Ministry of Health of the Russian Federation
Volgograd State Medical University

Department of Pharmaceutical and Toxicological Chemistry

GENERAL PHARMACEUTICAL CHEMISTRY

Pharmacist-analyst of a pharmacy. Equipment of the analytical room.

Lesson 12

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Discipline

GENERAL PHARMACEUTICAL CHEMISTRY

LESSON №12

Pharmacist-analyst of a pharmacy. Equipment of the analytical room.

Pharmacist-analyst of a pharmacy. 6. Analytical room. Requirements and recommendations. Equipment of the analytical room.

QUESTIONS FOR THE LESSON

1. What are the requirements for a pharmacist-analyst?
2. What guides the pharmacist-analyst?
3. Responsibilities of a Pharmacist Analyst
4. What must a pharmacist-analyst know?
5. What must a pharmacist-analyst be able to do?
6. Analytical room. Requirements and recommendations
7. List of equipment of the analysis room:
    a. Testing equipment:
    b. Laboratory utensils
    c. Auxiliary instruments and devices

PHARMACIST-ANALYST

At present, despite a significant reduction in the number of pharmacy organisations with prescription-manufacturing departments and a reduced list of extemporaneous dosage forms, there are still some groups of medicines that cannot be manufactured on an industrial scale. Therefore, manufacturing pharmacies are needed in the medicinal supply of the population.

In the prescription of manufacturing pharmacies, there are dosage forms containing both single and multiple ingredients. The variety of physical and chemical properties of the ingredients allows for the use of multiple identification reactions and quantification methods. However, in the case of multi-component mixtures, their choice is often difficult to select.

Quality control of dosage forms in the pharmacy is carried out by the pharmacist-analyst using express analysis methods. The pharmacist analyst uses rational quality control schemes for multi-component dosage forms.

A pharmacy analyst is a pharmacy specialist whose functional tasks include carrying out various types of intrachemist's controls of pharmaceutical substances, water purified/injectable water, concentrates, semi-finished products, pharmaceutical preparations manufactured in a pharmacy.

The pharmacy analyst must have higher pharmaceutical education, must be accredited, have a certificate of a specialist confirming the degree of compliance of his/her professional competence with established requirements. In his /her activity he / she submits to the head of the pharmacy.

The main work of the analytical pharmacist is to provide chemical and physico-chemical quality control of medicines manufactured in the pharmacy and substances used in the production of medicines. Also methodological management of all types of intrachemist's control.

The work of the pharmacist-analyst is regulated by orders of the Ministry of Health.

In his work, the pharmacist-analyst is guided by:

- ✓ regulatory documents on the issues of the work performed;
- ✓ methodological materials related to relevant issues;
- ✓ Regulations on pharmacy establishment;
- ✓ rules of the sanitary regime of pharmacies and labor regulations;
- ✓ orders and instructions of the director of the enterprise (immediate supervisor);
- ✓ job description.

Responsibilities of a Pharmacist Analyst:

a) master all types of chemical and physicochemical methods of analysis;

b) to exercise control over compliance with the preparation technology and storage conditions of medicines, the expiration date of concentrates and semi-finished products;

c) in necessary cases, give consultation on storage, manufacturing technology and control of medicines, sanitary regime, etc.;

d) to conduct a selective qualitative analysis of drugs that are in doubt;

e) to conduct a complete chemical analysis of the seized samples of medicines;

f) to conduct, in accordance with the established procedure, the withdrawal of samples of drugs for re-control;

g) to supervise the work of the subordinate pharmaceutical personnel;

h) to report all cases of errors to the head of the pharmacy and take measures to eliminate them.

Professional and job requirements for the pharmacy pharmacist-analyst

The professional and job requirements for the pharmacy dispensary analyst include two areas:

- ✓ contains the requirements for what the pharmacy pharmacist-analyst must know (theoretical training);
- ✓ contains the requirements for the pharmacist-analyst to be able to do (practical training).

Both of these areas are interconnected. Since it is impossible to master practical skills without appropriate theoretical knowledge.

A pharmacist-analyst must know:

- the system for organising the quality control service;
- the technology of different types of dosage forms;
- rules and norms of sanitary-hygienic and anti-epidemic regime, rules of aseptic medicine production, pharmaceutical procedure in accordance with the current regulatory documents, orders, instructions;
- rules for obtaining, collecting and storing purified water and water for injections;
- rules for storing medicines in the pharmacy, expiration date of medicines made in the pharmacy;
- all types of intrachemist's control of medicinal products as required by the current instructions on quality control of medicinal products manufactured in a pharmacy;
- express methods of quality control of medicines in the pharmacy;
- quantitative analysis of medicinal products using various methods;
- standards of deviations allowed during manufacture of medicines and packaging;
- health, safety and fire safety rules and regulations;
- normative legal acts and other guideline materials of higher authorities on pharmacy issues;
- the principles of providing pharmaceutical care to the population, and the professional activities of the position held;
- organisation and economics of pharmacy;
- normative and methodological materials on analysis and quality control of medicines, pharmaceutical order, sanitary regime of pharmacies;
- basics of labour legislation;

A pharmacist-analyst must be able to:

- use reference books, guidelines, orders and instructions
- on the organisation and management of quality control of medicines in the pharmacy;
- supervise the work of young specialists and specialist with secondary education;
- conduct all types of intrachemist's controls;
- determine the identity of medicinal substances;
- conduct daily analysis of purified water and water for injection;
- use calculation formulas for titrimetric methods of determination of medicinal substances;
- calculate the mass of drug substance required for analysis, the volume of titrated solution, calculate deviations in % and evaluate the quality of manufactured dosage forms;
- monitor compliance with storage conditions, expiration dates and correct registration of dosage forms;
- record the results of analysis, in case of unsatisfactory manufacturing to determine the cause of and take measures to eliminate the mistakes;
- prepare a report on the work of the Pharmacy Control and Analysis Room according to the prescribed form.
- monitor compliance with the technology for preparing dosage forms in the pharmacy;
- conduct qualitative analysis of powders after filling jar by defectar;
- monitor the conditions and expiration dates of medicines, concentrates and extemporaneous dosage forms produced in the pharmacy;
- monitor the accuracy of weighing instruments;
- monitor the quality of medicines received from suppliers;
- control the withdrawal of counterfeit medicines specified in the information letters of the Centre for Certification and Quality Control of Medicinal Products;

The work of a pharmacist analyst requires systematic improvement of skills in pharmacy, the use of the latest advances in in the field of analysis, the implementation of best practices and scientific organisation of work.

ANALYTICAL ROOM

A special workplace must be provided for chemical quality control of medicinal products manufactured in pharmacies. It must be equipped with a standard set of equipment, instruments and reagents, and provided with regulatory documents, reference literature.

Workplaces of pharmacists-analysts (chemists) in pharmacies must be equipped in an analytical room. Analytical room shall be located near the assistant's room, aseptic room and room for the manufacture of intra-pharmacy preparations, concentrates and semi-finished products. In pharmacies where there are no analytical pharmacists and no analytical room is provided by regulation, analytical tables shall be organized.

Recommendations:

- ✓ The analysis room should have a standard analytical table that complies with modern workplace requirements, is easy to use, has a good appearance, and is painted in light-coloured, which helps to increase working efficiency and the analyst's efficiency and fatigue is reduced.
- ✓ On a table under glass or on a special stand it is advisable to place the methods of analyses of concentrates and semi-finished dosage forms; tables of calculations of quantitative express analyses, tables of qualitative analyses, etc. Some reference materials it is convenient to arrange in the form of cards
- ✓ The analysis room should have: a fume cupboard for work with poisonous, volatile substances and concentrated acids; a water supply with cold and hot water; a sink with a drain to the sewer and an electric supply
- ✓ Analytical rooms should be equipped with the necessary equipment and inventory in accordance with the requirements of the instructions for drug quality control and the norms of technical and economic equipment of pharmacies

LIST OF EQUIPMENT OF THE ANALYSIS ROOM

Testing equipment:

The Analytical Balance

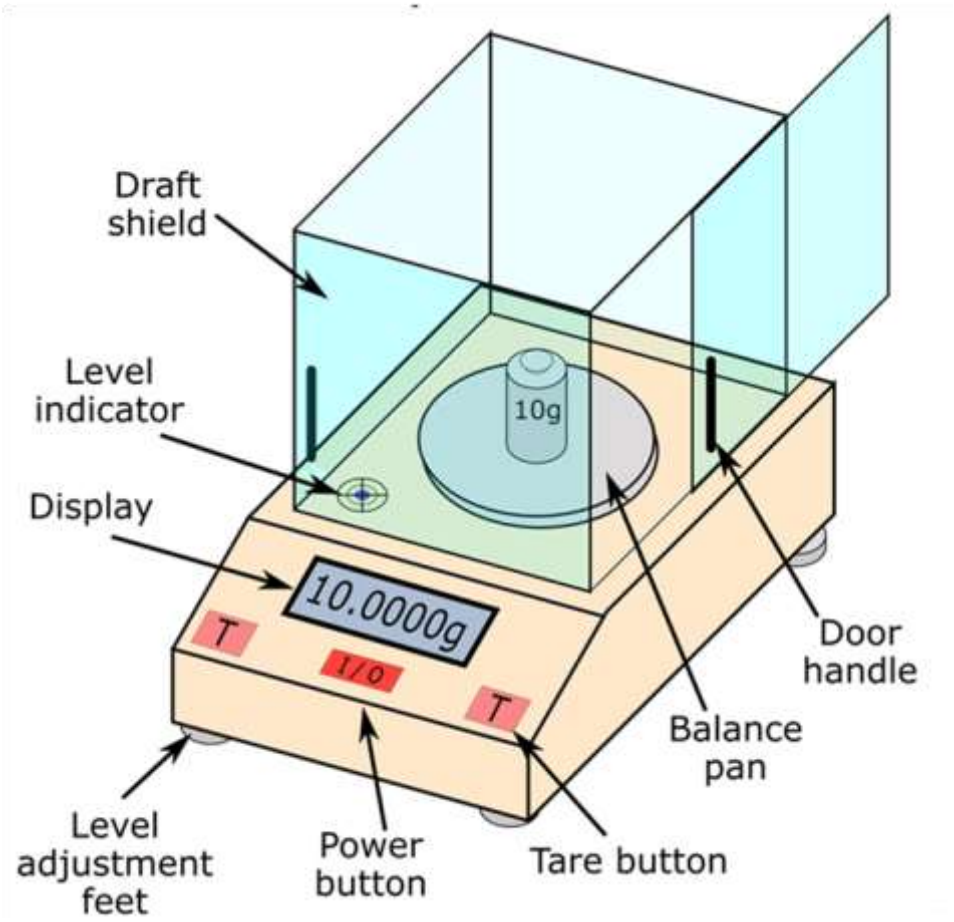
Quantitation in pharmaceutical analysis is based on accurate weighing of drug substances, chemicals, and samples. Such weighing is performed with analytical balances, semi-microbalances, microbalances, or ultra-microbalances to meet the requirements for high accuracy.

The different types of balance are defined in Table 1

Balance name	Readability	Quantity of decimal digits (g)
Ultra-microbalance	0.1 µg	0.0000001
Microbalance	1 µg	0.000001
Semi-microbalance	0.01 mg	0.00001
Analytical balance	0.1 mg	0.0001

Table 1

The main parts of the balance are shown in the picture:



A balance is characterized by its capacity, readability, and reproducibility. The capacity defines the maximum mass that can be weighed, and analytical balances have a weighing capacity up to 100 or 200 g.

The analytical balance should be located on a heavy table, such as a marble table, to minimize vibrations and ensure stable readings.

A normal weighing procedure with an analytical balance includes the following steps:

1. Place an empty weighing vessel on the weighing pan (use a vessel of such a size that the loading capacity is not exceeded).
2. Reset the reading of the balance (tare to 0.0000 or 0.00000 g).
3. Fill the substance or sample to be weighed into the weighing vessel.
4. Record the mass on the digital display.
5. Empty the vessel into the sample container.
6. Place the vessel on the balance again, read the balance, and subtract this mass from the mass from the first reading.
7. Clean the balance after use.

Hand scales are used for dosing bulk and viscous substances.

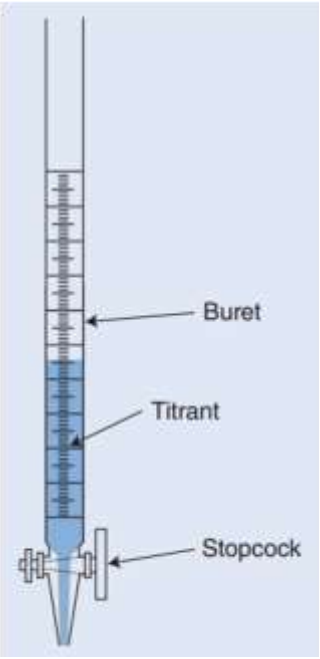
Technical weights are used for weighing solid, thick and liquid substances.

Laboratory utensils

Pipettes are used to deliver exact volumes of liquid. There are two different types of pipettes, namely a transfer pipette and a measuring pipette. Transfer pipettes deliver a specified volume, such as 5.00 or 10.00 mL. Measuring pipettes are graded and used to deliver variable volumes within a specified range, such as, for example, 8.4 mL.

Correct use of pipettes is essential in order to obtain high accuracy.

- ✓ Place the tip of the pipette into the solution.
- ✓ Use a rubber balloon to suck the liquid up into the pipette.
- ✓ Never use your mouth to suck up the liquid.
- ✓ The pipette is filled to a level higher than the calibration mark of the desired volume.
- ✓ Then remove the pipette from the solution and remove traces of solution on the outer surface of the pipette with a paper towel.
- ✓ Hold the pipette tip against the wall of an empty beaker (waste) and drain the liquid until the meniscus just reaches the calibration mark.



Micropipettes are typically used to deliver liquid volumes of between 1 and 5000 µL.

A burette is a long tube of glass with a tap at the lower end.

Along the tube there is a graduation (millilitre scale) that makes it possible to continuously read the volume of liquid delivered from the burette.

Burettes are used in titration, where a solution (titrant) is added gradually to a sample (titrate) until a given point (endpoint) where the titration is terminated.

At this point, the operator can read off the consumption of titrant with high accuracy on the burette. Readings on the burette are made the same way as for pipettes. This means that it is the level of the lower meniscus that is used. When reading the titrant level on a burette, the eye of the operator

should be at the same height as the top of the liquid.

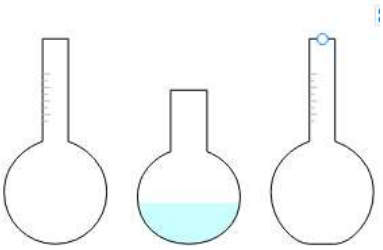
In high throughput laboratories, the manual pipettes are exchanged with software controlled automated systems, or laboratory robots that can dispense volumes automatically. Titrations are also performed by automatic titration systems.

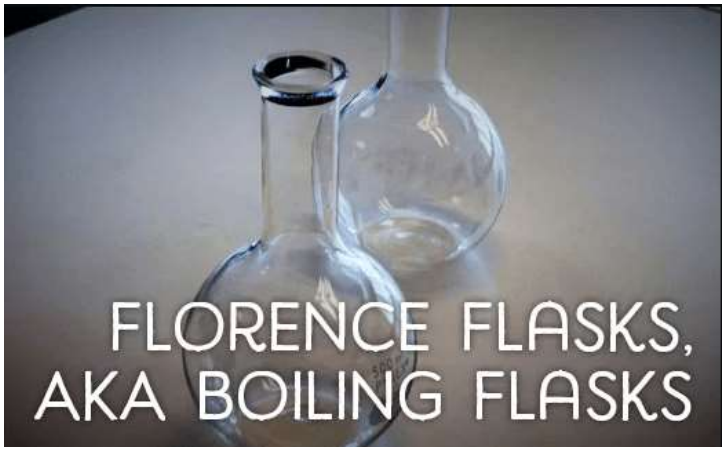
Beakers are cylindrical containers with a flat bottom. They are used to measure the volume of liquids but are not as precise as pipettes and burettes. You can also distinguish it from a flask by looking at the sides; the sides are upright instead of sloped. Here's how it looks like:

Conical flasks (Erlenmeyer flasks) are flasks with a flat bottom, a body in the shape of a cone, and a cylindrical neck. They have wide bases, and the sides are tilted to move towards the center as you go up. Conical flasks are usually used in the mixing of chemicals and titrations. Because of its shape, the risk of spilling is very low, which makes it convenient for mixing. Here's how it looks:

Boiling flasks are round in shape and come with both flat and rounded bottoms. The ones with round bottoms will, of course, need external support to stay upright. The boiling flasks are used to heat chemicals inside. They are made of borosilicate

glass; it is a good heat conductor while strong enough not to melt due to the heat. This is how they look:





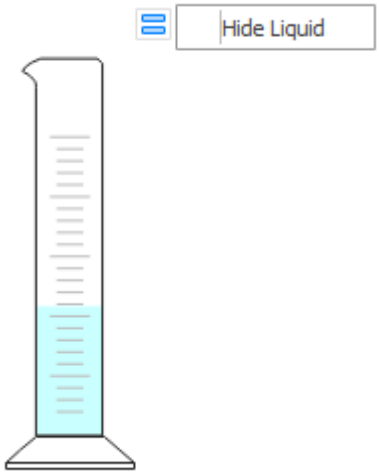
Volumetric flasks are round in shape, have a flat bottom and a long, slim neck. It is one of the most accurate ways to measure the volume of liquids. They also come with a cap on top to make sure no particles escape.

Test tubes are usually made of glass and are almost as long as your finger. They are closed at the bottom and open from the top and are used for general chemical work. You may use it for mixing, dissolving, and also heating to some extent.

Test Tube

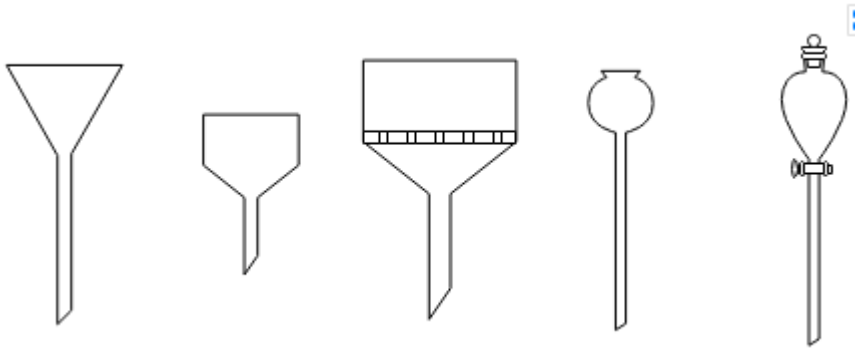
Watch glasses is a circular piece of glass that is concave in shape. It is often used to hold and weigh solids as well as the cover for beakers. You can also use watch glasses to separate dissolved solids from the solvents by applying heat. This is how they look like:

Graduated cylinders are the most common pieces of equipment to measure the volume of liquids. They are more accurate than beakers but hold in a lesser amount because of the smaller diameter. It comes with marking on one side for you to measure the volume accurately – hence, the name "graduated cylinder." There are various types of graduated cylinders in the chemical laboratory, ranging in size from 2 ml to 2 L. These cylinders are made of plastic (polypropylene) which is resistant and can be used sustainably. Here's how to identify one in a laboratory:

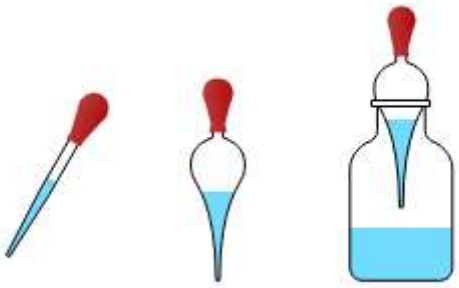


Crucibles are small-sized cups usually made of clay. They are capable of withstanding high amounts of heat, and therefore, they are used to heat substances at higher temperatures. Here’s how a crucible looks:

Funnels are used for the easy pouring of liquids from one container into another. A funnel makes it easy to pour without spilling the liquid on the surface because of a bottle's tight neck. They come in different sizes and are commonly made of plastic or glass. Below is a picture of how it looks like in a laboratory setup:

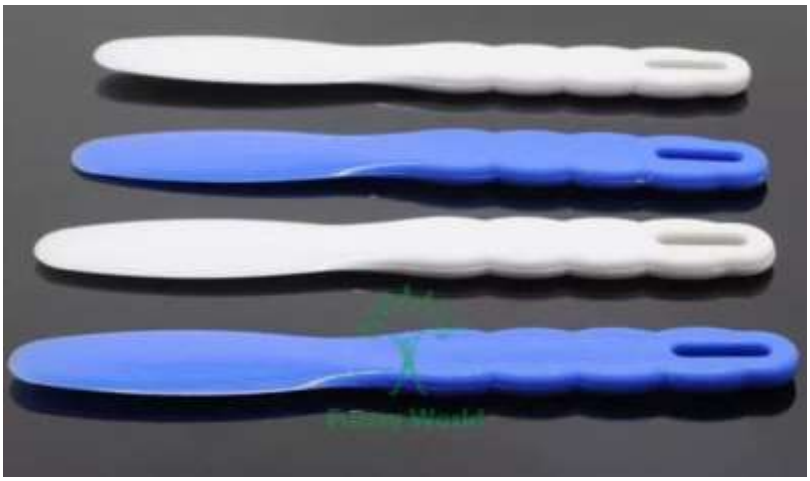


Droppers are little tubes made of glass that can hold liquids in small amounts. They come with a pump on the back that helps you suck in liquid and then squeeze it out as drops.



Mortar and Alue (Pestle) are two ingredients that complement each other to smooth and break solid zazt. The dimple is the container and the pestle is the breaking device. This laboratory tool is used to break down and mix various materials and substances.

Spatulas and scoopulas are used to scoop out chemicals and solids out of containers and onto a crucible for weighing. They are also sometimes used to mix chemicals.



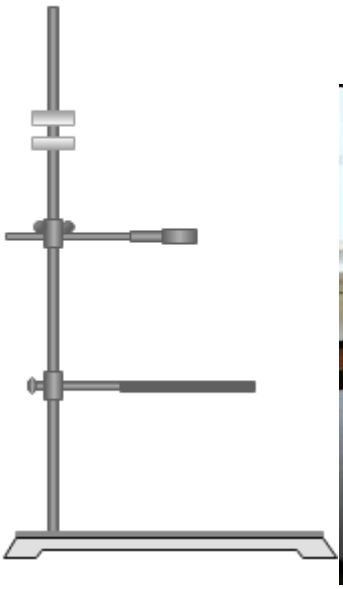
Stirring rod. There is also what is known as a stirring rod, this is used to stir a solution in the reaction tube. It is usually made of solid glass, borosilicate (pyrex) and is almost the same size and shape as a juice stirring spoon.

Not only stirring the solution, but this stir bar is also useful for breaking down emulsions, aiding in solution decantation, and inducing crystallization.

Auxiliary instruments and devices

Tongs and forceps are used to handle, hold and grab containers of different kinds. Tongs can hold wider tubes, while forceps usually work on smaller containers like graduated cylinders and test tubes.

Ring stands, rings, and clamps: Ring stands are used to suspend beakers, flasks, etc., usually above a heat source. Clamps are used to ensure a firm grip on the containers.



The test tube rack is a shelf for storing test tubes which are usually made of wood with 6 holes and six basins so that the test tubes can be very strong and do not collapse.On one side, there are six logs that serve as a drying area for the test tube.