

ERGONOMICS - NOISE AND ILLUMINATION IN THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

Applied ergonomics in the pharmaceutical industry, involves the design and adaptation of work spaces from the production area, equipment and tasks for operator safety, noise level and lighting, being the factors that create real discomfort. The noise is present in all machines in this industry, the noise level being the one that requires additional protection measures for some machines. In the following, the analysis of the data collected from the occupational medicine and the measurements carried out, it was found that the wearing hearing protection equipment and optimization of lighting are mandatory at the level of departments production, especially hearing protection is mandatory at the level of tablet presses, because the noise level is the highest with these machines.

Keywords: work hygiene, ergonomics, illumination, factory

Introduction:

Technical progress has led to the need of design jobs in all fields. This materialized through the automation of processes led to a change in the ratio between physical work and intellectual in the sense that the executor becomes more of an operator and leader of the process. Increasingly the demand for comfort and working conditions, the need for spaces, appeared more bright and air-conditioned and the design of workplaces should be done in such a way as to facilitate work.

All these things led to the development of a new science, called ergonomics. Etymologically, the word ergonomics comes from the Greek

words "ergos" = work and "nomos" = law. This term was used for the first time in 1857 by the Polish biologist Wojciech Zostryebowski in the book "General lines of ergonomics and science work", but in the common specialized language it will be released much later, far in 1949 by the English psychologist K.F.H. Marrell, at a meeting with specialists from several fields. So, ergonomics is considered the "science of work", having as its object of study the "man-work" relationship, synthesizing, correlating the data of all the sciences of the disciplines concerned with this field, formulating principles, own rules especially with an applicative nature, which ensures the mutual adaptation between the man

and his work.

Ergonomics cannot be regarded as a science on its own, it is practically an interdisciplinary science that uses knowledge from several branches in an integrated way, namely: from physics, biology, technological engineering, mechanical engineering, occupational safety and sociology, medicine, etc., all aiming at the long-term maintenance at an optimal level of work capacity, promoting human health. As Maurice de Montmollin mentions in a publication (1) it exists today in the world, two great complementary currents that characterize ergonomics, the first considering ergonomics as being the use of science to improve working conditions and the second considers ergonomics as being the specific study of work in order to improve it. International Ergonomics Association (IEA) defined ergonomics as "the scientific discipline aimed at the fundamental understanding of interactions." between people, the other components of a system and the profession that applies theoretical principles, data and methods to optimize the well-being of people and the overall performance of systems."

By applying these ergonomic principles, the pharmaceutical industry can improve the conditions of work, can reduce the risk of injury and promote employee efficiency and health. Ergonomics is the science that studies the relationship between the human being and his work environment, with the objective of optimizing safety, comfort and efficiency in work activities. The application of ergonomics in the pharmaceutical industry is essential to promote a safe, healthy and productive work environment (2). In addition to this, it contributes to the well-being and satisfaction of employees (3), leading at the same time to work efficiency.

An effective method that is already applied in many companies and factories in the world, is the method Japanese 5S, which consists of creating an orderly, clean, safe and efficient (4) work space in five steps. Those five steps are:

1. Sieri-Sort-Sorting, which involves keeping the necessary things around the fighting equipment and eliminating unnecessary things;
2. Seiton-Set in Order-Arrangement, organization of things needed during the

production process, for easy work;

3. Seiso-Shine-Cleaning, that is, keeping the workplace clean;

4. Seiketsu-Standardizing-Standardization, which involves maintaining discipline through compliance the work standards imposed;

5. Shitsuke-Sustain-Support, implies that SS must become a habit in any workplace.

As mentioned in one of the reference publications in the domain (5) of the system man-machine-environment two groups of physiological problems have to be considered biomechanical conditions of work execution and the repercussions of physical and intellectual work on body functions. This thing shows us that (6) within ergonomics, the study of isolated factors gives way to the complex approach of human activity in the work process, which involves interdisciplinary research. As he mentions the renowned specialist in the field of ergonomics E. Gradjean, "Man during his work constitutes a whole: he cannot be defined or understood if viewed only from the point of view of a single discipline" (7).

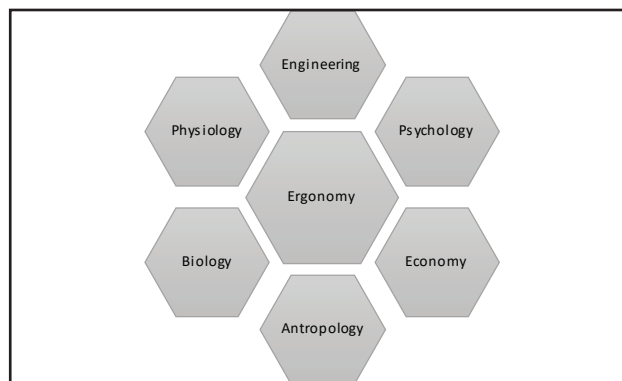


Figure 1 Fields used in ergonomics

Ergonomic norms in the pharmaceutical industry are important to ensure a safe work environment and comfortable for the employee and to reduce the risk of accidents and related actions of the workplace. Here there are only some of the norms of ergonomics used in pharmaceutical industry:

1. The ergonomic design of equipment and the furniture: the equipment and furniture used in the pharmaceutical industry must be designed to match the employee sizes and needs. This includes, for example, adjustable chairs and tables so employees can work in comfortable

positions and avoid fatigue and pain. The height, position of the seats and the work table: these must be adjusted so that employees can work in a comfortable position and healthy, without bending or stretching too much. The height of the chairs and the table must be adjusted individually for each employee.

2. Proper Material Handling: Material handling in the pharmaceutical industry can be difficult and can lead to workplace accidents and illnesses. Therefore, it is important to ensure that the weight and dimensions of materials are appropriate for handling and employees are trained to use correct handling techniques.

3. Adequate lighting: Adequate lighting is important to avoid eye strain and to reduce the risk of accidents. In general, the lighting level should be at least 500 lux in areas of production and at least 300 lux in storage and packaging areas.

4. Use of personal protective equipment: employees must be equipped with equipment of personal protection such as protective masks, gloves, safety glasses to reduce the risk of exposure to hazardous chemicals and to protect against accidents, helmets and/or plugs ears to protect against noises above a certain frequency.

5. Regular breaks and work rotation: Regular breaks and work rotation are important to reduce fatigue and to prevent work-related conditions such as carpal tunnel syndrome or back pain

These are only a few ergonomic norms used in the pharmaceutical industry. In general, it is important to consider the needs and safety of the employees in all aspects of the production process and to ensure a safe and comfortable working environment.

At the moment, the aim is to reduce the number of documents and specialize the place of the work. Reducing paperwork puts people in front of computers more often and for longer. Job specialization keeps workers in the same jobs doing the same work day after day. These factors, along with an increased production demand, increases the chances of suffering from hearing and visual disorders. Creating work equipment involves physical and intellectual effort, monotony in some cases when positioning in front of screens takes longer, repetitive

movements, awkward postures, noise, etc.

The purpose of the study is to identify the factors associated with noise and lighting in the operators of the tablet section, namely of those who deal strictly with obtaining tablets.

Ergonomic norms in the case of a rotary tablet machine cover almost the entire area, namely their applicability must lead to optimal working conditions. The rotary tablet machine can even have three presses, using a prepress force starting from 20 kN and a press force of 80-100 kN, with a turret rotation of up to 100 revolutions per minute, which leads to a productivity of 250,000 tablets per hour. This productivity results in high noise levels, requiring operator reaction speed and increased attention. Compliance with ergonomic noise regulations can only be achieved with this machine by wearing protective headphones or earplugs due to the high decibel level.

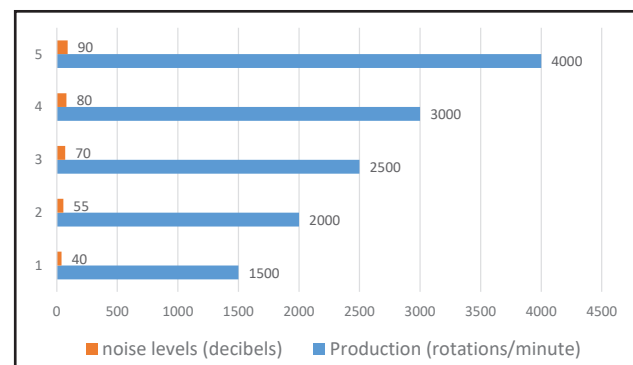


Figure 2 The relationship between the noise level and the number of revolutions

Action exposure values – the levels in decibels at which an employer must take action – are set at a daily or weekly exposure of between 80 dB (lower value) and 85 dB (upper value) according to (Directive 2003/10/EC) - directive of the European Parliament and of the Council of February 6, 2003 regarding the minimum safety and health requirements and the exposure of workers to risks generated by physical agents (noise). The effects on health are numerous, the most common being hearing loss, among which we also find:

1. tinnitus (or the disturbing auditory sensation of ringing, buzzing or buzzing)
2. communication disruption, high risk of injury psychological disturbances

3. physiological effects (fatigue, digestive disorders, cardiovascular)

The ear can be damaged by noise at noise levels of 85 decibels (dB) or higher. In general, the higher the noise level, the shorter the time it takes to cause damage to the ear. For example, at noise levels of 85 dB, exposure for 8 hours a day can cause hearing damage. Conversely, at noise levels of 100 dB, exposure for as little as 15 minutes a day can cause hearing damage. It is important for operators to protect their ears from excessive noise to prevent hearing loss and other hearing problems. In general, acceptable noise levels in the pharmaceutical industry vary between 60 and 85 decibels (dB), depending on the type of activity. In production areas, the noise level should be around 65 dB, while in loading and unloading areas, the noise level should be limited to around 85 dB. Depending on the working speed, at the level of the tablet machines, the noise can reach up to a maximum of 90dB. At the department level, the TESTO sound level meter is used weekly for quick and reliable measurement of the noise level. The device allows effective sensing of the noise level emitted by the most diverse noise sources within a measurement range of 40 to 130 dB. In addition, it is possible to display the minimum and maximum values, the measurements being consistent and accurate. To minimize worker exposure to high noise levels and to comply with occupational health and safety regulations, the following measures have been taken:

- using equipment with low noise levels, investing in tablet machines where the noise level does not exceed 70dB;
- the use of individual protective equipment
- the difference between the ambient noise level and the standard level of 85 dB is called SNR (Single Number Rating) and represents the main criterion for classifying hearing protection items - at the level of the production section, the workers opted for both measures of protection, namely one part for SMART FIT earplugs that have a detachable thermoplastic elastomer cord and storage box and offer a noise attenuation level of up to 30dB, and another part opted for MAGNY COURS 2 external earplugs helmet type, with ABS cups, adjustable headband, with damping element for increased comfort, with

noise attenuation level of up to 33dB;

- implementation of noise monitoring programs and operator exposure assessment;

- organization of work spaces to minimize workers' exposure to noise - three-layer safety glass panes, which are stronger than ordinary glass and can withstand impacts and vibrations, have been installed on doors and windows to reduce noise and to ensure better thermal and sound insulation. In the case of the production sections, according to the rules, there are no windows to the external environment, the secured windows being to the outer ring of the production area, and the use of triple layer glass is to prevent the propagation of noise to other areas of the factory;

- educating workers about the risks associated with exposure to noise and promoting a safety culture (there have been cases in which the workers initially refused to use hearing protection equipment, justifying that they cannot hear the noise produced by the machine and in the event of a malfunction, they cannot react in time; following the training, it was understood that all these machines have efficient safety systems and that the occurrence of deviations leads to the automatic stopping of the machine). It is important for each pharmaceutical company to identify and assess the specific noise-related risks within its own operations and implement appropriate measures to protect health. The noise level in this industry can vary depending on the specific activities and equipment used in the production process. In general, there are several sources of noise in this environment, such as machinery and equipment used in the manufacture of medicines, fans and ventilation systems, air compressors, pumps and water treatment systems, as well as packaging and transport activities.

And in the case of lighting, things must be carefully analyzed. Much of the research by specialists in the field shows that 80% to 85% of the information we assimilate comes to us visually, therefore visual comfort is essential. But the way of lighting affects not only the visual comfort, but also the physical one (a faulty lighting can create an unnatural position of the body and, implicitly, leads to ailments caused by repetitive stress). In pharmaceutical factories, lighting is an important factor in ensuring product

safety and quality. Insufficient lighting can affect production processes and lead to errors or accidents. It is therefore important that lighting is adequate and complies with safety and good manufacturing practice standards. The level of illumination is specific to the production area and the activity carried out there. The windows of pharmaceutical factories are designed to ensure adequate lighting, optimal ventilation and effective sound and thermal insulation, in this industry both natural and artificial light are needed, depending on the requirements of the production process. Natural light can be used in certain areas of the factory, such as offices, conference rooms or storage area, to reduce energy costs and create a more comfortable working environment for employees. Artificial light is used in most production areas, such as compression, primary and secondary packaging areas. This can be achieved by using fluorescent or LED lamps, which provide uniform and efficient lighting and a clearer and more natural color perception. In accordance with GMP standards, the minimum level of illumination for the production areas of drug factories is 500 lux. This level of illumination is necessary to ensure adequate visibility and to prevent errors and accidents. Also, the lighting level can be higher in certain areas, such as laboratories or primary and secondary packaging areas for optimal visibility, as well as in the compression area. In the production department, 45W LED ceiling lights are used, emitting a luminous flux of 4500 lm, with cold light, which provides uniform and efficient lighting. They are positioned to provide uniform illumination throughout the work area, which helps to avoid shadows and other lighting problems that can lead to eye strain and other health problems. The height of the rooms in the production departments can vary, depending on which part of the technological process is carried out in the respective room, from 3-4m up to 6m. This height is necessary to allow the installation of equipment and infrastructure necessary for pharmaceutical production, as well as to ensure adequate air circulation in the room. Concretely, referring to the rooms where the tableting machines are installed, the lighting must be optimal for a good performance of the process. These rooms have a height of up to 6

meters because it is necessary to position the containers with the homogeneous mixture above the tableting machine, for its flow through the feeding funnel to the rotary press fitted with the appropriate molds and punches. In this case, the light sources are at a great distance from the operator, and to observe the deviations that may occur at the level of the tablets and the comfort of the operator, the following measures were taken:

1. installation of additional lighting sources at the tablet collection troughs;
2. adding more light sources and replacing lamps with more powerful ones;
3. choosing light colors for walls and floors, they have a better reflective power and help create a brighter atmosphere;
4. reducing the brightness of the screens to the optimal level for you to see comfortably;
5. taking regular breaks and moving to areas with better lighting to reduce eye strain;
6. wearing safety glasses, if necessary.

Seeing a specialist to check for vision problems that could be exacerbated by poor lighting.

Conclusions:

Following this study, the following conclusions were reached:

In case of exposure for 8 hours to a noise level between 75-80 dB, it is recommended to wear hearing protection.

In case of exposure for 8 hours to a noise level between 80-85 dB, the hearing protection device must be permanently available to the worker and if the noise level exceeds 85 dB, the hearing protection device must be worn.

Following the periodic control by occupational medicine, it was found that the noise level acted differently on the operators, the basic criterion for the tie-breaker being the seniority of work at the tablet press, there being no differences between women and men.

In the case of lighting, after periodic checks at occupational medicine, every three months, it was found that artificial lighting and seniority in production work led to a decrease in visual acuity, gradually leading to the need for optical correction in more than 50% of the operators.

References

1. Maurice dM. L'Ergonomie: Editions La Decourvete, Paris; 1986.
2. Burloiu P, Burloiu S. Managementul resurselor umane: tratare globală interdisciplinară: Lumina Lex, Bucuresti; 1997.
3. Moldovan M. Ergonomie: Editura didactica si Pedagogica. Bucuresti; 1993.
4. 5S - DISCIPLINĂ LA LOCUL DE MUNCĂ. Capital2010; Available from: <https://www.capital.ro/5s-disciplina-la-locul-de-munca-134435.html>.
5. Manolescu A, Moldovan-Scholz M. Managementul resurselor umane: Editura Economică, Bucuresti 2000.
6. Baci I, Derevenco P. Bazele fiziologice ale ergonomiei: Editura Dacia, Cluj-Napoca; 1984.
7. Gradjean E. Principii de ergonomie: Editura Științifică, București; 1972.