INSTITUT NATIONAL DES SCIENCES APPLIQUÉES LYON

DPT BIOSCIENCES
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Engineering science

Processes of the pharmaceutical industries

IDENTIFICATION

CODE : BS-5-S1-EC-COPROCP
ECTS : 2.0

HOURS

Lectures :	24.0 h
Seminars :	0.0 h
Laboratory :	0.0 h
Project :	0.0 h
Teacher-student contact :	24.0 h
Personal work :	26.0 h
Total :	50.0 h

ASSESSMENT METHOD

Cases Study Written Report Oral Exam

TEACHING AIDS

Written Documents

TEACHING LANGUAGE

French

CONTACT

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AIMS

* To understand validation methodology (pharmaceutical industry)
* Composition of marketing authorization dossier

CONTENT

Validation methodology :
Introduction : quality, authorities and regulatory references (AFSAP, EMEA, FDA, BPF, GMP, Normes ISO...), qualification and validation.
Control of validation :
Scope
Principle
Methodology :
Qualifications : design qualification, installation qualification, operational qualification, performance qualification.
Validation : process mapping, criticality analysis (critical and operational parameter), reproducibility and robustness, process validation.
Actors of validation
Documentation
Exercises.
Marketing authorization dossier :
Aims
Composition
Summary of product characteristics (SPC)
Pharmaceutical dossier
Pre-clinical dossier
Clinical dossier
The Common Technical Document (CTD)

PRE-REQUISITE

Industrial Processes I

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