

EUROPASS DIPLOMA SUPPLEMENT

TITLE OF THE DIPLOMA (ES)

Técnico Superior en Fabricación de Productos Farmacéuticos, Biotecnológicos y Afines

TRANSLATED TITLE OF THE DIPLOMA (EN)⁽¹⁾

Higher Technician in Pharmaceutical, Biotechnological and Related Products Manufacturing

(1) This translation has no legal status.

DIPLOMA DESCRIPTION

The holder of this diploma will have acquired the General Competence with regard to:

Managing and participating in operations for the production, handling and storage of pharmaceutical, biotechnological and related products, organising the functioning, the startup and stop of systems and equipment, according to normalised working procedures and fulfilling regulations on safety, risk prevention and environmental protection.

Within this framework, the PROFESSIONAL MODULES and their respective LEARNING OUTCOMES acquired by the holder are listed below:

“Organization and Management Pharmaceutical, Biotechnological and Related Products Manufacturing”.

The holder:

- Defines the organization and working areas of pharmaceutical and biotechnological companies, recognising internal and external relational mechanisms.
- Characterises good manufacturing practices, relating them to the safety and traceability of the product obtained.
- Applies the production guide of a pharmaceutical or biotechnological process, following good manufacturing practices.
- Organises activities for a working area, analysing proposed requirements and possibilities for improvement.
- Characterises regulations on authorisation, pharmacovigilance of medicines and duty of confidentiality in the procedures of a company, analysing their foundations.

“Quality Control of Pharmaceutical, Biotechnological and Related Products”.

The holder:

- Applies quality control systems in production and handling processes of pharmaceutical, biotechnological and related products, guaranteeing their operation and traceability.
- Interprets plans for assays and analyses of production processes of pharmaceutical, biotechnological and related products, relating them to quality assurance criteria.
- Takes samples according to the sampling plan, using the procedures and resources of each phase.
- Carries out physical and physicochemical assays for quality control of products, applying standardised techniques.
- Carries out quantitative chemical analyses for quality control of products, applying standardised techniques.
- Carries out microbiological and biotechnological assays for quality control of products, applying standardised techniques.

“Basic Operations in the Pharmaceutical, Biotechnological and Related Industry”.

The holder:

- Determines the characteristics of diffusional operations and guarantees the proper functioning of the equipment for the preparation of raw materials and products, relating them to its function in the production process.
- Determines mechanical separation operations for the preparation of raw materials and products, relating them to their properties.
- Determines pharmaceutical operations for the preparation of raw materials and products, relating them to their function in the production process.
- Operates reactors, controlling the variables involved.
- Applies regulations for occupational risk prevention and environmental protection, identifying risks related to equipment.

“Principles of Biotechnology”.

The holder:

- Determines organisms of biotechnological interest, identifying their properties and biotechnological applications.
- Applies chromatographic techniques in order to identify cellular metabolites, describing their characteristics.
- Applies extraction and separation techniques in order to identify cellular macromolecules, describing their characteristics.
- Identifies metabolic processes, relating them to cellular development.
- Applies genetic modification techniques, identifying their advantages to improve production.
- Applies basic techniques of bioinformatics, identifying their applications in biotechnological processes.

“Safety in the Pharmaceutical, Biotechnological and Related Industry”.

The holder:

- Determines the characteristics of the types of risks, relating them to the production process in pharmaceutical, biotechnological and related industries.
- Determines the characteristics of safety systems, equipment and devices for risk prevention, interpreting safety regulations.
- Applies safety measures, considering procedures and methods of work.
- Applies environmental protection measures, relating them to regulations.
- Defines actions in case of emergency situations in a pharmaceutical, biotechnological and related process, relating them to safety requirements.

“Areas and Assistant Services in the Pharmaceutical, Biotechnological and Related Industry”.

The holder:

- Determines the areas in a production plant of pharmaceutical, biotechnological and related products, relating them to quality, environmental and hygienic requirements.
- Operates with equipment and systems of water purifications, relating them to the needs of the process.
- Operates with systems for the supply of air and other gases, fulfilling current regulations.
- Operates with pressure and vacuum systems, following normalised working procedures.
- Handles heating and cooling production systems, relating environmental conditions to those required for the development of processes.
- Handles material transport equipment, analysing the characteristics of installation according to the products transported.
- Determines sanitation, cleaning and disinfection processes in a production plant, relating them to the requirements of the process.

“Biotechnological Production Techniques”.

The holder:

- Prepares systems and equipment for biotechnological production processes, relating them to their use and application.
- Applies microorganism culture techniques for production, following normalised procedures.
- Applies animal and plant cell culture techniques for production, following normalised procedures.
- Determines the characteristics of bioreactors, relating them to biotechnological production processes.
- Determines the characteristics of biocatalysis processes, relating them to biotechnological production.
- Recognises biotechnological production processes, relating them to separation and purification methods of final products.

“Pharmaceutical and Related Production Techniques”.

The holder:

- Determines the characteristics of pharmaceutical and related products, relating them to classification criteria and their application.
- Determines the characteristics of production procedures and techniques of solid pharmaceutical forms, relating them to good manufacturing practices.
- Determines the characteristics of production procedures and techniques of liquid, semisolid and other forms, relating them to good manufacturing practices.
- Determines the characteristics of production techniques for sterile products, relating them to good manufacturing practices.
- Manufactures pharmaceutical and related products, controlling the variables involved.

“Regulation and Control in the Pharmaceutical, Biotechnological and Related Industry”.

The holder:

- Defines parameters for controlling the process, analysing its requirements.
- Handles measuring instruments, relating them to controlled parameters.
- Applies basic control systems, describing their elements and importance in the industrial process.
- Determines the characteristics of advance control systems, justifying their importance in the optimization of processes.
- Carries out basic programming of programmable logic controllers (PLC), simulating production operations.

“Handling and Storage of Pharmaceutical, Biotechnological and Related Products”.

The holder:

- Defines handling operations, relating them to stability, safety and efficacy assurance of the final product.
- Determines the characteristics of the main types of packages, relating them to the characteristics of the products.
- Operates equipment and systems for dosage and primary and secondary handling of pharmaceutical and related products, guaranteeing the optimal development of the whole process.
- Determines the characteristics of storage facilities, interpreting established regulations.
- Determines the characteristics of operations for the receipt and shipping of products and materials, checking associated documentation.
- Carries out product storage, justifying their distribution and organisation according to their characteristics.

“Electromechanical Maintenance in Process Industries”.

The holder:

- Identifies materials that constitute equipment and systems of the process industry, relating them to their characteristics and their use.
- Analyses mechanical elements of equipment, machines and systems, recognising the function that they carry out.
- Determines the characteristics of hydraulic and pneumatic systems, valuing their intervention in industrial processes.
- Identifies electric machines, relating them to the purpose inside the process.
- Determines the characteristics of maintenance actions, justifying their need.

“Project on Pharmaceutical, Biotechnological and Related Products Manufacturing”.

The holder:

- Identifies the needs of the production sector, relating them to the standard projects that may satisfy them.
- Designs projects related to the competences described in the diploma, including and developing their constituting stages.
- Plans the project implementation, determining the intervention plan and associated documentation.
- Defines the procedures for the monitoring and control of the project implementation, justifying the selection of variables and instruments used.

“Professional Training and Guidance”.

The holder:

- Selects job opportunities, identifying the different possibilities of labour integration, and the alternatives of lifelong learning.
- Applies teamwork strategies, assessing their effectiveness and efficiency on the achievement of the company's goals.
- Exercises rights and complies with the duties derived from labour relationships, recognising them in the different job contracts.
- Determines the protective action of the Spanish Health Service in view of the different covered eventualities, identifying the different types of assistance.
- Assesses risks derived from his/her activity, analysing job conditions and risk factors present in his/her labour setting.
- Participates in the development of a risk prevention plan in a small enterprise, identifying the responsibilities of all agents involved.
- Applies protection and prevention measures, analysing risk situations in the labour setting of the Higher Technician in Pharmaceutical, Biotechnological and Related Products Manufacturing.

“Business and Entrepreneurial Initiative”.

The holder:

- Recognises skills related to entrepreneurial initiative, analysing the requirements derived from job positions and business activities.
- Defines the opportunity of creating a small enterprise, assessing the impact on the performance setting and incorporating ethic values.
- Carries out the activities for the setting-up and implementation of a company, choosing the legal structure and identifying the associated legal obligations.
- Carries out basic administrative and financial management activities of an SME, identifying the main accounting and tax obligations and filling in documentation.

“On the Job Training”.

The holder:

- Identifies the structure and organization of the enterprise, relating them to the production and commercialisation of the products that obtains.
- Applies ethical and work habits in the development of his/her professional activity, according to the characteristics of the job and the procedures established in the enterprise.
- Prepares areas and assistant services in a pharmaceutical, biotechnological or related industry, following normalised procedures.
- Prepares pharmaceutical, biotechnological and related products, following good manufacturing practices.
- Handles and stores pharmaceutical, biotechnological and related products, following good manufacturing practices.
- Participates in the fulfilment of quality control of products, applying the corresponding techniques.

RANGE OF OCCUPATIONS ACCESSIBLE TO THE HOLDER OF THE DIPLOMA

The Higher Technician in Pharmaceutical, Biotechnological and Related Products Manufacturing works in pharmaceutical, biotechnological and related enterprises –in the public or private sector-, where s/he develops /her/his work in areas for production or packaging of pharmaceutical and related forms, such as cosmetics, perfumes, special food, and diet, herbal and drugstore goods. Moreover, s/he is able to work in obtaining biotechnological products, both in sectors whose main activity is using living organisms or their components, and in those activities where they can innovate with biotechnological production techniques on some products and processes, even though they are not her/his main activity.

The most relevant occupations or jobs are the following:

- Manager of machine operators for the production and handling of chemical products.
- Production area manager.
- Handling area manager.
- Planning area manager.
- Area coordinator.
- Reactor/Bioreactor team leader.
- Control technician.
- Warehouse coordinator.
- Production manager.
- Team leader of extraction and purification processes of biotechnological products.
- Clean room team leader in biotechnology.
- Manager in the area of processes and biotechnological service.
- Safety manager in biotechnological processes.

AWARD, ACCREDITATION AND LEVEL OF THE DIPLOMA

Name of the body awarding the diploma on behalf of the King of Spain: Spanish Ministry of Education or the different Autonomous Communities according to their areas of competence. The title has academic and professional validity throughout Spain.

Official duration of the education/ training leading to the diploma: 2000 hours.

Level of the diploma (national or international)

- NATIONAL: Non-University Higher Education
- INTERNATIONAL:
 - Level 5 of the International Standard Classification of Education (ISCED5).
 - Level 5 of the European Qualifications Framework (EQF 5).

Entry requirements: Holding the Certificate in Post-Compulsory Secondary Education (Bachillerato) or holding the corresponding access test.

Access to next level of education/training: This diploma provides access to university studies.

Legal basis. Basic regulation according to which the diploma is established:

- Minimum teaching requirements established by the State: Royal Decree 832/2014, of 3 October, according to which the diploma of Higher Technician in Pharmaceutical, Biotechnological and Related Products Manufacturing and its corresponding minimum teaching requirements are established.

Explanatory note: This document is designed to provide additional information about the specified diploma and does not have any legal status in itself.

COURSE STRUCTURE OF THE OFFICIALLY RECOGNISED DIPLOMA

PROFESSIONAL MODULES IN THE DIPLOMA ROYAL DECREE	CREDITS ECTS
Organization and management for the production of pharmaceutical, biotechnological and related products.	6
Quality control of pharmaceutical, biotechnological and related products.	9
Basic operations in the pharmaceutical, biotechnological and related industry.	10
Principles of biotechnology.	9
Safety in the pharmaceutical, biotechnological and related industry.	7
Areas and assistant services in the pharmaceutical, biotechnological and related industry.	9
Biotechnological production techniques.	7
Pharmaceutical and related production techniques.	9
Regulation and control in the pharmaceutical, biotechnological and related industry.	6
Handling and storage of pharmaceutical, biotechnological and related products.	5
Electromechanical maintenance in process industries.	7
Project on production of pharmaceutical, biotechnological and related products.	5
Vocational Training and Guidance.	5
Business and Entrepreneurial Initiative.	4
On the Job Training.	22
	TOTAL CREDITS
	120
OFFICIAL DURATION (HOURS)	2000

* The minimum teaching requirements shown in the table above comprise 55% official credit points valid throughout Spain. The remaining 45% corresponds to each Autonomous Community and can be described in the **Annex I** of this supplement.

INFORMATION ON THE EDUCATION SYSTEM

