

1. TITLE OF THE CERTIFICATE (ES)

**Certificado de Profesionalidad de nivel 3 en
QUIM0110 ORGANIZACIÓN Y CONTROL DE LA FABRICACIÓN DE PRODUCTOS FARMACÉUTICOS Y AFINES**

2. TRANSLATED TITLE OF THE CERTIFICATE (EN)

**Professional Certificate Level 3 in
QUIM0110 ORGANISATION AND CONTROL OF THE MANUFACTURE OF PHARMACEUTICAL AND SIMILAR PRODUCTS
(This translation has no legal status)**

3. PROFILE OF SKILLS AND COMPETENCES

The holder of this certificate will have acquired the **general competence** to organise and participate in all the operations in the process of manufacturing pharmaceutical and similar products, supervising the operation, start-up and shutdown of equipment, complying with the rules on correct manufacture, ensuring traceability and supervising the established safety and environmental conditions. This general competence is divided into the following **skills units** (UC):

- Organise the production of pharmaceutical and similar products (UC0334_3).
- Check conformity of process materials, equipment, installations and conditions (UC0335_3).
- Coordinate and control the manufacture of pharmaceutical and similar products (UC0339_3).
- Guarantee quality in the processing of pharmaceutical and similar products (UC0340_3).
- Abide by and ensure compliance with the safety and environmental rules in pharmaceutical and similar processes (UC0338_3).

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

- Organisation in pharmaceutical and similar industries (MF0334_3).
- Areas and services in pharmaceutical plants and similar (MF0335_3).
- Coordination and control in the manufacture of pharmaceuticals and similar (MF0339_3).
- Guarantee quality in the processing of pharmaceuticals and similar products (MF0340_3).
- Safety and environmental rules for the pharmaceutical and similar processes (MF0338_3).
- Practical training at the workplace in organisation and control of the manufacture of pharmaceutical and similar products (MP0244)

(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:

- Manage operations and the documentation required in the planning and control of batch production.
- Describe the operation of equipment for pressure and vacuum production, relating the function it performs in the different zones of production to the characteristics of the equipment.
- Apply criteria to supervise, manage and organise the routine and special activities of a working group in the production area.
- Determine the need for auxiliary products or services for the distribution of energy and/or auxiliary services.
- 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 and similar companies, in the production of pharmaceutical forms and similar products, such as cosmetics, perfumes, diet products, herbal remedies, special foods and household goods. This work is in the following sectors: pharmaceutical, cosmetics, special food, diet food, household goods, herbal remedies, parapharmacy and perfumery. The most pertinent occupations and positions are:

- Team leader in facilities for the manufacture of pharmaceutical products and cosmetics.
- Machine operator manager for the manufacture and packaging of chemical products.
- Production area supervisor.
- Planning area supervisor.
- Area coordinator

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 3 of the National Repertoire of Professional Certificates corresponds to level 4 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 3 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 1534/2011 of 31 October, establishing five professional certificates in the professional family Chemicals, which are included in the National Repertoire of Professional Certificates. (Appendix III, Code: QUIM0110)

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	88	580
Practical training at the workplace	12	80
Total duration of training leading to the certificate		660

Entry/access requirements:

- *Bachiller* Diploma (upper secondary education); or
- Professional Certificate Level 2 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

National Europass Centre: 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

