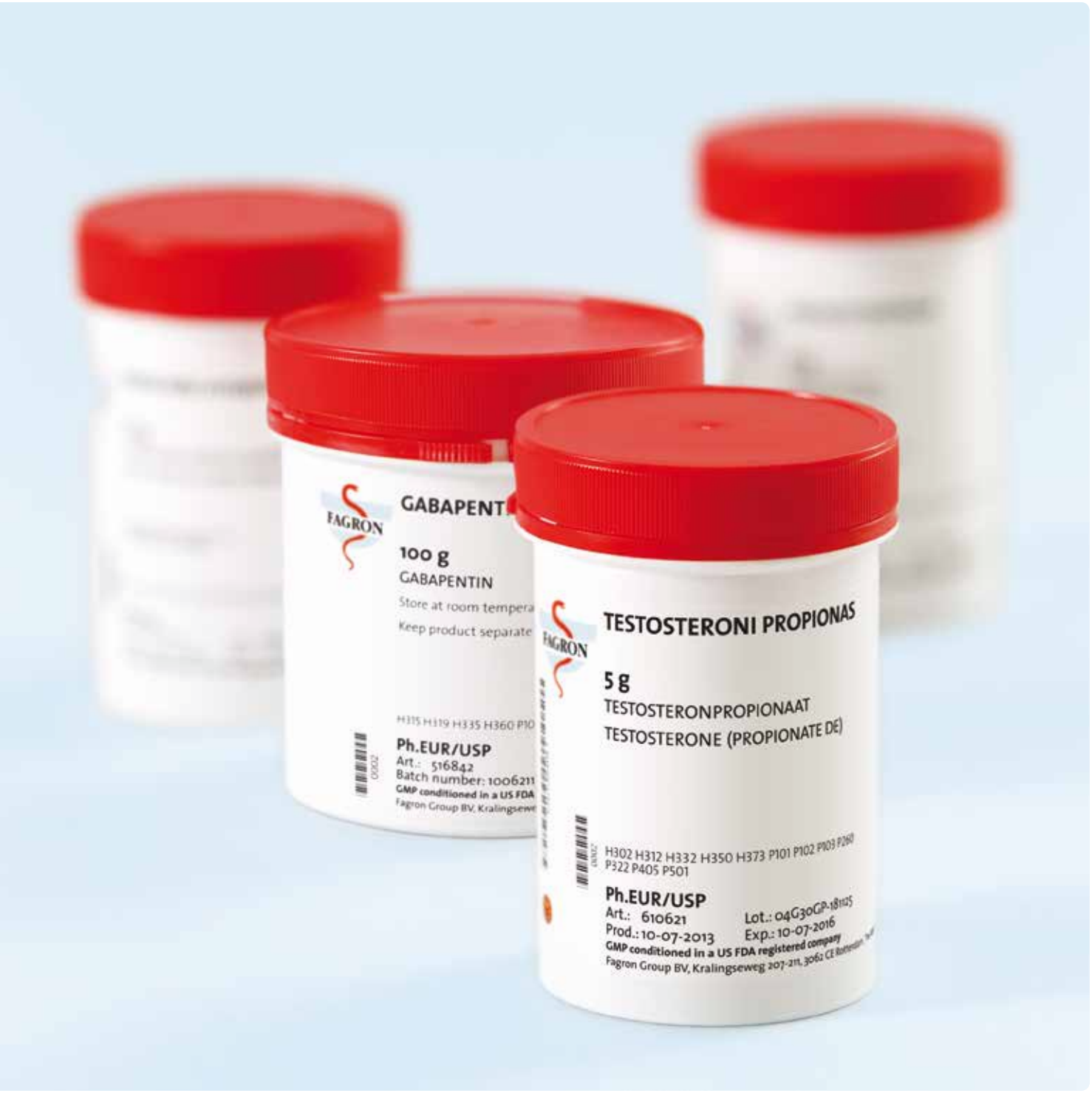
The Unique Quality of Fagron



FAGRON

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More than 200,000 customers worldwide have access to over 5,000 high quality pharmaceutical raw materials thanks to Fagron's global product and producer qualification, full analysis of incoming and produced products, GMP conditioning and release by a qualified person. This unique position makes Fagron attractive to pharmacies, hospitals and the pharmaceutical industry.

Fagron has sourcing offices in South America, North America, Europe and Asia. So Fagron can source its pharmaceutical raw materials globally while operating close to the production sites of pharmaceutical raw materials. This results in full traceability and a high standard of quality. On-site producer audits, (re)qualifications and regular performance assessments guarantee continuous control of Fagron's product portfolio.

Securing that pharmaceutical raw materials quality is in accordance with the latest editions of worldwide pharmacopoeias, and ensuring that all raw materials in Fagron's range are produced in factories which are inspected by regulatory agencies and are GMP-compliant, is essential for Fagron to guarantee its high quality standards.

Pharmaceutical raw materials are subjected to a rigorous process of tests. The results of these tests and the extensive range of documents Fagron demands from the producers, are reviewed by a qualified person before release.

Fagron produces standardised products and products tailored to specific customer needs, in a manufacturing network that includes its own production facilities and contract manufacturers on three continents, all meeting the latest national and international standards (GMP and GDP).

To go further in meeting our customers' needs, Certificates of Analysis (CoA), Material Safety Data Sheets (MSDS), and technical specifications are available for all our products online or upon request.

Fagron quality activities

From selecting a producer until delivery of a Fagron product to the customer, Fagron Quality goes through multiple steps as the following table shows. Fagron employs over 150 pharmacists worldwide.

Quality tasks	Quality tasks
Quality (in coordination with Procurement)	**Quality (in coordination with Sales)**
1. Set up confidentiality agreements with producers	19. Handling complaints
2. Producers qualification	20. Handling recalls
3. Products qualification	
4. Audits of producers	
Quality (in coordination with Production)	**Quality (general)**
5. Incoming product analysis	21. Manage quality system
6. Manage out of specifications	22. Write and implement global procedures
7. Incoming product release	23. Keep site master file
8. Perform and review in-process controls	24. Communication with competent authorities
9. Perform stability testing	25. Host competent authorities' audits
10. Process validation and calibration	26. Stay updated on new regulations
11. Handling deviations	27. Host audits from customers
12. Manage change control	28. Perform internal audits
13. Implement corrective and preventive actions	29. Provide GMP training
14. Approve labelling	30. Quality helpdesk
15. Review production data and documents and release/reject produced products	31. Product quality review
16. Check and publish MSDS	32. Perform risk assessment
17. Check warehousing	33. Obtain manufacture licences and certificates
18. Check transports (GDP)	34. Set up vendors' technical agreements

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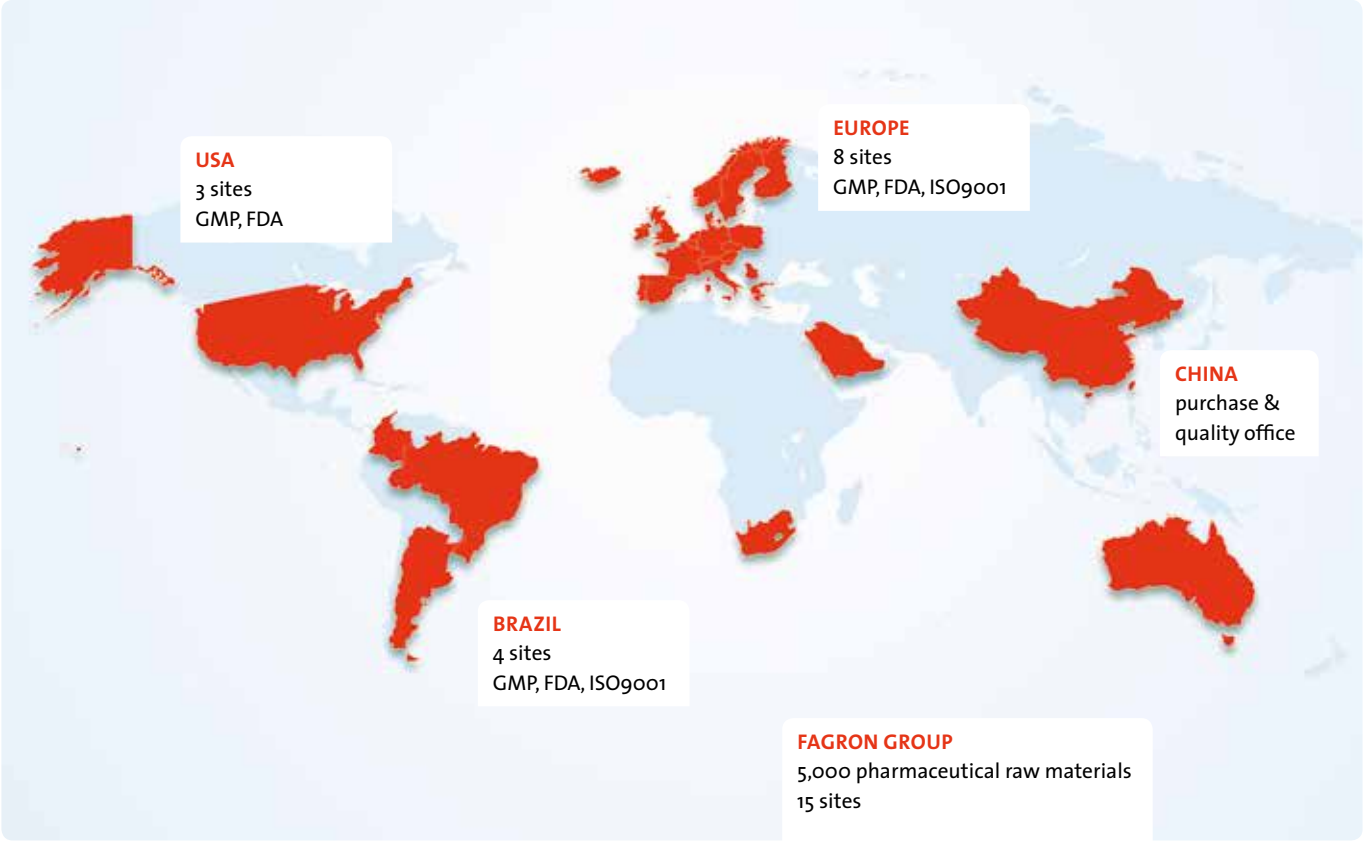
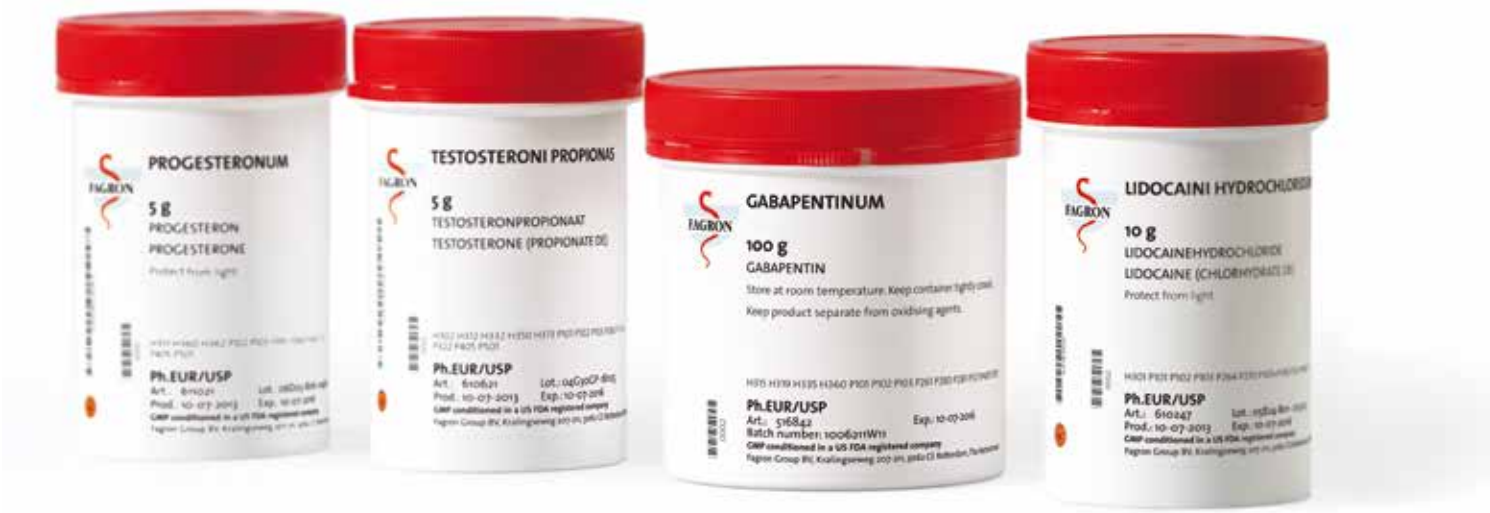


Product and producer qualifications

Qualification of a product from a specific producer is a cooperation between Fagron Procurement and Fagron Quality. Fagron Procurement selects producers for specific products in accordance with strict criteria, and requests documents from the producer for a pre-evaluation by Fagron Quality. If this is approved, Fagron Quality requests an extensive range of documents (e.g. GMP certificate, manufacturing licence, CoA, questionnaire product and producer, stability data, MSDS, methods of analysis and solvents, TSE/BSE statement) relating to the quality of the product and the producer. In the case of a new producer, a sample of the product is also requested for testing. Based on the documentation, Fagron Quality conducts a risk analysis and approves or rejects the product from that producer. Only when the product and producer are fully approved by Fagron Quality, can Fagron Procurement place its first order.



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Internal and external audits

Fagron Quality conducts internal and external audits to ensure consistency of the high quality standard Fagron must deliver. The internal audits are performed to guarantee compliance with local and global legislation and with Fagron's internal procedures.
Fagron conducts on-site audits of producers, agencies, third-party laboratories and distribution companies. This is to ensure that the companies with which Fagron is cooperating maintain the same quality standards as Fagron, and that they will therefore contribute to the high quality of Fagron products.

Falsified Medicines Directive

The Falsified Medicines Directive 2011/62/EU is in force since 2 July 2013 and requires each import of an API from a country outside the EU to be accompanied by a written confirmation to secure patient safety and controlled trading.

In the written confirmation the competent authority of the country outside the EU needs to confirm that:

- The producer's standards are equivalent to EU GMP;
- The producer is subjected to regular, strict and transparent control;
- Findings of non-compliance are communicated to the EU without delay.

The producer is responsible for requesting a written confirmation from the local competent authority.

Fagron is compliant with this new Directive. Suppliers are only being approved after going through the Fagron Group supplier qualification process, which also includes on-site audits. Fagron thus ensures patient safety and product availability worldwide.

In terms of the Falsified Medicines Directive, Fagron Quality conducts on-site producer audits in China, India and other countries outside the EU to check that their standards are equivalent to the EU GMP. Fagron manages this compliance through a comprehensive global database covering the quality status of each product and producer.

Complaint management

All customer complaints received by Fagron are logged in a system. Complaints related to quality are immediately assessed and if applicable, a root cause analysis is performed.
Where required, corrective and preventive actions are implemented in accordance with the change control procedure. For these complaints, all information and actions are documented in a complaint report. The customer is notified of the status and outcome of the investigation.

FAGRON

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