

## 1. TITLE OF THE CERTIFICATE (ES)

Certificado de Profesionalidad de nivel 2 en  
QUIM0109 ELABORACIÓN DE PRODUCTOS FARMACÉUTICOS Y AFINES

## 2. TRANSLATED TITLE OF THE CERTIFICATE (EN)

Professional Certificate Level 2 in  
QUIM0109 PREPARATION OF PHARMACEUTICAL PRODUCTS AND SIMILAR GOODS  
(This translation has no legal status)

## 3. PROFILE OF SKILLS AND COMPETENCES

The holder of this certificate will have acquired the **general competence** to carry out all the operations in the process of manufacturing pharmaceutical products, controlling the operation, set-up and shutdown of equipment, under the safety, quality and environmental conditions established, and assuming responsibility for the first-level maintenance of the equipment. This general competence is divided into the following **skills units** (UC):

- Dispense materials for the manufacturing process (UC0049\_2).
- Prepare equipment and installations and operate auxiliary services for pharmaceutical and similar processes (UC0050\_2).
- Manufacture batches of pharmaceutical and similar products (UC0051\_2).

The professional skills are acquired through the **learning outcomes** defined within the related Training Modules (MF):

- Dispensing of materials (MF0049\_2).
- Installations, services and equipment for the manufacture of pharmaceutical products and similar goods (MF0050\_2).
- Manufacture of pharmaceutical batches (MF0051\_2).
- Practical training at the workplace in preparation of pharmaceutical products and similar goods (MP0151)

(See legal basis for all learning outcomes information acquired by the holder of this Certificate in each MF).

As a reference the learning outcomes include in the Practical training at the workplace that complete and reinforce the learning outcomes acquired in the other training modules, are:

- Correctly use the technical information related to the dispensing of materials for the manufacture of pharmaceutical and similar products.
- Analyse the operation of the process and auxiliary machines, and check and record the data relating to their working condition.
- Operate the control systems of a pharmaceutical or similar unit.
- Operate the systems for heat generation and exchange, as well as the sterilisation of installations, machines and accessories.
- Use process fluids in the manufacture of pharmaceutical products and similar.
- Take part in the company's working processes, following the rules and instructions established at the workplace.

## 4. RANGE OF OCCUPATIONS ACCESSIBLE TO THE HOLDER OF THIS CERTIFICATE

The holder of this certificate may work in pharmaceutical companies and similar in the area of manufacturing pharmaceutical products (pharmaceutical forms). The holder may work in the pharmaceutical and similar sectors. The most pertinent occupations and positions are:

- Machine operator for the preparation of pharmaceutical products, in general.
- Machine operator for the manufacture of pharmaceutical and cosmetic products.
- Other operator in chemical processing facilities.
- Operator of chemical substance separation and filtration equipment.
- Other chemical manufacturing machine operator.

The holder of this professional certificate has recognition of the basic level training in labour risk prevention, according to Annex IV of the Royal Decree 39/1997 of 17 of January approving the Labour Risks Prevention Act.

## 5. OFFICIAL BASIS OF THE CERTIFICATE

### Name and status of the national/regional authority providing accreditation/recognition of the certificate

The Ministry of Employment and Social Security or the corresponding autonomous regional administration within the scope of its competence, in the name of the King. The certificate is valid throughout Spain.

### Level of the certificate

The Professional Certificate Level 2 of the National Repertoire of Professional Certificates corresponds to level 3 of the International Standard Classification of Education (ISCED-P 2011).

The European Qualification Framework (EQF) level:

### Grading scale/Pass requirements

The grading scale and pass level of the training modules are expressed on a scale of 0 to 10. The minimum score for a pass is 5 in every training module including a pass in the practical training at the workplace module.

The grading system is as follows:

- FAIL: 0 to 4.9
- PASS-SATISFACTORY: 5 to 6.9
- PASS-GOOD: 7 to 8.9
- PASS-EXCELLENT: 9 to 10

### Access to next level of education/training

This Professional Certificate Level 2 gives access to Professional Certificate Level 3 within the same professional area and family.

For validation purposes, the educational authorities will recognise the professional module or modules of the VET diplomas corresponding to the skills units included in the training modules of this certificate.

### Legal basis

Royal Decree 719/2011 of 20 May, establishing ten professional certificates in the professional family Chemistry which are included in the National Repertoire of Professional Certificates, and updating the professional certificate established as Appendix III of Royal Decree 1970/2008 of 28 November. (Appendix II, Code: QUIM0109)

## 6. OFFICIALLY RECOGNISED WAYS OF ACQUIRING THE CERTIFICATE

This certificate may be acquired by:

1. Training: Completion with a pass grade of the face-to-face or online training programme.
2. Recognition of the professional skills acquired through professional experience or non-formal training (prior learning): Completion of a process of skills evaluation and accreditation in all the skills units making up the professional certificate.
3. Dual training: Completion of a training and apprenticeship contract, which may range from 1 year (or 6 months, if stipulated as such in the collective agreement) to 3 years, during which effective working time is combined with time dedicated to training under the training programme for the professional certificate.

The training method (number 1 above) requires successful completion of the training modules and the practical training at the workplace:

Description of vocational training received	Percentage of total programme (%)	Duration (hours)
Training modules	87	520
Practical training at the workplace	13	80
<b>Total duration of training leading to the certificate</b>		<b>600</b>

### Entry/access requirements:

- Compulsory Secondary Education Diploma (Lower secondary education); or
- Professional Certificate Level 1 in the same professional area.
- If neither of the above or higher certifications are held, a pass in the key skills tests.

**Additional information:** Professional certificates are instruments for official accreditation of the professional qualifications in the National Catalogue of Professional Qualifications for all economic activities, within the scope of the labour administration. The National Repertoire of Professional Certificates is divided into three qualification levels (Level 1, Level 2 and Level 3), and by sectors into 26 professional families and 102 professional areas. More information is available at: [www.sepe.es](http://www.sepe.es)

National Europass Centre: [www.oapee.es](http://www.oapee.es)

(\*) **Explanatory note:** This document is designed to provide additional information about the specified certificate, but has no legal status in itself. The format of the description is based on the following texts: Council Resolution 93/C 49/01 of 3 December 1992 on the transparency of qualifications; Council Resolution 96/C 224/04 of 15 July 1996 on the transparency of vocational training certificates; and Recommendation 2001/613/EC of the European Parliament and of the Council of 10 July 2001 on mobility within the Community for students, persons undergoing training, volunteers, teachers and trainers.

More information is available at: <http://europass.cedefop.eu.int>

## Information on Professional Certificates of the Map of Qualifications and Vocational Training in Spain

