

**NATIONAL UNIVERSITY OF PHARMACY  
DEPARTMENT of PATHOLOGICAL PHYSIOLOGY**

**HYGIENE IN PHARMACY AND ECOLOGY**

**“HYGIENIC ASSESSMENT OF MICROBIAL  
AIR CONTAMINATION OF PHARMACY  
PREMISES”**



**Kharkiv, 2017/18**

# **Plan of lecture**

1. Microbial air pollution of pharmaceutical premises, causes, consequences.
2. Standardization of microbial air pollution of the pharmacy premises and pharmaceutical enterprises.
3. Air decontamination.

# Suggested Reading

## Basic

- Hygiene in Pharmacy. Manual for foreign students of higher schools / O. S. Kalyuzhnaya, O. P. Strilets, L. S. Strelnikov et al. – 2nd Edition, supplemented and revised. – Kharkiv: NUPh, 2013. – 224 p.
- Bardov V. G. Hygiene and Ecology/ Editer by V. G. Bardov. – Vinnytsya : Nova Knyha Publishers, 2009. – 687 p.

## Auxiliary

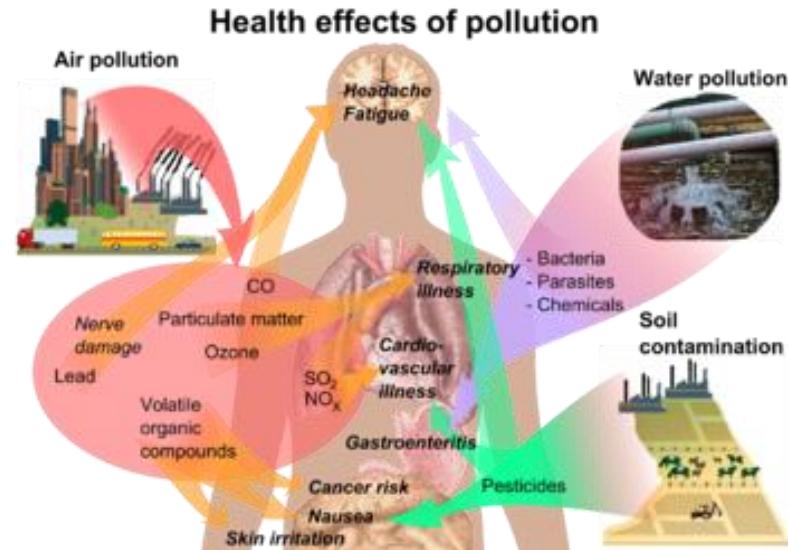
- Kjellstrom Y. Basic environmental health / Y. Kjellstrom, K. Guidotti. – Oxford. – 2001. – 546 p.
- General Hygiene and environmental health / Zaporozhan V. M., Bazhora Yu. I., Vitenco I. S. et al. – Odessa, 2005. – 300 p.

## Information resources, including the Internet

- 1. Library of NPhaU: <http://lib.nuph.edu.ua>
- 2. Specialized medical and biological portals of the Internet.

# BIOLOGICAL AIR POLLUTANTS

Except chemical and physical air pollutants, **biological air pollutants (viruses, bacteria and microscopic fungi)** are responsible for some serious local and general diseases (systemic diseases) of epidemiological scale.



## Infectious agents



Bacterium



Virus



Protozoan

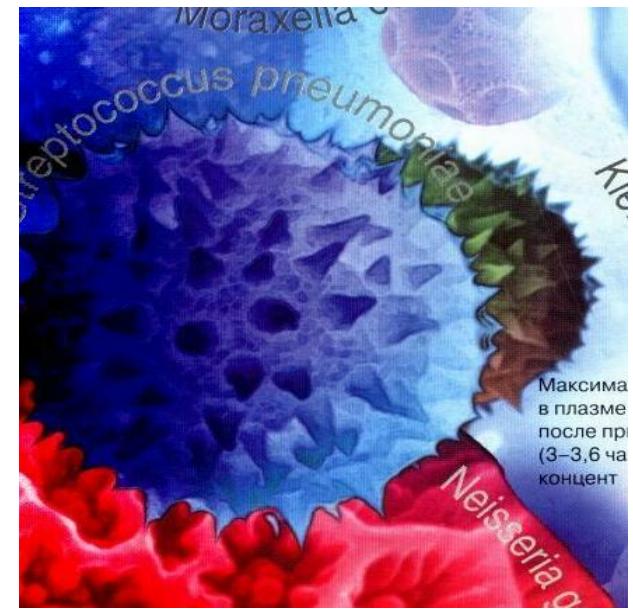
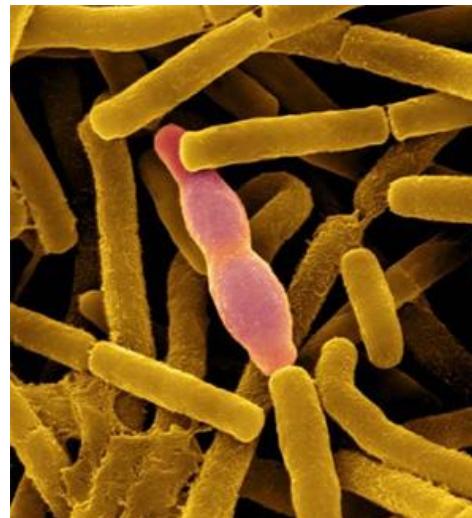
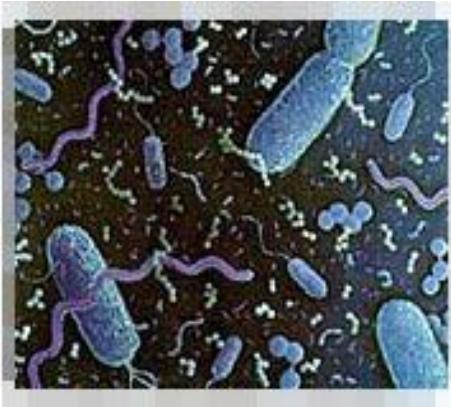


Helminth

Fungus

# MICROBIAL CONTAMINATION

## THE PROCESS OF AIR POLLUTION WITH MICROORGANISMS (MICROBIAL DISSEMINATION).



NOTA BENE!

# Airborne Infections

- Viruses



Measles



Varicella

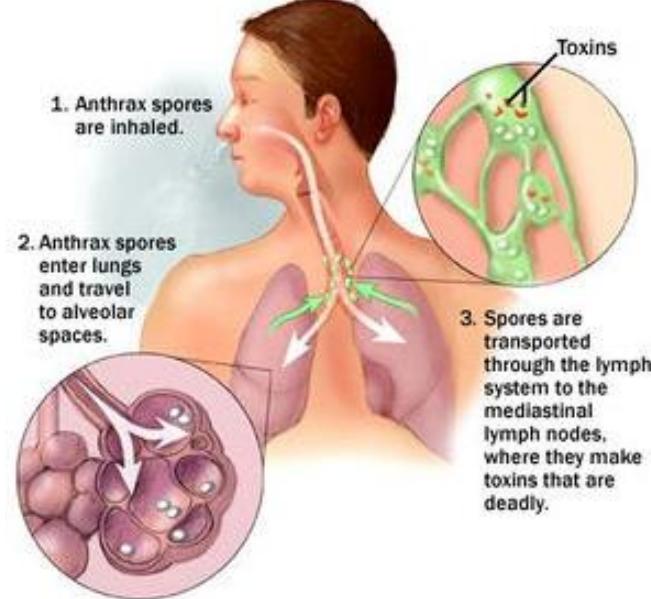
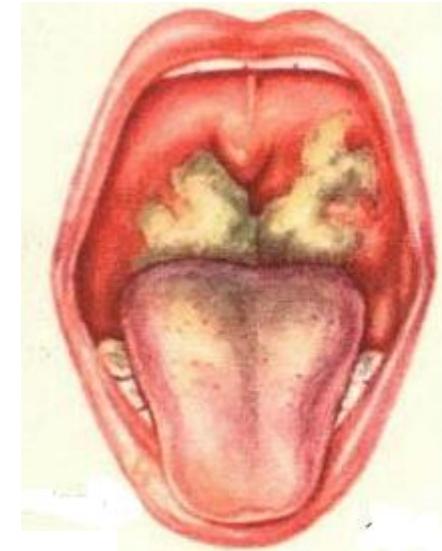
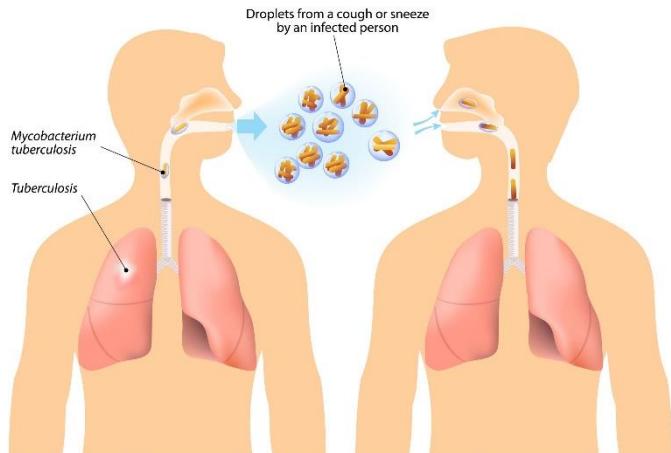


Rubella

# Airborne Infections

- **Bacteria**

## TUBERCULOSIS



# **THE SOURCES OF MICROBIAL CONTAMINATION OF AIR**

- CLOTHES AND HANDS OF THE STAFF;
- PRIMARY PACKAGE MATERIAL;
- AUXILIARY MATERIALS: PAPER, COTTON, WOOL, GLASSWARE;
- SURFACES OF WORKING PREMISES;
- TECHNICAL EQUIPMENT AND ACCESSORIES;
- INITIAL SUBSTANCES;
- PURIFIED WATER



# THE CAUSES OF MICROBIAL CONTAMINATION

- BAD CLEANING OF PREMISES;
- NONFULFILLMENT OF RULE OF PERSONAL HYGIENE BY THE STAFF;
- LOW-QUALITY DISINFECTION OF AIR;
- VIOLATION OF WORK OF VENTILATION SYSTEM
- VIOLATIONS OF HYGEINIC REQUIREMENT TO PLANNING OF INDUSTRIAL PREMISES AND SOME OTHERS



# THE SIGNS OF MICROBIAL CONTAMINATION OF MEDICINES

- ▶ A VISIBLE GROWTH OF MICROORGANISMS;
- ▶ APPEARANCE OF AN ODOUR AND ODOUR CHANGE;
- ▶ APPEARANCE OF TURBIDITY, COLOURATION;
- ▶ SEDIMENTATION;
- ▶ APPEARANCE OF GAS BUBBLES.



# THE EFFECTS OF MICROBIAL CONTAMINATION OF MEDICINES

- **RISK OF INFECTION OF PATIENTS;**
- **BIODEGRADATION OF THE MEDICINES;**
- **PYROGENIC REACTIONS;**
- **APPEARANCE OF INTRAPHARMACY AND HOSPITAL-ACQUIRED (NOSOCOMIAL) INFECTIONS.**



# OBJECTS OF BACTERIOLOGICAL CONTROL IN PHARMACY

**PURIFIED WATER  
(distilled) AND WATER  
FOR INJECTIONS**



**MEDICINES PREPARED  
IN PHARMACY**



**AUXILIARY MATERIALS  
(paper, glassware, gauze)**



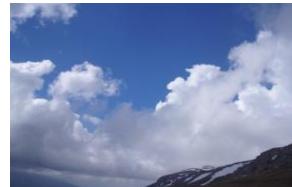
**PRODUCTION  
EQUIPMENT**



**HANDS AND  
SANITARY  
CLOTHES OF  
THE STAFF**



**AIR**



**THE SANITARY-HYGIENIC ASSESSMENT OF AIR PURITY IN PREMISES OF PHARMACY IS BASED ON THE COUNT OF MICROORGANISMS IN 1 M<sup>3</sup> OF AIR.**

**AIR IS SAMPLED IN THE FOLLOWING ROOMS:**

- ASEPTIC, STERILIZING ROOM;**
- ASSISTANTS', PACKING, PRIMARY PROCESSING, MATERIAL ROOMS;**
- WASHING ROOM.**



# CONDITIONS FOR AIR SAMPLING

- A CLEAN ROOM PREPARED FOR WORK;
- CLOSED DOORS AND VENTS;
- THE LEVEL OF THE AIR SAMPLING HEIGHT CORRESPONDS TO THE WORKTABLE HEIGHT;
- NOT EARLIER THAN IN 30 MINUTES AFTER WET CLEANING OF THE PREMISE.



# **ASSESSMENT CRITERIA FOR MICROBIOLOGICAL CONTAMINATION OF AIR IN PREMISES OF PHARMACY**

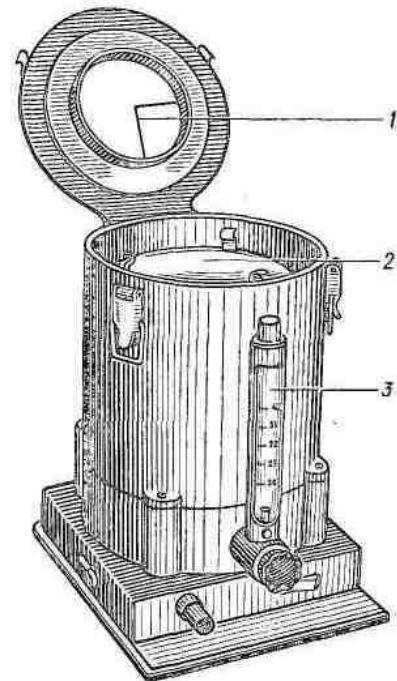
<b>NAME OF ROOM</b>	<b>WORKING CONDITIONS</b>	<b>Total number of colonies of microorganisms in 1 m<sup>3</sup> of air</b>
<b>Aseptic, sterilizing room (clean half)</b>	<b>before work</b>	<b>not more than 500</b>
	<b>after work</b>	<b>not more than 1,000</b>
<b>Assistants', packing, primary processing, material rooms</b>	<b>before work</b>	<b>not more than 750</b>
	<b>after work</b>	<b>not more than 1,000</b>
<b>Washing room</b>	<b>during work</b>	<b>not more than 1,000</b>

# **SANITARY-HYGIENIC ASSESSMENT OF AIR PURITY IN WORKROOMS OF PHARMACY**

## **TECHNIQUES**

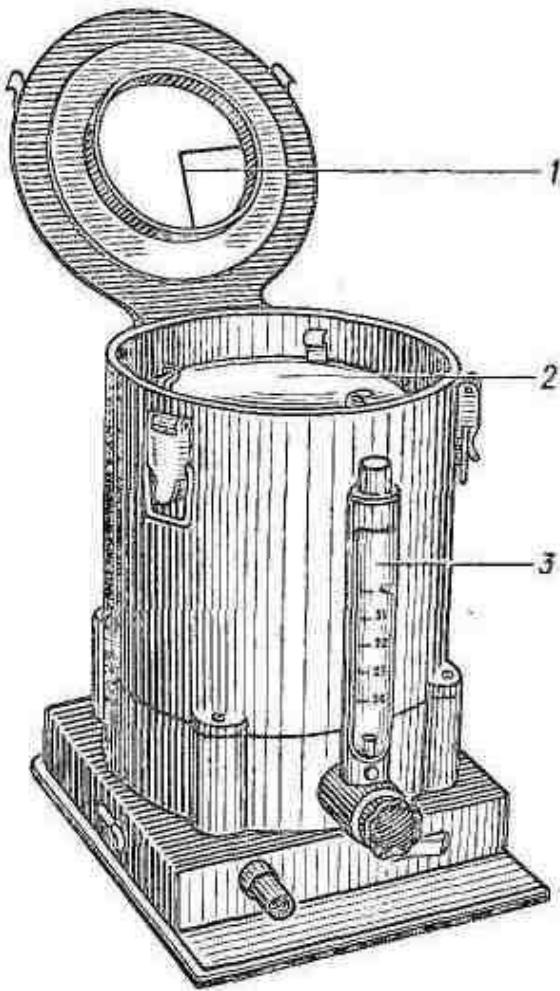
**ASPIRATION**

**SEDIMENTATION**



**KROTOV'S  
DEVICE**

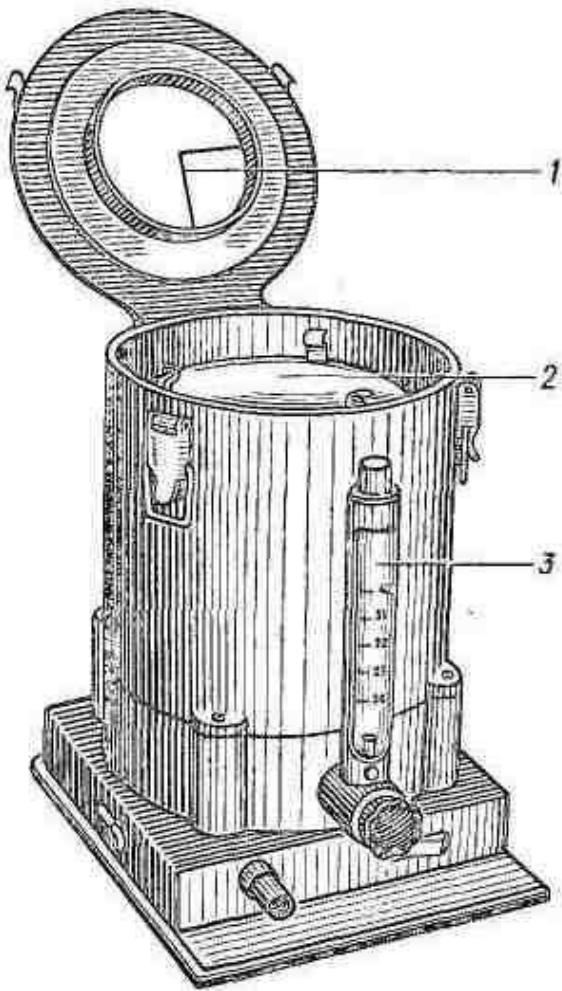




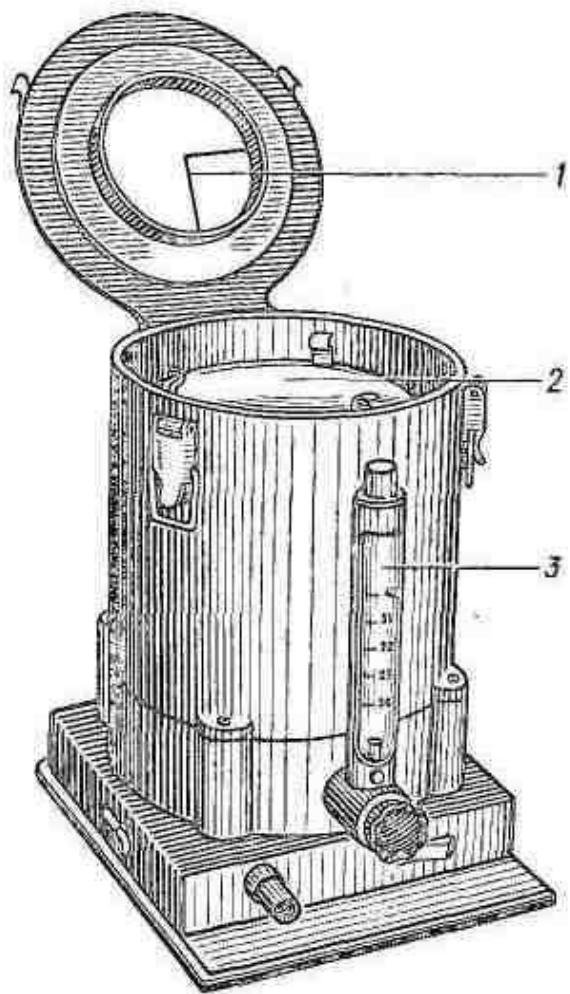
# **KROTOV'S DEVICE**

## **FOR BACTERIOLOGICAL STUDY OF AIR**

- 1 – WEDGE-SHAPED SLOT**
- 2 – ROTATING DISC**
- 3 - RHEOMETER**



**WITH HELP OF THE VENTILATOR THE AIR IS SUCKED THROUGH THE WEDGE-SHAPED SLOT, WHICH IS PLACED ALONG A RADIUS OVER THE PETRI DISH.**



**IT IS NECESSARY TO PLACE THE PETRI DISH WITH A NUTRIENT MEDIUM ONTO THE DEVICE DISC**  
**THE DEVICE IS CONNECTED TO ELECTRIC MAINS WITH HELP OF ITS RHEOMETER.**

**AIR SPEED IS ADJUSTED: 25 l\min.**  
**THE AMOUNT OF THE AIR PASSED FOR COUNTING THE TOTAL NUMBER OF BACTERIA SHOULD BE 100 LITRES.**

**THE DISC ROTATES. AS A RESULT, MICROORGANISMS COVER THE SURFACE OF THE NUTRIENT MEDIUM.**

# NUTRIENT MEDIA

**MEAT-PEPTONE AGAR – FOR DETERMINATION OF THE COUNT OF BACTERIA**

**SABOURAUD AGAR – FOR DETERMINATION OF THE COUNT OF FUNGI**



# CONDITIONS FOR INCUBATION

Temperatures during incubation in the thermostat are kept at the level of:

- – for bacteria –  $(32.5 \pm 2.5)^\circ\text{C}$   
**(2 days);**
- – for fungi –  $(22.5 \pm 2.5)^\circ\text{C}$   
**(5 days).**



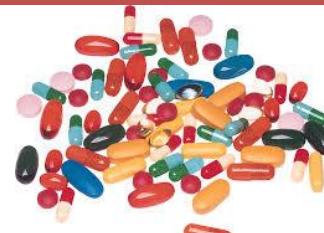
# MICROBIAL AIR CONTROL IN PHARMACEUTICAL ENTERPRISES

Nowadays it is recommended to follow the **GMP** rules – **good manufacturing practice** in order to provide microbiological purity of sterile and to minimize the risk of contamination of non-sterile medicines.

## STERILE MEDICINES



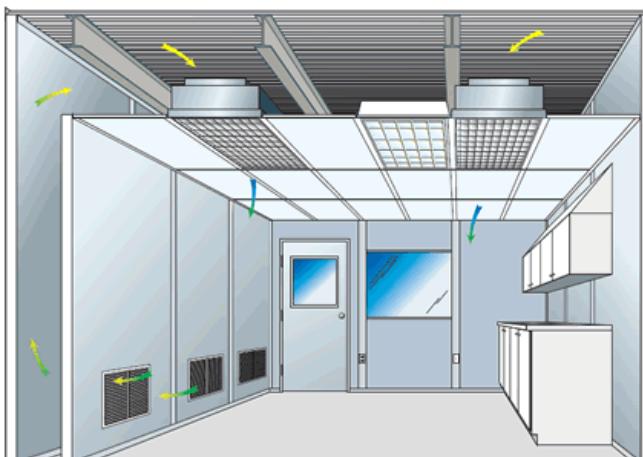
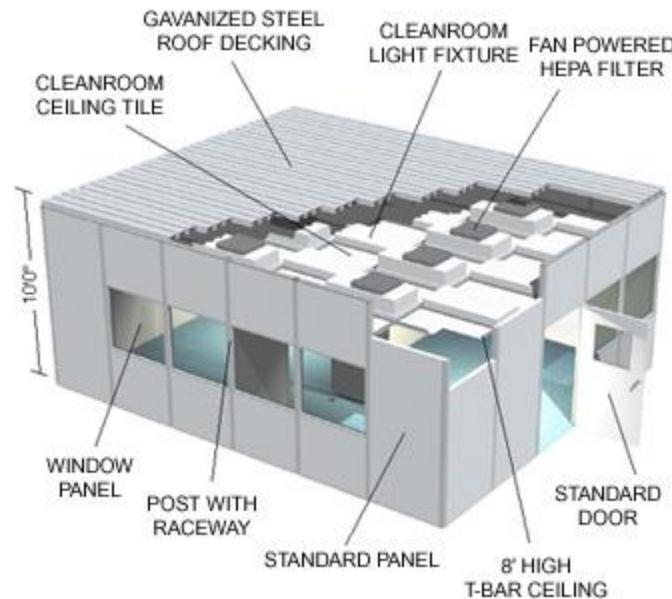
## NON-STERILE MEDICINES



# GMP RULES

Medicines must be manufactured in some «clean» zones or premises.

A **«clean» premise** is an artificially built environment with controlled levels of particles and viable microorganisms in 1 m<sup>3</sup> of the air. The level of the room cleanliness is determined by the level of the content of the particles and viable microorganisms in 1 m<sup>3</sup> of the air.



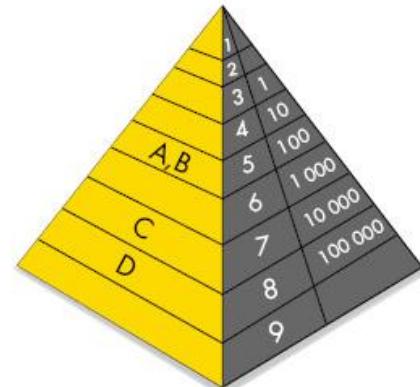
# CLEAN ROOMS

«*Clean*» premises are classified into the levels of cleanliness – **A**, **B**, **C**, and **D**.

**Class A** is the local zones for technological operations requiring the minimal risk of contamination, e.g. zones of filling, packing, opening of ampoules and vials, mixing of solutions under aseptic conditions.

**Class B** is the environment for a zone of the class A in cases of preparing and filling under aseptic conditions.

**Classes C** and **D** are «clean» zones for performing some technological operations, which allow a risk of contamination rather than while producing sterile products. Manufacture of non-sterile medicines is recommended to perform in premises of classes C and D.



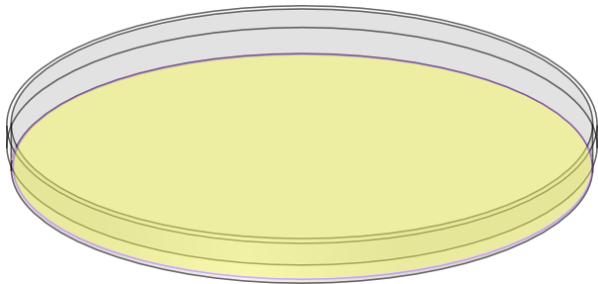
# CLEAN ROOMS

The maximum allowable level of the content of viable microorganisms in the air of working premises is the following:

- ❖ *for the premises of class A – less than 1 colony-forming units for 1 m<sup>3</sup> (CFU/m<sup>3</sup>);*
- ❖ *for the premises of class B – 10 CFU/m<sup>3</sup>;*
- ❖ *for the premises of class C – 100 CFU/m<sup>3</sup>;*
- ❖ *for the premises of class D – 200 CFU/m<sup>3</sup>.*

# SEDIMENTATION METHOD

Two Petri dishes (1 – for growing bacteria, 2 – for growing fungi) with a medium (with an open lid) is set on the definite places in the room for 4 hours. Then we close Petri dishes and put them to the thermostat for incubation of microorganisms.



A Petri dish filled with agar

**THE METHOD OF SEDIMENTATION IS USED FOR AN APPROXIMATE ASSESSMENT OF MICROBIAL CONTAMINATION OF AIR IN PREMISES**



**IN THOSE CASES, WHEN AN EXAMINATION WITH THE ASPIRATION METHOD IS IMPOSSIBLE (IN PRODUCTION OF INFLAMMABLE OR EXPLOSIVE SUBSTANCES)**

# CALCULATION OF RESULTS

We calculate the number of colonies grown in a Petri dishes after incubation.

**Total amount of colonies of microorganisms** (bacteria and fungi) from two Petri dishes for rooms of **class A and class B** - must be absent.

**Total amount of colonies of microorganisms** (bacteria and fungi) from two Petri dishes for rooms of **class C** – not more than 50.

**Total amount of colonies of microorganisms** (bacteria and fungi) from two Petri dishes for rooms of **class D** – not more than 100.

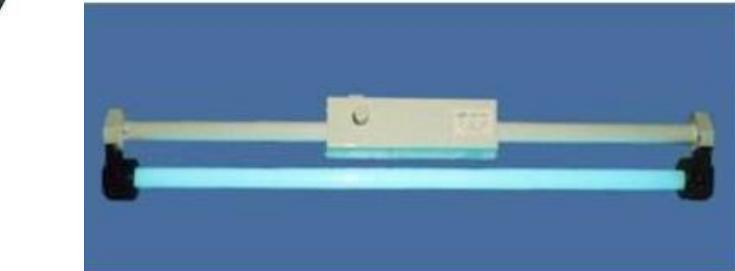
# AIR DECONTAMINATION

Bactericidal radiators are used for sanitation (disinfection) of the air in premises of the pharmacy. They include germicidal lamps of different types, the so-called uviol lamps (BUV-25, BUV-30, BUV-60, etc.), both screened and non-screened.

**THE DIRECT ANTIMICROBIAL FACTOR OF GERMICIDAL TUBES:  
ULTRAVIOLET RAYS WITH A WAVELENGTH OF 254-257 nm**



**SCREENED BACTERICIDAL RADIATORS**



**NONSCREENED BACTERICIDAL  
RADIATORS**

# Rules for the installation of non-screened bactericidal lamps

1. The average specific power should be at the level of 2 to 2.5 W per 1 m<sup>3</sup> of the air.
2. They are switched on 30-40 minutes prior the beginning of the work shift in the absence of the personnel (ultraviolet rays can cause lesions of the mucous membrane of the eyes - conjunctivitis).
3. Need the ventilation of room after the work of lamps during 15 minutes



# Rules for the installation of screened bactericidal lamps

1. The average specific power should be at the level of 1 W per 1 m<sup>3</sup> of the air.
2. They are operated in the presence of the personnel.



**THANK YOU FOR ATTENTION!**