.
8. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of infective endocarditis and pleurisy.
9. To describe the route of transmission, preventive measures, disease states (pathophysiology, symptoms, etc.), and pharmacotherapy (drug selections, etc.) in the treatment of hospital-acquired infections caused by the following drug-resistant bacteria:
methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), *Serratia* spp., *Pseudomonas aeruginosa*, etc.
10. To describe the disease state (pathophysiology, symptoms, etc.), route of transmission, preventive measures, and pharmacotherapy (drug selections, etc.) in the treatment of the following systemic bacterial infections:
diphtheria, fulminant group A β -hemolytic streptococcus infection, neonatal group B streptococcal infection, tetanus, and sepsis.

④ **Drugs Used for the Treatment of Viral Infections and Prion Diseases**

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat herpesvirus infections (herpes simplex, varicella zoster) as well as disease state (pathophysiology, symptoms, etc.).
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat cytomegalovirus infections as well as disease state (pathophysiology, symptoms, etc.).
3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat influenza as well as disease state (pathophysiology, symptoms, etc.).
4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of the drugs used to treat viral hepatitis A, B, and C (HVA, HVB, and HCV) infection, acute hepatitis, chronic hepatitis, cirrhosis, and liver cell carcinoma as well as routes of transmission, preventive measures, and disease state (pathophysiology and symptoms, etc.).
5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of the drugs used to treat acquired immunodeficiency syndrome (AIDS) as well as the routes of transmission, preventive measures, and disease states (pathophysiology, symptoms, etc.).
6. To describe the routes of transmission, preventive measures, disease states (pathophysiology, symptoms, etc.), and pharmacotherapy (drug selections, etc.) to treat the following viral infections (including prion diseases): infectious erythema, hand-foot-and-mouth disease, mononucleosis, exanthema subitum, pharyngoconjunctival fever, viral diarrhea, measles, rubella, mumps, common cold syndrome, and Creutzfeldt-Jakob disease.

⑤ Drugs Used for the Treatment of Fungal Infections

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of antifungal drugs.
2. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) for the treatment of the following fungal infections:
skin mycosis, candidiasis, pneumocystis pneumonia, pulmonary aspergillosis, and cryptococcosis.

⑥ Drugs Used for the Treatment of Protozoal and Parasitic Infections

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following protozoal infections as well as disease state (pathophysiology, symptoms, etc.):
malaria, toxoplasmosis, trichomoniasis, and amoebic dysentery.
2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following parasitic infections as well as disease state (pathophysiology, symptoms, etc.):
ascariasis, pinworm disease, and anisakiasis.

⑦ Malignant Tumors

1. To describe the definition of tumors (the differences between benign and malignant tumors).
2. To describe the following aspects related to malignant (cancerous) tumors:
histological type classifications, stages, tumor examinations (cytodiagnosis, tissue diagnosis, diagnostic imaging, tumor markers (including mutant genes and gene products), epidemiology (trends in morbidity and mortality), risks for development, and preventive measures.
3. To describe the significance of pharmacotherapy in the treatment of cancers.

⑧ Drugs Used for the Treatment of Malignant Tumors

1. To describe the pharmacology (effects, mechanisms of action, major side effects, interactions, and tissue migration) of the following anticancer agents and their clinical applications:
alkylating agents, antimetabolites, antitumor antibiotics, mitotic inhibitors, topoisomerase inhibitors, hormonal agents, platinum agents, molecular-targeted therapy, etc.
2. To describe the mechanism of acquired resistance to anti-cancer agents.
3. To describe treatments to reduce the following major side effects of anti-cancer agents: diarrhea, nausea, vomiting, leukopenia, and skin disorders including hand-foot syndrome and thrombocytopenia.
4. To describe major chemotherapy regimens (FOLFOX, etc.) including the agents involved, their roles and side effects, and target diseases.
5. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat the following types of leukemia:
acute (chronic) myelogenous leukemia, acute (chronic) lymphocytic leukemia, and adult T-cell leukemia (ATL).
6. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat malignant lymphoma and multiple myeloma.

7. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat osteosarcoma.
8. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat the following digestive tract cancers:
stomach, esophageal, liver, colon, gallbladder, bile duct, and pancreatic.
9. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat lung cancer.
10. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat malignancies of the following head/neck and sensory organs:
brain, retinoblastoma, larynx, pharynx, nasal cavity, paranasal sinuses, and oral cavity.
11. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat the following genital cancers:
prostate, uterine, and ovarian.
12. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat kidney and bladder cancers.
13. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat breast cancer.

⑨ Terminal and Palliative Care

1. To describe disease state (pathophysiology, symptoms, etc.) and treatments for the terminal stages of cancer.
2. To describe disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used for the treatments of cancer-related pain.

⑩ Chemical Structure and Drug Activities

1. To describe the basic structures and activities (pharmacology, pharmacokinetics) of drugs used to treat pathogenic microorganism infections and malignant neoplasms.

(8) Biologics, Cell Therapy, and Genomics

GIO: To acquire fundamental knowledge of treatments utilizing proteins, genomics, and cellular agents for appropriate use with ethical considerations as well as an understanding of basic genomics.

① Recombinant Pharmaceutical Products

1. To describe the characteristics and significance of recombinant pharmaceuticals.
2. To list major recombinant pharmaceuticals.
3. To describe the safety risks of recombinant pharmaceuticals.

② Gene Therapy

1. To describe the mechanisms, methods, and procedures of gene therapies and to describe the current status of associated ethical issues.

③ Transplantation Therapy Utilizing Cells and Tissues

1. To describe the mechanisms, methods, and procedures of transplantation therapies, and to describe the current status of ethical issues associated with the utilization of genomic information.
2. To describe transplantation therapies utilizing isolated or cultured tissues.
3. To describe transplantation therapies utilizing blood stem cells derived from umbilical cord blood, peripheral blood, and bone marrow.
4. To describe cell transplantation therapies utilizing embryonic stem cells (ES cells) and induced pluripotent stem cells (iPS cells).

(9) Over-the-Counter and Behind-the-Counter Drugs and Self-Medication

GIO: To acquire fundamental knowledge of behind-the-counter, over-the-counter drugs, and self-medication to contribute to the community health and medical care by offering the appropriate drug therapy and to collect appropriate information for providing drug therapy.

1. To describe the role of pharmacists in caring for the health of the community, health promotion, and self-medication.
2. To describe both over-the-counter and behind-the-counter drugs and to list the major ones by risk category (class-1, -2, and -3).
3. Based on major symptoms, to list the diseases that appear to be strongly related and diseases that should not be overlooked.
4. To collect specific patient information to determine whether over-the-counter or behind-the-counter drugs should be used or whether patients should be advised to consult a physician.
5. To list over-the-counter and behind-the-counter drugs for self-medication that can be used to treat the following conditions and symptoms:
fever, pain, itching, digestive and respiratory symptoms, allergies, bacterial/fungal infections or lifestyle-related diseases.
6. To describe health improvement methods (including exercise, diet, supplements, and health-promoting food) and to describe their significance in maintaining/ promoting people's health.
7. To describe major interactions among over-the-counter and behind-the-counter drugs, prescription drugs, supplements, and health-promoting food.
8. To collect and evaluate information on therapeutic outcomes and side effects of over-the-counter and behind-the-counter drugs.

(10) Kampo Medicine

GIO: To acquire basic knowledge of Kampo medicines, including disease concepts, indications, side effects and precautions.

① Fundamentals of Kampo Medicine

1. To describe the characteristics of Kampo medicine.
2. To describe the following basic words of Kampo medicine:
Yin/Yang , Deficiency/Excess Cold/Heat, Exterior/Interior, Qi/Blood/Fluid, and Patterns.

3. To describe the systematic classification of Kampo medicines based on the components of crude drugs.
4. To describe the differences between Kampo medicines and modern pharmaceuticals, folk medicines, supplements, and health-promoting food.

② Application of Kampo Medicines

1. To describe the diagnostic methods, patient approach such as, conditions and disease states, and treatments used in Kampo medicine.
2. To describe with examples the patterns, symptoms, and diseases related to the Kampo medicines listed in the Japanese Pharmacopoeia.
3. To describe the significance of Kampo medicines in modern pharmacotherapy.

③ Precautions Related to the Use of Kampo Medicines

1. To describe with examples possible side effects and precautions for the use of Kampo medicines.

(11) Therapeutics Optimization

GIO: To acquire fundamental knowledge of collecting and analyzing information for treatments and appropriate use of pharmaceuticals in order to contribute to the optimal drug therapy.

① Comprehensive Exercises

1. To discuss optimal drug therapies based on patient and drug information.
2. To discuss treatments for overdose toxicity (including antidotes).
3. To list complications associated with long-term care and discuss their drug therapy.

E3. Essential Information for Pharmacotherapy

GIO: As part of interprofessional teamwork, to acquire fundamental knowledge of and skills in providing and applying drug information and patient information into clinical problems, in order to provide necessary information on pharmacotherapy, to develop pharmaceutical care plans, and to solve clinical problems.

(1) Drug Information

GIO: To acquire fundamental knowledge of and skills in applying drug information, evidence-based medicine (EBM), biostatistics, and clinical research designs and analytics.

① Fundamentals of Drug Information

1. To identify essential drug information for pharmaceutical administration and handling.
2. To describe which professionals (governmental, clinical, and pharmaceutical) provide different types of drug information and the roles those professionals play.
3. To describe examinations and clinical trials in new drug development including generic drugs, and drug information data to those trials.
4. To describe outline of post-marketing surveillance and studies and drug information obtained from them.

5. To describe major regulations such as Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), Good Postmarketing Study Practice (GPSP), risk management plans (RMP), etc. and regulatory science.

② Drug Information Resources

1. To describe primary, secondary, and tertiary drug information resources.
2. To list major secondary and tertiary resources and to describe the characteristics of each each.
3. To describe the types of drug information provided by the Ministry of Health, Labor and Welfare, Pharmaceutical and Medical Devices Agency (PMDA), and Pharmaceutical companies.
4. To describe the legal roles of package inserts.
5. To list the items (boxed warnings and precautions, contraindications, indications and usage, dosage and administration, cautions, etc.) in package inserts and to explain each item.
6. To describe the difference between the roles of drug interview forms and package inserts.

③ Clinical Applications of Drug Information (Collection, Evaluation, Processing, Provision, Management)

1. To select the appropriate source for each purpose (usage, adverse reactions, interactions, identification, pregnancy and nursing, toxicity, etc.) and to retrieve and collect drug information effectively from each source.
2. To understand the importance of key words and thesauruses in literature retrieval and to search secondary databases of medical and pharmaceutical publications (e.g., MEDLINE) appropriately.
3. To identify the items for evaluating the reliability and scientific validity of drug information.
4. To evaluate the quality of original articles on clinical trials and in the tertiary literature.
5. To describe handling methods and ethical issues (intellectual property and privacy policy) in applying drug information.

④ Evidence-based Medicine

1. To summarize the meaning of “evidence-based medicine” and to explain the 5 steps of the evidence-based medicine process.
2. To explain the advantages and disadvantages of different study designs (randomized controlled trial, cohort study, case-control study, etc.), and describe the evidence level of each study design.
3. To describe critical literature evaluation and identify internal validity (accuracy and reproducibility) and external validity (generalizability).
4. To understand the concept of meta-analyses and to explain the results.

⑤ Biostatistics

1. To describe and distinguish the basic statistics used in clinical trials (mean, median, standard deviation, standard error, confidence interval, etc.)
2. To explain the null hypothesis and define tests of significance and estimations.
3. To describe basic statistical distributions (normal, t-, binomial, Poisson, chi-squared, and F-).
4. To list major parametric tests and non-parametric tests and describe their usage.
5. To analyze significance differences between patient/treatment/placebo groups in clinical trials (t-test, chi-squared test, etc.).

6. To describe the major methods for conducting regression analyses (linear regression, logistic regression, etc.), and tests to determine correlation coefficients.
7. To describe knowledge of methods used to analyze survival time (Kaplan-Meier curve, etc.)

⑥ Clinical Study Design and Analysis

1. To describe the main clinical study designs (interventional study, observational study) and to explain the characteristics of each.
2. To describe bias and confounding in clinical trial design.
3. To describe the main epidemiological study designs for observational studies (case report, case series, case-controlled study, nested case-control study, case-cohort study, etc.).
4. To describe the algorithms used to determine causality in analyzing adverse drug reactions.
5. To describe the difference between superiority and noninferiority trials.
6. To describe the techniques applied in interventional studies (sample size, randomization, blinding, etc.).
7. To describe factors involve in statistical analysis.
8. To describe different endpoints used in interventional studies (true and surrogate endpoints, primary and secondary endpoints) by giving examples.
9. To describe and calculate the major outcomes (efficacy and safety) in clinical trials (relative risks, relative risk reduction, absolute risks, absolute risk reduction, number needed to treat, odds ratios, incidence rates, and incidence proportions).

⑦ Drug Evaluation

1. To describe how formularies are produced in hospital and community pharmacies.
2. To compare and evaluate efficacy and safety in major allogeneic same effect pharmaceuticals with the same activities using drug information.
3. To compare and evaluate quality, safety, and economy in branded and generic drugs using drug information.

(2) Patient Information

GIO: To acquire basic knowledge of how to obtain and assess patient information.

① Fundamentals of Patient Information

1. To list the basic patient information necessary to determine the most appropriate pharmacotherapy.
2. To list the resources for obtaining patient information and to explain the differences among them.

② Clinical Assessment

1. To describe the problem-oriented system (POS)
2. To describe SOAP and how to record patient information.
3. To describe the types of patient information necessary to evaluate drug efficacy and adverse drug reactions.
4. To describe the importance of privacy policies when managing patient information.

(3) Personalized Medicine

GIO: To acquire the fundamental issues about personalized pharmacotherapy.

① Genetic factors

1. To give examples and describe the major genetic factors influencing drug main drug effects and side effects.
2. To give examples and describe the major genetic factors (gene mutations in drug-metabolizing and transporter groups, etc.) affecting pharmacokinetics.
3. To give examples and describe pharmacotherapy taking genetic factors into consideration.

② Age-Related Factors

1. To describe the cautions in pediatric pharmacotherapy and pharmacokinetics in low-birth weight infants, newborns, and infancy.
2. To describe the cautions in geriatric pharmacotherapy and pharmacokinetics in the elderly.

③ Special Populations (Liver Dysfunction, Renal Dysfunction, Heart Diseases, etc.)

1. To describe the cautions of pharmacotherapy as well as pharmacokinetics and how to develop pharmaceutical care plans for patients with kidney disease and renal dysfunction.
2. To describe the cautions of pharmacotherapy as well as pharmacokinetics and how to develop pharmaceutical care plans for patients with liver disease and liver dysfunction.
3. To describe the cautions of pharmacotherapy as well as pharmacokinetics and how to develop pharmaceutical care plans for patients with heart diseases.

④ Other Special Populations (Pregnant and Lactating Women, Obese or Emaciated Patients, Menopausal Women, et al.)

1. To identify the physiological factors affecting drug effects: gender, menopausal status, circadian rhythm, etc.
2. To describe the cautions of pharmacotherapy and pharmacokinetics as related to reproductive status, pregnancy, lactation, etc.
3. To describe the cautions of pharmacotherapy as well as pharmacokinetics and to develop pharmaceutical care plans based on nutrition status such as obesity, hypoalbuminemia, presence of ascites, etc.

⑤ Personalized Therapeutics Plans

1. To develop pharmaceutical care plans based on individual patient background (genetics, age, organ function, etc.) and drug information.
2. To give examples and explain pharmacotherapy based on companion diagnostics.

E4. Drug Disposition

GIO: In order to understand drug disposition and to provide dosage regimens for individual patients, to acquire fundamental knowledge of pharmacokinetics and skills in their applications.

(1) Drug Disposition

GIO: To acquire the fundamental issues of the processes of drug absorption, distribution, metabolism, excretion (ADME) and pharmacokinetic interaction.

① Permeation through Biomembranes

1. To describe simple diffusion, facilitated diffusion, and active transport in the permeation of drugs across the cell membranes.
2. To list the transporters involved in drug permeation across the cell membranes and to describe their characteristics as well as their roles in pharmacokinetics.

② Absorption

1. To describe drug absorption after oral administration.
2. To describe drug absorption after non-oral administration.
3. To list and describe the factors (drug properties, physiological factors, etc.) affecting drug absorption.
4. To list and describe drug interactions in the process of drug absorption.
5. To describe the first-pass effect.

③ Distribution

1. To list major plasma-binding proteins and identify drugs with high proteins-binding rates.
2. To describe the quantitative relationship between tissue distribution (distribution volume) and plasma/ tissue binding of drugs.
3. To describe the how to measure and analyze drug protein binding and binding inhibition.
4. To describe the structure and function of the blood–tissue barrier, and drug distribution into the brain or fetus.
5. To describe distribution of drugs into the lymphatic system and breast milk.
6. To list and describe drug interactions in the process of drug distribution.

④ Metabolism

1. To list major drug-metabolizing enzymes and to describe the sites of drug metabolism (tissue and subcellular organelles) and mode of reaction.
2. To give examples of and explain phase I reactions (oxidation, reduction, and hydrolysis) and phase II reactions (conjugation) in drug metabolism.
3. To list drugs metabolized by major drug-metabolizing enzymes.
4. To list and explain prodrugs and active metabolites.
5. To list and describe the mechanisms of inhibition and induction of drug-metabolizing enzymes, and related drug interactions.

⑤ Excretion

1. To describe the mechanisms of renal drug excretion.
2. To describe the quantitative relationships between renal clearance and glomerular filtration, tubular secretion, and tubular reabsorption.
3. To list major drugs excreted mainly by the kidneys.
4. To describe the biliary excretion and enterohepatic circulation of drugs.
5. To list and describe drug interactions in the process of drug excretion.

(2) Pharmacokinetic Analysis

GIO: To acquire the fundamental issues of pharmacokinetic analysis and drug dosage regimens.

① Pharmacokinetics

1. To describe the concept of the linear compartment model and the associated pharmacokinetics parameters (total body clearance, distribution volume, elimination half-life, bioavailability, etc.).
2. To analyze pharmacokinetics based on a linear 1-compartment model (bolus injection, oral administration [single and repeated dosage], constant infusion).
3. To list drugs with nonlinear pharmacokinetics and analyze them based on a nonlinear model.
4. To describe the moment analysis and how to calculate the associated parameters.
5. To describe hepatic clearance, renal clearance, and intrinsic clearance and to describe their relationships using equations.
6. To describe pharmacokinetics-pharmacodynamics (PK-PD) analysis.

② Therapeutic Drug Monitoring and Dosage Regimens

1. To describe the significance of therapeutic drug monitoring (TDM) and to list the drugs requiring TDM.
2. To describe sampling timing, sample handling, and drug assays in for TDM.
3. To apply pharmacokinetic parameters to individual dosage regimens.
4. To describe the concept of population pharmacokinetics and its applications.

E5. Science for Drug Formulation

GIO: To acquire the fundamentals of the physical properties of drugs and other formulation ingredients, formulation designs, and drug delivery systems to understand the significance and the features of drug formulations.

(1) Properties of Formulations (Dosage Forms)

GIO: To acquire the fundamentals of the physical properties of drugs and other formulation ingredients.

① Solid Ingredients

1. To describe the properties of powders.
2. To describe the properties of crystals (stable and meta-stable forms), amorphous forms, anhydrides, and hydrates.

3. To describe the dissolution phenomena of solid ingredients (including the solubility and the dissolution equilibrium) as well as the diffusion of dissolved materials and dissolution rates.
4. To describe the factors (including pH and temperature) affecting the dissolution of solid ingredients.
5. To list and explain typical pharmaceutical technologies that increase the solubility and dissolution rates of solid ingredients.

② Semisolid and Liquid Ingredients

1. To describe flow and transformation (rheology).
2. To describe the structures of polymers and characteristics of polymer solutions (including viscosity).

③ Dispersion System

1. To describe the properties of interfaces (including interfacial tension, distribution equilibrium, and adsorption), and the typical surfactants and their properties.
2. To list and explain typical dispersion systems and their properties, including self-assembly, colloids, emulsions, and suspensions.
3. To explain stability and separation phenomena (including precipitation) of dispersed particles.
4. To explain typical pharmaceutical technologies that increasing dispersion stability.

④ Physical Properties of Drugs and Other Formulation Ingredients

1. To understand the structures of polymers which are commonly used in drug formulation and to describe the physical properties of the polymers.
2. To describe drug stability, including reaction rates and complex composite reactions as well as factors (including pH and temperature) affecting drug stability.
3. To describe typical pharmaceutical technologies improving drug stability.

(2) Design of Formulations

GIO: To learn the types, production processes, and qualities of formulations.

① Typical Formulations

1. To describe the general information and significance of drug formulations.
2. To describe various formulations for oral applications and their features.
3. To describe various formulations for mucous-membrane applications (including ophthalmic formulations and agents) and their features.
4. To describe various formulations for injections and their features.
5. To describe various formulations for cutaneous applications and their features.
6. To describe other drug formulations (including those for natural medicines and dialysis) and to describe their features.

② Methods for Formulation and for Formulation Testing

1. To list typical pharmaceutical excipients and to describe their usages and properties.
2. To explain individual formulation processes, commonly used formulation devices, and formulation processes.
3. To explain commonly used containers and packaging and their features.
4. To list and explain formulation-related tests.

③ Bioequivalence

1. To describe bioequivalence as related to formulation features including drug application sites and the release of active ingredients.

(3) Drug Delivery Systems

GIO: To Acquire basic knowledge of drug delivery systems (DDS) in related to the optimization of administration routes and pharmacokinetics.

① Use of DDS

1. To describe the concept and usefulness of DDS.
2. To list and describe typical DDS technologies.

② Controlled Release

1. To describe the concept and significance of controlled-release drugs.
2. To list and describe typical controlled-release technologies for each drug application site and their features.
3. To list typical drugs using controlled-release technologies.

③ Targeting

1. To describe the concept and significance of drug targeting.
2. To list the typical targeting technologies for each drug application site and to describe their features.
3. To list typical drugs using targeting technologies.

④ Absorption Enhancement

1. To describe the concept and significance of absorption enhancement.
2. To list and describe the typical absorption enhancement technologies for each drug application site and their features.
3. To list typical drugs using absorption enhancement technologies.