ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4

Journal of Coastal Life Medicine

Features of the Technological Process in the Production of Injectable Drugs at Pharmaceutical Enterprises and Hygienic Assessment of Microclimate at Workplaces

Received: 22 October 2022, **Revised:** 18 November 2022, **Accepted:** 28 December 2022

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Keywords:
pharmaceutical enterprise, injection preparations production workshop, technological process, production environment, harmful factor, microclimate, wellness measures.

Abstract

The microclimate in the studied Enterprises is characterized by discomfort. One of its parameters is the relative humidity of the air above the permissible norm in some main permanent work places (sections for cutting and preparing ampoules, preparing sterile solutions and filling ampoules) during the cold period of the year. This is due to the irrational heating system organization, which can lead to working conditions that do not meet hygienic requirements for employees.

1. Relevance of the Topic.

In the Republic of Uzbekistan, at the beginning of the XXI century, the hygiene industry went down in history with the search for new effective ways to preserve health and disease prevention, as well as the widespread promotion of living and working in an environmentally friendly, harmless environment.

One of the most important importance of the production process is the organization of safe working conditions and the rationalization of the labor process [1, 2]. In Uzbekistan, great attention is paid to the preparation of medicines from local herbal raw materials, but, among other things, the working conditions of workers at pharmaceutical enterprises and the modern pharmaceutical industry have not been sufficiently studied [4, 8, 10, 11]. When preparing medicinal preparations, organic and inorganic chemicals are released into the atmospheric air, which are considered dangerous to the environment and human health. Therefore, the assessment of working conditions and the development of health-improving measures in the

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
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study of preventive security problems at pharmaceutical enterprises acquires special relevance [3, 5, 12].

The purpose of the study is a hygienic assessment of the microclimate in the main workplaces as a study result of the technological process in the production of injectable drugs at pharmaceutical enterprises.

Objectives of the study:

1. To study the organization of the technological process in the pharmaceutical enterprises worshops for the production of injectable drugs and to identify groups of workers in the main profession;

2. Hygienic assessment of the microclimate in the production of injectable drugs.

As the object of the study were employees of J.S.K. "UZKIMYOFARM" named after S.K.Islambekov situated in T. Shevchenko Street, Mirabad District, Tashkent City, and LLC "INTEGRA DD" pharmaceutical enterprise located in the Yerteshar Street, Kimyogar district, Samarkand city who works as the main profession in the production of injectable drugs. As the subject of the study have been selected employees of the pharmaceutical enterprise in the production of injectable drugs and physiological indicators of their functional states.

2. Materials and Methods.

The main description of technological processes in the study of working conditions at pharmaceutical enterprises, taking into account the state of sanitary technical devices, it was found that the chemical factor in the production environment, pollination and gasification of the air of the working areas, the reasons and sources of dressing noise in production, insufficient lighting in the workplaces, the presence in the process of labor during the working day, it was determined that the presence in the state of a forced worker and the monotony of work are factors of production that have a special morality [6, 7, 9]. As a result of the technological process in production, the factors that are formed during the operation of tools and equipment have a different complex description. In order to assess the harmful and dangerous factors in a highly productive environment, we used the sanitary and hygienic method in our research. In the study of factors in the production environment at pharmaceutical enterprises, methods of continuous examination were used, which, in turn, make it possible to assess the level of factors in warm and cold periods of the year and hygienic description of the dynamics of the working day, as well as to determine the maximum and minimum levels of influence of factors.

Studies were conducted in 2020-2022. The presence of pollinated and aerated air of the working fan at the enterprise, microclimate indicators, noise and illumination, harmful factors in production, which include the amount of checks for the study of working conditions. The current methods were used to study the microclimate conditions in production during the working day. Air temperature, relative humidity and operating speed were measured with a meteoscope-m instrument (RF), the results obtained were compared with the norms of Sanitary norms and rules of Uzbekistan No. 0324-16 "Sanitary and hygienic standards of the microclimate in production premises". Meteomil indicators were measured at a distance of 1.25-1.5 m from the floor level in the permanent places of work of workers of various professions.

Inspections were carried out in cold and warm periods of the year for 2-3 weeks. The microclimate of the studied Enterprises was determined paralelically in order to compare it with the state of the air of the external environment.

To assess the microclimate indicators of the working conditions of workers at the enterprises under study, it was carried out according to the warm and cold periods of a separate year, according to the category of work, Sanitary Norms and Rules No. 0141-03 (Tables 1, 2).

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ISSN: 2309-6152 (Online)
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Table 1 Classes of working conditions according to microclimate indicators for closed rooms in production during the warm period of the year

Microclimate indicators	Work conditions class						
	Optimal 1-class	Permitted 2-class	Harmful – 3 class				Class 3-level-4-harmful, (extremal)
			Class 3-level-1	Class 3-level-2	Class 3-level-3-harmful and (hard)	Class 3-level-4-very harmful and (very hard, dangerous)	
Air temperature according to the work category, °C	indicators of high limits						
Ia	27	31	34	36	38	40	
Ib	26	31	34	36	38	40	
IIa	25	30	33	35	37	39	
IIb	24	29	32	34	36	38	
III	23	27	30	32	34	36	
exceeding the permissible norm, times:							
Air flow rate, m / s	According to Sanitary norms and rules	According to Sanitary norms and rules	2 гача	2.5	3	>3	
exceeding the permissible norm, the number of:							
Relative air humidity, %	According to Sanitary norms and rules	According to Sanitary norms and rules	10	15	20	25	

When determining the class of working conditions according to individual indicators of the microclimate, their highest indicators in terms of harmfulness and danger are taken into account.

Table 2 Class of working conditions according to microclimate indicators for closed rooms in production during the cold period of the year

Work category	Work conditions class			
	Optimal 1-class		Harmful – 3 class	

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
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		Permitted 2-class	Class 3-level-1	Class 3-level-2	Class 3-level-3-harmful and (hard)	Class 3-level-4-very harmful and (very hard, dangerous)	Class 3-level-4-harmful, (extremal)
Air temperature according to the working category, °C	indicators of lower limits						
Ia	According to Sanitary norms and rules	According to Sanitary norms and rules	18	16	14	12	
Ib	-"-	-"-	17	15	13	11	
IIa	-"-	-"-	14	12	10	8	
IIb	-"-	-"-	13	11	9	7	
III	-"-	-"-	12	10	8	6	
exceeding the permissible norm, times:							
Air flow rate, m / s	According to Sanitary norms and rules	According to Sanitary norms and rules	2 гача	2.5	3	>3	
exceeding the permissible norm, the number of:							
Relative air humidity, %	According to Sanitary norms and rules	According to Sanitary norms and rules	10	15	20	25	

3. Discussion

The enterprises under study are among the sectors that are developing in our republic. One of the leading manifestations of such production industries is considered to be the enterprises of JSC "UZKIMYOFARM" in Tashkent city and LLC "INTEGRA DD" in Samarkand city, where various injectable drugs are produced. In the production of injectable drugs of the above enterprises, kupir, eufillin, lidocaine, novocaine, riboxin, platifillin, nicotinic acid, dibazole and other drugs are produced for injection.

In the production of injectable preparations of the enterprise JSC "UZKIMYOFARM", an old type of technological process is used and carried out in five stages:

- automatically cut sterile ampoule capillaries and place the collection of ampoules in the cassette;

- opened ampoules are sequentially washed with hot water, the outer and inner parts are sucked out of the ampoules, after which the opened ampoules are placed in a drying cabinet, where the ampoules are completely dried under the influence of high

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
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temperature (180°C), and then they are sent to filling machines;

- in the filling machines, the ampoules are filled automatically by the syringe method, the remnants of the drug solution are sucked out of the capillaries, and then the ampoules are sealed in the sealing machine;

- for sterilization, ampoules are placed in an autoclave, ampoules from an autoclave are washed with hot desalinated water and checked for hermeticity;

- after that, it is sent to the viewing tables, where the ampoules are visually checked on mechanical attachments. The ampoules are then packaged and labeled.

At the Enterprise LLC "INTEGRA DD", modern conveyor lines are used, the technological process is carried out in three stages:

- conveyor line (filling ampoules);
- ampoules are sterilized in an autoclave;
- on the viewing tables, the mechanical inserts are visually checked and packaged and then marked.

The preparation of Drug Solutions is carried out in a separate room: the powder drug mass is mixed in the reactor with a certain amount of apirogen water, the solution is passed through a filter and sent to the filling machines through a tubular path. In addition to water, glycerin and 0.1 n-HCI are added to prepare certain drugs in the reactor.

When performing a number of operations (collecting and unloading ampoules, bringing them into an autoclave), the absence of a mechanization system, insufficient anti - dust measures that are released into the working area (soldering ampoules, malfunctions in the supply and removal ventilation system), the use of old noise-generating equipment (pumps) increase the likelihood of exposure to these factors.

The production of injectable preparations is made up of several departments and rooms, and the following main work areas are established:

- administration-controller of medical products, head of workshop, technologist of workshop, master;

- solution preparation department-apparatus worker for preparing sterile solutions;

- department of ampoule cutting and preparation - chemical laboratory technician, gas construction repair and commissioning plumber, pipe and ampoule cutter;
- ampoule washing department - ampoule and dishwasher;
- section for filling sterile solutions into ampoules - ampoule filler;
- soldering and sterilization department - ampoule soldering, materials and preparations sterilizer;
- department of control and marking of finished ampoules - ampoule controller with injection solution, packer;
- auxiliary workers' room - the janitor of production rooms, locksmith-repairman, auxiliary worker.

Taking into account the high demand for the sterility of injectable drugs in the ampoules produced, appropriate requirements are imposed on employees, the working area and the technological process. In particular, unauthorized persons are strictly prohibited from entering the workplace, and employees are restricted from leaving the workplace for no reason.

Employees are strongly required to follow the rules of personal hygiene. It is mandatory to wash hands and process with disinfectant solutions every 2-3 hours. In accordance with the technological regulations, the workers themselves are obliged to carry out cleaning work at workplaces, treat equipment with detergents and a 3% hydrogen peroxide solution.

The production of injectable preparations of pharmaceutical enterprises named after JSC "INTEGRA DD" and LLC "UZKIMYOFARM" was determined taking into account the Metereological conditions, the specifics of the technological process, the climatic region, the periods of the year, the location of the building. Studies of the production of injectable drugs for the hygienic assessment of the microclimate in the main

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
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working areas were carried out taking into account the periods of the Year (warm and cold).

Since the work performed by the workers of the enterprises under study is associated with walking, moving small items (weighing up to 1 kg) or objects from one place to another, performing work in a sitting or standing position, as well as requiring certain physical exertion, category II a belongs to the type of work. It turned out that in the cold period of the year, the microclimate conditions in worshop are provided through the central heating system.

One of the indicators of the microclimate of closed rooms of production, which has the main effect, is the temperature of the air. "Sanitary and hygienic standards of the microclimate in production premises" at pharmaceutical enterprises in SanN and R No. 0324-16, the optimal (permissible) air temperature, providing a high level of working capacity in workers, should be equal to +23-25^{0}C (+22-30^{0}C) in the warm period of the year, and +18-20^{0}C (+17-23^0 C) in the cold period of the year. The relative humidity of the air, which is one of the next indicators of the microclimate, should not exceed the optimal (permissible) 40-60% in the warm period of the year (40% is set at 30^0 C), and in the cold period of the year - 40% (75%). Another indicator of the microclimate is the air flow rate, which should be calculated in the warm period of the year - 0.3 m/s (0.3-0.7 m/s), and in the cold period of the year - 0.2 m/s (no more than 0.3 m/s).

Microclimate indicators in the production of injectable drugs in warm and cold periods of the year are described in tables 3-4, with the data presented. The data obtained showed that in the warm period of the year (summer months), the highest average air temperature indicator in the main permanent places of work of the enterprise "UZKIMYOFARM" was recorded in the soldering and sterilization department at 35.6±0.85^0 C, but at the same time, it was also observed that the air temperature in all departments of injection preparations production units of these enterprises exceeded the norm given in SanN and R No. 0324-16.

It turned out that the relative humidity of the air is below the norm by the average of ruminations and sterilizations (37.3±1.14%), control and marking of finished ampoules (35.2±0.23%) and packaging sections (36.4±0.45%). And the average indicator of air flow rate was found in the solution preparation department (0.17±0.01 m/s) to be the lowest of the norm (Table 3). From the indicators obtained at the enterprise" INTEGRA DD", it turned out that the air temperature was 33.8±0.56^0 C in the soldering and sterilization department, 31.5±1.5^0 C in the solution preparation Department, 31.6±0.02^0 C in the packaging department, and 31.8±0.32^0 C in the ampoule cutting and preparation department, these indicators became higher than usual norm. In the rest of the departments, it was observed that the air temperature did not exceed the sanitary and hygienic standards of the microclimate in the "Production premises" San N and R No. 0324-16. Relative air humidity was proved to be below the norm, being in the control and marking department of ampoules (36.1±0.32%), in the soldering and sterilization department (36.8±1.04%), and in the packaging department (38.3±0.51%). In the rest departments of this enterprise it was determined that the relative humidity is in moderation. It turned out that the speed of air movement is at the level of the norm in all sections (Table 3). The same indicators of the microclimate as described above were studied even in the cold period of the year.

Table 3 Microclimate indicators in the warm period of the year (July) in the production of injectable drugs, m±m

№	Sample taken place (section)	"UZKIMYOFARM"		"INTEGRA DD"		Norm	
		Air temperature, ^{0}C	Air humidity, %	Air temperature, ^{0}C	Air humidity, %	Air temperature, ^{0}C	Air humidity, %
1.	Preparation of solutions	32,4±0,6	43,7±1,01	31,5±1,5	44,5±0,28	22-30	40-60

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
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2.	Cutting and preparation of ampoules	32,7±0,53	44,9±0,80	31,8±0,32	45,3±0,67	22-30	
3.	Ampoule washing	34,5±0,52	56,8±1,34	30,5±0,26	55,6±1,42	23-31	
4.	Preparation of sterile solutions and filling into ampoules	32,5±0,20	48,3±0,66	29,5±0,20	50,4±0,28	22-30	
5.	Soldering and sterilization	34,6±0,85	37,3±1,14	33,8±0,56	36,8±1,04	23-31	
6.	Control and marking of ampoules	34,6±0,5	35,2±0,23	30,6±0,25	36,1±0,32	23-31	
7.	Packaging	34,7±0,22	36,4±0,45	31,6±0,02	38,3±0,51	22-30	

Table 4 Microclimate indicators in the cold period of the year (January) in the production of injectable drugs, m±m

№	Sample taken place (section)	"UZKIMYOFARM"		"INTEGRA DD"		Norm	
		Air temperature, ^{0}C	Air humidity, %	Air temperature, ^{0}C	Air humidity, %	Air temperature, ^{0}C	Air humidity, %
1.	Preparation of solutions	19,6±0,44	59,7±0,63	20,7±0,57	58,5±0,32	15-21	up to 75
2.	Cutting and preparation of ampoules	16,3±0,93	79,6±0,54	18,0±0,15	78,2±0,46	15-21	
3.	Ampoule washing	17,1±0,28	65,7±1,05	18,6±0,81	63,8±0,05	17-23	
4.	Preparation of sterile solutions and filling into ampoules	16,6±0,30	80±1,44	17,5±0,02	78,6±0,43	15-21	
5.	Soldering and sterilization	18,4±0,39	65,4±1,40	19,5±0,23	64,2±0,14	17-23	
6.	Control and marking of ampoules	16,6±0,38	62,8±0,75	17,5±0,43	60,1±0,52	17-23	
7.	Packaging	17,5±0,26	74,0±0,21	18,6±0,37	72,8±0,16	15-21	

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
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From the studies carried out, it turned out that at the enterprise "UZKIMYOFARM" in the cold period of the year (winter months), the lowest average air temperature in the main permanent places of work was determined in the section for cutting and preparing ampoules by 16.3±0.93^0 C. in the rest of the sections, it turned out that the average air temperature.

The relative air humidity was also manifested in the department for cutting and preparing ampoules (79.6±0.54%) and in the department for the preparation and filling of sterile solutions into ampoules (80.0±1.44%), the average indicator of which is the highest of the norm. And the average air flow rate indicator proved to be the lowest of the norm in the sections for cutting and preparing ampoules (0.16±0.01 m/s), preparation of sterile solutions and filling into ampoules (0.13±0.02 m/s) (Table 4)From the indicators obtained during the cold period of the year at the enterprise "INTEGRA DD", it was found that the air temperature and air flow rate did not exceed the norms listed in San N and R No. 0324-16 in all departments.

It was observed that the relative air humidity is higher than the norm in the department for cutting and preparing ampoules (78.2±0.46%), and in the department for the preparation of sterile solutions and filling into ampoules (78.6±0.43%). In the rest of the sections, it was manifested that this indicator of the microclimate is at the level of the norm (Table 4).

According to the result of the analysis of the studies carried out, it was found that the air temperature averages in the production environment of injection preparations of pharmaceutical enterprises "UZKIMYOFARM" JSC and LLC "INTEGRA DD" are higher than the permissible norm only in a warm period of the year.

As a result of the study of the microclimate in the production facilities of injection drugs of pharmaceutical enterprises, "Hygienic classification of indicators of the severity and tension of the labor process in the production environment, harmfulness and danger of working conditions "SanN and R No. 0141-03 made it possible to determine the general class of working conditions in the main permanent places of work (Table 5).

Table 5 Class of working conditions for the microclimate of workers in the production of injectable drugs at pharmaceutical enterprises

№	Professional group employees	“UZKIMYOFARM”	“INTEGRA DD”
1.	Apparatus for preparing sterile solutions	3.1	3.1
2.	Cutting and chemical water claening apparatus worker	3.1	-
3.	Ampoule and dishwasher	3.2	3.1
4.	Ampoule filler	3.1	-
5.	Soldering, sterilizer	3.3	3.2
6.	Controller, Packer	3.2	3.1

Thus, the generation of heat and the transfer of heat in the human body is not only related to the temperature of the environment, but also to the humidity of the air. As a result of the addition of the temperature factor with air humidity, it is possible to determine the dynamics of the above processes. It

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
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should be taken into account that in many production enterprises, air humidity is a necessary factor in production technology, in addition to being a factor affecting the physiological state of the organism of workers. Changes in relative humidity can affect the technological process, leading to a change in product quality and the formation of a poor-quality product. During the study of microclimate indicators, the rate of movement of air in the production environment was also studied. Insufficient air flow rate can cause the air of the work areas to have a high degree of pollination and gasification. In the analysis of the results of the examinations carried out, it was found that the indicators of the rate of movement of air in the sections of the production of injection drugs do not correspond to the optimal quantities, taking into account hygienic requirements. Based on the results of inspections of the enterprises on the study of the microclimate in the main workplaces of workers, it can be concluded as follows. The microclimate in the studied enterprises is characterized by discomfort. One of its parameters is the relative humidity of the air above the permissible norm in some main permanent places of work (sections for cutting and preparing ampoules, preparing sterile solutions and filling ampoules) during the cold period of the year.

This is due to the informal organization of the heating system, which can lead to working conditions that do not meet hygienic requirements for workers.

4. Conclusions

Thus, the main reasons for the formation of unfavorable working conditions are the use of old equipment, their imperfection, insufficient labor mechanization, incorrect selection and low efficiency of the ventilation system, the fact that the workers are not fully provided with personal protective equipment and the lack of constant control over their use. In improving working conditions of pharmaceutical enterprises, the main attention should be paid to the perfection of technology and devices, mechanization of the performance of auxiliary operations, execution of a monotonous type of labor on automated conveyor lines and rationalization of working positions. Ensuring uninterrupted operation and control of the efficiency of the existing ventilation system in production rooms at pharmaceutical enterprises, preventive inspection 1 time in 1 year and, if necessary, technical repairs are necessary.

To reduce the negative impact of the heating microclimate, it is necessary to install saturators in order to provide drinking water and create conditions for condensing in special recreation rooms.

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ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
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