

# INTEGRATION OF SIMULATION INTO THE TEACHING OF PHYSICAL AND CHEMICAL TESTING OF MEDICINES

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## Abstract

*Quality control of medicines is carried out throughout the entire life cycle of a medicine. The physical and chemical tests defined in the monographs of the European Pharmacopoeia (Ph. Eur.) enable the identity, purity, content, and control of critical impurities of active ingredients and pharmaceutical forms to be verified. However, current teaching of these techniques is often limited to theoretical courses or practical laboratory work with limited resources. Educational simulation offers a modern alternative, allowing students to realistically reproduce physicochemical tests, analyze and interpret the results in accordance with European pharmacopoeia standards in an interactive and reproducible environment. This study presents a model for integrating simulation into the teaching of physicochemical testing applied to drug control, detailing the methodology, observed results, educational benefits, and prospects for improving training.*

**Keywords:** Simulation, Physicochemical Testing, European Pharmacopoeia, Drug Quality Control, Active Training.

## 1. Introduction:

The physical and chemical testing of drugs is a fundamental part of pharmacy students' training. Mastery of the analytical tools used for these tests, particularly those described in the European Pharmacopoeia monographs—identification, dosage, purity, impurities, and stability of active substances and finished products—is essential to guarantee the quality and safety of drugs [1]. However, the complexity of instrumental techniques, material constraints, and the high cost of analyses often limit students' experimental practice [2].

In this context, Simulation represents an innovative approach of education [3]. This simulation allows for the realistic reproduction of the steps involved in physicochemical testing: sample preparation, adjustment of analytical parameters, acquisition of chromatograms or other experimental results, and interpretation in

accordance with Ph. Eur. standards. This method promotes active learning, reinforces scientific rigor, develops critical thinking, and effectively prepares future pharmacists for the demands of industrial and hospital laboratories.[4]

This article examines the potential of simulation in teaching physicochemical testing of drugs, highlighting its educational benefits and its integration into pharmaceutical training programs.

## 2. METHODS AND MATERIAL

A simulation workshop was designed for third-year pharmacy students ( $n = 120$ ), divided into four groups of five students, over four separate sessions. The main objective of this workshop was to realistically reproduce the steps of a complete paracetamol quality control process, in accordance with the European Pharmacopoeia monograph. This educational activity illustrated the analytical process, from reading the operating procedure to interpreting the results, with particular emphasis on identification and high-performance liquid chromatography (HPLC) assay.

The educational objectives set included several complementary dimensions. First, understanding the fundamental principles of testing, particularly for HPLC technology with regard to the role of the mobile phase and stationary phase, and the role of chromatographic conditions. Second, the acquisition of analytical skills, such as the selection of appropriate analytical parameters (flow rate, detection wavelength, mobile phase composition, and choice of chromatographic column) in accordance with the recommendations of the Ph. Eur. monograph.

Finally, the workshop focused on interpreting test results by comparing the values and spectra to be analyzed with those of references and chromatographic results, analyzing retention times and peak areas, verifying the resolution and quantification of paracetamol, and comparing the results with the specified purity and impurity limits. Students were also asked to identify and understand possible anomalies, such as co-elution with impurities or related substances, injection errors or simulated instrumental defects, as well as baseline noise and ghost peaks for chromatographic analyses

The simulated teaching scenario involved analyzing a simulated batch of paracetamol tablets, applying the requirements of the European Pharmacopoeia to perform a complete check. The activities included identifying the active ingredient using simulated IR and UV spectroscopy results, colorimetric reactions, and comparison with reference spectra; physicochemical tests, including verification of content, purity, main impurities (p-aminophenol and other specific impurities), and physical characteristics of the tablets; and HPLC assay, with adjustment of the mobile phase, column choice, flow rate, temperature, and detection wavelength, followed by acquisition and interpretation of simulated chromatograms. The students then verified the compliance of the results with the criteria defined in the Ph. Eur. monograph.

The educational activity took place in three main phases. Phase 1 – Pre-briefing consisted of introducing the practical case study, explaining the educational objectives, presenting the concepts of HPLC and the Ph. Eur. requirements for paracetamol, and distributing educational materials and guide sheets. Phase 2 – Simulation involved each group performing virtual injections, including calibration with five standard concentrations, repeated analyses to verify reproducibility, and management of simulated error scenarios,

such as co-elution, contamination, or the presence of air bubbles. The students then acquired and interpreted the chromatograms to identify paracetamol and its impurities. Finally, phase 3 – Debriefing allowed for the comparison of results between groups, the interpretation of discrepancies and anomalies, the justification of analytical choices, the formulation of proposals for improvement, and feedback from teachers on the accuracy, reproducibility, and compliance of the results.

### 3. RESULTS AND DISCUSSION

We included 120 third-year pharmacy students at the FMPT, divided into teams, to carry out a complete simulation of the quality control of a batch of paracetamol according to the European Pharmacopoeia monograph.

#### 3.1. Debriefing on the workshop

A debriefing session was held at the end of the simulation to gather feedback from the learners. They were asked to evaluate various aspects of the workshop. The results are summarized in the following table:

**Table 1. Learners' satisfaction levels regarding the different aspects of the simulation workshop**

Evaluated item	Very satisfied (%)	Satisfied (%)	Not satisfied (%)	Comment
Workshop duration	20	55	25	More than half of the students found the duration appropriate and suitable for the session.
Room / facilities	18	55	27	The material conditions were considered satisfactory by the majority.
Teaching method	22	55	23	The method was perceived as clear, interactive, and effective for understanding.
Student participation	25	55	20	Students felt sufficiently involved in the workshop activities.
Teaching materials (Ph. Eur. monograph, appendices)	19.3	50	30.7	Satisfaction was lower for the provided documents; some students wished for more detailed materials.
Practical simulation (dosage and analysis)	25	50	25	Practical exercises were considered useful, but some students wanted more time to complete them.
Group size	15	42.9	42.1	Some students felt that the group size limited individual practical experience.

### 3.2. Technical skills acquired

To provide a clearer overview of the competencies developed through the simulation workshop, the acquisition rates of the targeted technical skills were evaluated. The following table summarizes the percentage of students who demonstrated mastery of each specific skill.

**Table 2. Acquisition rates of targeted technical skills during the simulation workshop**

Target skill	Acquisition rate
Critical reading of a paracetamol monograph	95%
Correct interpretation of identification tests (IR + color reactions )	88%
Analysis of impurity limits	76%
Simulated performance of a dosage by HPLC (according to teaching appendix)	82%
Writing a conclusion of compliance/non-compliance	84%

### 3.3. Results observed during the simulation

84% of students correctly concluded that the simulated batch was compliant. 16% of students incorrectly concluded that it was non-compliant, mainly due to misreading the limits for certain impurities, particularly p-aminophenol and impurity B.

## 4. DISCUSSION

Analysis of learner feedback and assessment of technical skills acquisition provide essential information on the effectiveness of the simulation workshop on physicochemical testing of paracetamol batches according to the European Pharmacopoeia monograph. Overall, the results show a high level of satisfaction and confirm that the workshop achieved its educational objectives.

### 4.1. Educational impact of the simulation approach

The results presented in Table 2 show a solid acquisition of the targeted skills. The highest performance was in the critical reading of the paracetamol monograph (95%), indicating that students were able to extract and interpret essential information from regulatory documents.

The data show that simulation based on the chosen case study, such as paracetamol, using the monograph, provides a better understanding of regulatory requirements. This guided immersion in the regulatory protocol promotes better integration of analytical knowledge, in particular mastery of identification methods, purity tests, limit tests, and dosage. Students learn not only to recognize pharmacopoeia specifications, but more importantly to apply them correctly, interpret analytical results, and judge the compliance of a sample. The results are consistent with scientific evidence on the effectiveness of simulation in pharmaceutical science learning, particularly for decision-making and clinical and analytical reasoning [5] [6].

### 4.2. Strengthening pharmaceutical reasoning in quality control

Working on a very common molecule such as paracetamol is particularly instructive because its monograph includes: several identification tests, critical impurities such as p-aminophenol, strict purity and content

requirements, and precise analytical criteria (IR, UV, HPLC). [7] The correct interpretation of identification tests (88%) and the drafting of conclusions of compliance or non-compliance (84%) also attest to a good consolidation of analytical reasoning. These results are consistent with studies showing that simulation reinforces the transfer of theoretical knowledge to practical decision-making [9].

#### **4.3. Development of cross-disciplinary skills**

The physicochemical testing simulation workshop is not limited to the acquisition of technical skills; it also helps to strengthen a set of cross-disciplinary skills that are essential for the profession of pharmacist. Simulation enables them to learn how to make decisions in a structured, reasoned manner that complies with the requirements of pharmaceutical practice [10], and to document and justify analytical conclusions. Simulation is based on the principle of “learning by doing,” widely documented as one of the most effective pillars of experiential learning [11]. By manipulating, observing, analyzing, and making decisions in an environment close to reality, learners memorize more and transfer their knowledge more easily to authentic professional situations. This approach fits perfectly within the framework of competency-based medicine and pharmacy, which require operational mastery rather than simple theoretical acquisition [12].

#### **4.4. Limitations observed**

Some students confused specific impurities with total impurity limits. The lack of actual handling limited sensory learning but reinforced the cognitive and decision-making aspects. The working time (4 hours) was considered insufficient to practice all the steps with ease.

#### **4.5. Relevance for training future pharmacists**

Quality control of paracetamol cuts across the roles of: pharmacists working in drug control agencies, pharmaco-toxicology laboratories (checking suspicious batches, understanding non-compliance), industrial pharmacists (batch release), Teachers of analytical and therapeutic chemistry. Simulation is therefore a powerful tool for preparing future pharmacists for the real-world aspects of drug quality.

### **5. CONCLUSION**

The integration of a simulation workshop dedicated to physicochemical testing of drugs into the pharmacy curriculum is fully in line with the evolution of teaching approaches focused on the acquisition of professional skills. This study highlighted the importance of simulation for teaching physicochemical testing of drugs in pharmaceutical training. By reproducing the entire analytical process required for paracetamol quality control according to the European Pharmacopoeia, the simulation workshop enabled students to actively engage in understanding the regulatory requirements, analytical reasoning, and decision-making processes essential to pharmaceutical practice.

These results are consistent with the literature, which recognizes simulation as an effective, learner-centered pedagogical approach that promotes understanding, autonomy, and the transfer of knowledge to real-life situations in the pharmacy program [13]. The results as a whole highlight the relevance and effectiveness of integrating simulation into the pharmaceutical curriculum.

In conclusion, simulation, when judiciously integrated into curricula, improves students' preparation for professional practice and reduces the gap between academic training and real-world experience,

particularly in disciplines with stringent regulatory requirements such as industrial pharmacy. Thus, the introduction of simulation into this module contributes significantly to professionalizing training and enhancing the quality of experiential learning within the pharmacy program.

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