

| | |
|--|---|
| Identification data: | |
| Name of the institution: | Autonomous University of Nuevo Leon |
| Name of the school: | School of Medicine |
| Name of the degree program: | Clinical Chemistry |
| Name of the course (learning unit): | Toxicology and legal chemistry |
| Total number of class hours-theory and practice: | 80 |
| Class hours per week: | 4 hours |
| Independent study: | 10 |
| Course modality: | Face-to-face instruction |
| Module level: | Eighth semester |
| Core/elective module: | Mandatory |
| Curriculum area: | ACFP-F |
| UANL credit points: | 3 |
| Create date: | June 18 th , 2018 |
| Date of last amendment made: | Janaury 1 st , 2024 |
| Person(s) responsible for the design | Dr. med. Lourdes Gaza Ocañas Dr. C. Christian Tadeo Badillo Dr. C. Sandra Lucía Montoya Eguía |

and amendment of the module:

2. Presentation:

The learning unit is designed according to the recommendations of toxicology teaching in health sciences degrees at an international level. Throughout the learning unit, the student of the Clinical Biological Chemist degree acquires the competencies to solve problems related to toxic substances in the regional, national and international environment. This learning unit develops a formative sequence to solve problems through research that is intended to be accomplished in the following stages:

Stage 1: Fundamental Toxicology. The student learns the basic concepts used in toxicology and the processes of the toxic phenomenon. They understand the processes that occur once the toxicant enters the organism, the mechanisms by which it causes toxicity, the processes of the organism to bio-transform and eliminate toxic substances. At this stage, toxic agents are classified under different headings: heavy metals, pollutant gases, pesticides and persistent organic pollutants, substances of abuse and prescription, household and occupational chemicals, toxins of plant and animal origin.

Stage 2: Applied Toxicology. The student identifies the agencies responsible for the regulation of toxic substances, reviews the regulations and the proposed regulatory framework to prevent adverse effects on the population and delimit exposure to toxic substances in the workplace, food, environmental and domestic environment.

Stage 3 Regulatory Chemical Toxicological Analysis. In this stage, the regulatory criteria for analytical methods in toxicology, guidelines for sample collection, conservation and storage, as well as guidelines and standards for validation as a means of support to ensure the reliability of the results are reviewed.

Stage 4: Regulatory framework and interpretation of results. In this stage, the skills acquired for the interpretation of a result are applied, considering from the sampling to the quality control applied in the analysis, the compliance with the regulatory framework is interpreted according to the maximum residual limit established.

PIA: The student prepares a proposal for a toxicological analysis to determine a toxic agent in an established matrix. The agent and matrix are assigned by the professor. The student must select the sample processing and instrumental analysis based on the regulatory framework applicable to the analyte in the matrix.

3. Purpose(s):

Provides the basic elements for the application of toxicological analysis to meet national and/or international regulatory requirements.

The learning unit promotes the development of general competencies, in which the student will be able to solve problems of identification and quantification of chemical substances in biological and non-biological matrices through the use of logical and critical thinking in the selection, design, development and validation of toxicological chemical analysis procedures.

During the learning unit, the student intervenes in the challenges of society by selecting the regional, national and global regulatory framework regarding the maximum permissible limits of toxic substances in air, water, soil and food, thus contributing to consolidate wellbeing and sustainable development. The student will be able to solve specific personal and social conflicts by adequately selecting the analysis techniques that apply to the different groups of xenobiotics, considering the analyte to be determined, type of matrix, required accuracy and sensitivity, number of samples to be analyzed and the concentration of the analyte in the matrix.

During the learning unit, specific competencies are developed jointly, since the student will be able to determine the presence of chemical substances of the different groups of toxicants (metals, substances of abuse, pesticides, organic solvents, drugs, etc.) in biological and non-biological matrices. In addition, it ensures the reliability and defense of the results through the design and validation of the analytical procedure based on current national and international regulations, as well as through the interpretation of the toxicological analysis through the fulfillment of the acceptance criteria established during validation, and in the operation, documentation and interpretation of the implemented quality control parameters.

Within the learning units of previous semesters, there is a relationship with Fundamentals of analytical chemistry by using mathematical models for the quantification of the analyte in a matrix; with Applied analytical chemistry by establishing the performance criteria for the validation of an analytical method; with Instrumental analysis by applying the fundamentals for the correct selection of equipment and instruments in chemical analysis; with Physiology by reviewing the processes involved in the biotransformation and elimination of xenobiotics as well as the understanding of the modification of physiological processes resulting from the interaction between the xenobiotic and its targets in the organism. This learning unit provides fundamental bases for the development of social service and professional practices in which chemical toxicological analysis is carried out in a standardized environment.

4. Competences of the graduate profile

General competences to which this module (learning unit) contributes:

Instrumental skills:

5. To use logical, critical, creative and proactive thinking to analyze natural and social phenomena that allow them to make relevant decisions in their sphere of influence with social responsibility.

Personal and social interaction skills:

11. To intervene in the face of the challenges of contemporary society at the local and global level with a critical attitude and human, academic and professional commitment to contribute to consolidating general well-being and sustainable development.

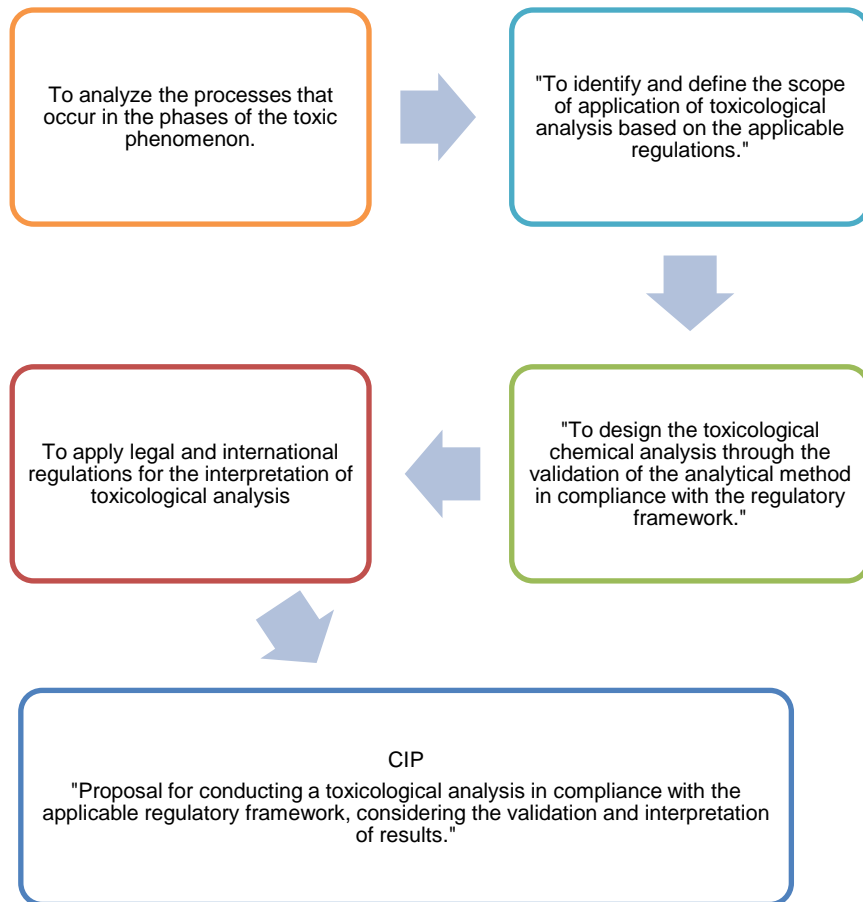
Integrative skills:

14. To resolve personal and social conflicts, in accordance with specific techniques in the academic field and in their profession for appropriate decision-making.

Specific competences of the graduate profile to which this module (learning unit) contributes:

4. To validate bioanalytical methods under established performance criteria that allow reliability of the results obtained in chemical-biological samples.
6. To interpret the results of analyses based on established criteria that allow timely and pertinent decision-making in clinical, toxicological, chemical, food, forensic, and environmental diagnosis..

5. Course roadmap:



6. Structuring into stages or phases:

Stage 1: Fundamental toxicology.

Component(s) of the competence: To analyze the different processes that occur in the phases of the toxic phenomenon by studying the toxicokinetic properties and toxicity mechanisms of the different groups of agents of toxicological interest to assess the risk of health impact after exposure to xenobiotics.

| Evidence of student learning | Performance criteria | Learning activities | Content | Resources |
|---|--|---|---|--|
| Evidence 1. Documentary research report on the first phase of the toxic phenomenon. | <ul style="list-style-type: none"> – Work individually.. – Describe the exposure pathways and physicochemical properties of a toxic agent of your choice. – Classifies intoxication in terms of time and alteration of health status. – Classifies the etiology of poisoning and includes the scenarios or environments in which the toxic phenomenon occurs. – Include references cited in Vancouver format, they must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. – Deliver evidence through the use of the Moodle platform. | <ul style="list-style-type: none"> – The professor presents the course in the classroom, reviews with the students the analytical program, the evaluation of the learning unit and the schedule of sessions, practices and written evaluations. – Students are assigned to work teams for the development of the PIA. – The teacher randomly assigns the projects to the working groups. – The student, in extra classroom session, reviews chapter 2 of the book Fundamental Toxicology, pages, 21-23,32-39. – The teacher explains the classification of intoxication, classifying it by time and alteration in the state of health. – The teacher explains the classification of toxic agents (xenobiotics). – Students provide examples of toxic substances belonging to the different categories. – Students analyze cases of poisoning from the book Fundamental Toxicology and present their opinions in session. – Students receive feedback on their opinions from the teacher. | <p>Classification of intoxication by time and alteration of health status.</p> <p>Concept of toxicant, poison, xenobiotic, and toxin.</p> <p>Classification of intoxication according to time.</p> <p>Etiology of poisoning Intoxication and its types.</p> <p>Bioavailability of toxic substances.</p> <p>Classification of toxic agents:</p> <ul style="list-style-type: none"> – Heavy metals – Polluting gases – Pesticides and persistent organic pollutants – Substances of abuse and prescription drugs – Household and occupational chemicals – Toxins of animal and plant origin – Sources of toxics generation | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Repetto, M. Fundamental Toxicology (4^a ed.) Chapter 2, pp 22-56. ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ Repetto, G., Moreno, I. M., Peso, A. d., Repetto, M., & Cameán, A. M. (2001). The search for toxicological information: a practical learning module. Revista de Toxicología, 18(2), 92-98. ▪ Moodle Platform ▪ Klassen, C., & Watkins, J. (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.). McGraw-Hill Education ▪ Projector and computer equipment for slide projection. ▪ Toxicology Newspaper Library, Compendium of newspaper articles on cases of poisoning. ▪ Massive Open Online Course (MOOC) in Toxicology, http://moodle.toxoer.com/ ▪ Bibliographic reference manager |

| | | | | |
|---|--|--|---|---|
| <p>Evidence 2.</p> <p>Comparative table of toxicokinetics of toxic agents.</p> | <ul style="list-style-type: none"> - Work individually.. - Describe the toxicokinetics (absorption, distribution, metabolism and excretion) for three toxic agents of your choice, each from a different family. - Indicates the most important metabolites, emphasizes biological indicators of exposure. - Include references cited in Vancouver format, they must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. | <ul style="list-style-type: none"> - The student, in an extra-classroom session, reviews Chapter 3 of the book Fundamental Toxicology, pages 60-82. - The teacher describes the kinetics by which xenobiotics enter and leave the organism. - The teacher describes the operation of the toxicokinetics simulation interface. - The student, in an extra-classroom session, reviews Chapter 3 of the book Fundamental Toxicology, pages 86-99. - The student performs on computer, as well as on semilogarithmic and millimeter paper, simulations on the impact of alteration in toxicokinetic processes on the maximum concentration and area under the curve of toxic substances. - Students in teams solve first order kinetics exercises. - Accredited activity 2. Students, in teams, solve zero-order kinetics exercises. - In extra classroom session, the student reviews chapter 4 of the book Fundamental Toxicology pages 118-131,132-138. - The teacher exposes the reactions that occur for the metabolism of xenobiotics. - Students postulate metabolites of toxic agents from phase 1 and phase 2 reactions. | <p>Transport mechanisms, ABC, BB transporters.</p> <p>Absorption, distribution, metabolism, excretion.</p> <p>Metabolism reactions. Induction, enzyme inhibition.</p> <p>Polymorphisms.</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Repetto, M. Fundamental Toxicology (4^a ed.) Chapter 3, pp 60-82, 86-99. ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ Klassen, C., & Watkins, J. (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.). McGraw-Hill Education. ▪ Stella - Isee systems computational software with toxicokinetic simulation interface developed by the Department of Pharmacology and Toxicology, School of Medicine, UANL. ▪ Semi-logarithmic and millimetric paper for toxicokinetic representation. ▪ Bibliographic reference manager. |
|---|--|--|---|---|

| | | | | |
|---|--|--|--|---|
| <p>Evidence 3.</p> <p>Comparative table of the mechanisms of toxicity.</p> | <ul style="list-style-type: none"> - Work individually.. - Describe the mechanisms of toxicity (toxicodynamics) for three toxic agents of your choice, each from a different family (other than those in evidence 2). - Include references cited in Vancouver format, they must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. | <ul style="list-style-type: none"> - In an extra classroom session, the student reviews chapter 3 of the book Essentials of Toxicology. - In extra classroom session, the student reviews chapter 6 of the book Fundamental Toxicology, pages 161-208. - The professor explains the main mechanisms of toxicity. - The student performs a search of toxicity mechanisms for different toxic agents. - The student receives feedback from the teacher regarding the mechanisms of toxicity. | <p>Effects of toxic agents on target molecules.</p> <p>Affection of the cellular structure.</p> <p>Alteration of cellular function.</p> <p>Alteration of cellular maintenance.</p> <p>Gene expression disorder.</p> <p>Toxicity by organs and systems.</p> <p>Factors that modify toxicity.</p> <p>Toxicification vs. detoxification.</p> <p>Tissue necrosis, fibrosis and Carcinogenesis.</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Moodle platform. ▪ Repetto, M. & Repetto, G. (2009). Fundamental Toxicology (4^a ed.). ▪ Klassen, C. (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.). ▪ Bibliographic reference manager. |
| <p>Evidence 4.</p> <p>Toxic risk analysis investigation report.</p> | <ul style="list-style-type: none"> - It is carried out as a team. - Choose a case: Anaversa, Tekchem, Dragon Accident, Ecoltec, Buenavista del Cobre, Séveso, Bhopal. - Identifies the toxic agent involved and describes the dose assessment, exposure, characterization, management, control and monitoring of the risk. - Include references cited in Vancouver format, they must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. | <ul style="list-style-type: none"> - Students read case studies of chemical emergencies in Mexico and around the world: <ul style="list-style-type: none"> *Anaversa *Tekchem *Dragon accident *Ecoltec *Good view of copper *Séveso *Bhopal. - Review chapter 14 of the book: Environmental, Clinical and Everyday Toxicology. Basis and Case Studies. - Students argue the regulations and discuss the cases in the classroom. - Students, individually, respond to a written evaluation of the topics reviewed in this stage. | <p>Toxic risk analysis.</p> <p>Identification of potential hazards.</p> <p>Dose assessment.</p> <p>Exposure assessment.</p> <p>Risk characterization.</p> <p>Risk management.</p> <p>Risk communication.</p> <p>Risk control or monitoring.</p> <p>Risk, Danger.</p> <p>Risk characterization.</p> <p>NOAEL, IDA.</p> <p>Risk communication.</p> <p>Reach System.</p> <p>Biomarkers.</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and case studies (2022). ▪ Repetto. Fundamental Toxicology (4^a ed.). ▪ Klassen (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.). ▪ Albert, L. (2015). Toxic Mexico: chemical emergencies. ▪ Anna M. Fan (Editor), Toxicology and Risk Assessment-Jenny Stanford Publishing (2015). ▪ Greim, Helmut. Toxicology and risk assessment a comprehensive introduction, Wiley (2019). ▪ Robinson, Laura. A practical guide to toxicology and human health risk assessment (2019). ▪ Helmut Greim. Toxicology and risk assessment: a comprehensive introduction, 2nd Edition (2018). ▪ Woolley Adam. A Guide to Practical Toxicology. Evaluation, Prediction, and Risk-Informa Healthcare (2008). ▪ Bibliographic reference manager. |



NEW LEON AUTONOMOUS UNIVERSITY
MEDICAL SCHOOL
ANALYTICAL PROGRAM



Stage 2: Applied Toxicology.

Component(s) of the competence To establish the field of application of toxicology through the review of the regulatory framework in order to prevent, reduce and eliminate risk in the occupational, food, environmental and clinical fields.

| Evidence of student learning | Performance criteria | Learning activities | Content | Resources |
|---|---|--|--|--|
| Evidence 5. Comparative table of the regulatory framework applicable to the different fields of toxicology. | <ul style="list-style-type: none"> – Work individually.. – Select three toxic agents from different application areas of toxicology. – Indicates the agency or entity in charge of its regulation. – It includes the NOM numeral, as well as what it establishes for that substance. – Indicates the Maximum Residual Limit or Biological Exposure Indicator. – Compare national versus international regulation. – Include references cited in Vancouver format, must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. | <ul style="list-style-type: none"> – The student analyzes the pages of official agencies and organizations in charge of issuing standards on the regulation of toxic agents in different matrices. – The student visits the NOMS and NMX catalog of the Ministry of Economy and identifies key words. – Accredited activity 4. The student, individually, prepares a research report on the analysis of a case of poisoning related to a branch of toxicology (food, environmental, clinical, home, occupational). Describe the case and relate it to the relevant regulatory agency. – The professor presents documented cases of non-compliance with toxic agent standards. – The student reviews the Good Clinical Practice guidelines. | <p>Etiology of intoxication.</p> <ul style="list-style-type: none"> *Clinical toxicology (drugs and therapeutic monitoring, substances of abuse). *Food toxicology (food safety, chemical residues and maximum residual limit). *Environmental toxicology (emerging contaminants). *Occupational toxicology (heavy metals, hydrocarbons and pesticides). *Toxicology in the home (drugs, solvents). <p>Regulatory entities for toxic agents.</p> <ul style="list-style-type: none"> *SENASICA. *EPA. *FDA. *SEMARNAT. *SAGARPA. *SE. *WADA. *Cofepris. <p>Toxic agents regulations.</p> <ul style="list-style-type: none"> *NOM-010-STPS-2014. *NOM-127-SSA1-1994 (Modified in 2000). | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Repetto, M. (2009). Fundamental Toxicology (4ª ed.). ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ Klassen, C. (2015). Casarett & Doull's Essentials of Toxicology (3ª ed.). ▪ Toxicology Newspaper Library, Compendium of newspaper articles on cases of poisoning. ▪ Albert, L. A. (2014). Basic course in environmental toxicology. ▪ Caméan, A. (2006). Food Toxicology. Spain. ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ NOM-127-SSA1-1994, Environmental health. Water for human use and consumption. Permissible quality limits and treatments to which water must be subjected for its potabilization (Modification of the year 2000). ▪ Mexican Official Standard NOM-047-SSA1-2011, Environmental Health - Biological exposure indexes for personnel occupationally exposed to chemicals. |

| | | | | |
|--|--|--|---|---|
| | | | <p>*NOM-047-SSA1-2011. *Occupational exposure limits for chemical agents 2018. *NIOSH. *OSHA. *Table of maximum limits of toxic residues and contaminants Senasica. *2002/657/EC: SANTE Decision/11813/2017. *Regulation (EU) no.37/2010.</p> | <ul style="list-style-type: none"> ▪ NORMA Oficial Mexicana NOM-047-SSA1-2011, Salud ambiental-Índices biológicos de exposición para el personal ocupacionalmente expuesto a sustancias químicas. ▪ Bibliographic reference manager |
|--|--|--|---|---|

Step 3: Regulatory toxicological chemical analysis.

Component(s) of the competence: Design and select analytical methods, considering the scope and orientation of the toxicological analysis. Assess the different processes involved in the analysis, from sample collection, transport and storage, to validation of the processing and instrumental analysis, in compliance with the regulatory framework, to ensure the validity of the toxicological analysis.

| Evidence of student learning | Performance criteria | Learning activities | Content | Resources |
|--|---|--|--|---|
| <p>Evidence 6.</p> <p>Proposal for sample collection, transport and storage for toxicological analysis.</p> | <ul style="list-style-type: none"> - Work individually. - Select a toxic agent and elaborate a proposal based on standards, guidelines or scientific articles, on the collection, transport and storage of a sample of that substance. - Include references cited in Vancouver format, they must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. | <ul style="list-style-type: none"> - The professor explains in The biological and non-biological matrices to be considered for toxicological analysis. - The teacher exposes the guidelines regarding sampling. - The student in an extra-classroom session reviews the variables that influence the analytical results, timing and stability of the compound, textbook Fundamental Toxicology, pages 505-510. - In an extra-classroom session, the student performs a bibliographic search on sample collection, conservation, transport and storage according to the regulatory framework. - The teacher provides feedback to the student regarding the search performed. | <p>The sample for toxicological analysis (judicial, clinical, environmental, food, occupational).</p> <p>Chain of custody, general considerations on biological samples.</p> <p>Sampling for analysis.</p> <p>Sampling times.</p> <p>Transport and storage of samples.</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Repetto, M. (2009). Fundamental Toxicology (4ª ed.). ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ Flanagan, R. (2008). Fundamentals of Analytical Toxicology. ▪ Official Mexican Standard NOM-004-ZOO-1994, fat, liver, muscle and kidney in poultry, cattle, goats, deer, horses, sheep and pigs. Toxic residues. ▪ Maximum permissible limits and sampling procedures. ▪ Laboratory. Presumptive testing kit for substances of abuse. |

| | | | | |
|---|---|--|---|---|
| <p>Evidence 7.</p> <p>Interpretation of presumptive and confirmatory analysis.</p> | <ul style="list-style-type: none"> - Works on an individual basis. - Individually interprets presumptive and confirmatory tests from the electronic booklet. - Justify and substantiate your answers. | <ul style="list-style-type: none"> - The professor explains the scope of presumptive and confirmatory analysis. - Weighted activity 5. The student performs the laboratory practice of presumptive analysis of substances of abuse in solid samples and biological fluids. - The teacher explains the acceptance criteria of a confirmatory analysis. - The student searches for regulatory documents on toxic agents, the procedure for confirmatory analysis of toxic substances. - The student analyzes demonstration videos of laboratory practices on the determination of toxicants in different matrices. - The teacher provides data obtained in the laboratory practices. - Weighted activity 6. The student completes the lab report. | <p>Orientation of the analysis.</p> <p>Presumptive and confirmatory analysis.</p> <p>Tandem mass spectrometry for confirmation.</p> <p>Characteristics for confirmatory analysis.</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Repetto, M. (2009). Fundamental Toxicology (4^a ed.). ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ Klassen, C. (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.). ▪ Laboratory, presumptive testing for the presence of substances of abuse. |
| <p>Evidence 8</p> <p>Comparative table of the different validation parameters, indicators and acceptance criteria.</p> | <ul style="list-style-type: none"> - Works as part of a team. - Mentions a guide to bioanalytical methods. - Mentions a forensic toxicology guide. - Mention a pesticide guide. - Compare the indicators and acceptance criteria for the validation parameters of the different guides chosen. - Include references cited in Vancouver format, must come from books, articles, or websites of educational institutions, associations or governmental agencies. It is not allowed to use information from .com domain sites. | <ul style="list-style-type: none"> - The professor exposes the performance criteria of analytical methods. - The student consults in the guides the different procedures to evaluate the validation parameters. - The student compares the procedures for evaluating each validation parameter. - The professor explains the importance of method validation as a means of support to guarantee the validity of the result. - Students review news releases from WG200 ADE651 and Theranos. - The professor presents documented cases of non-compliance with method validation. - Accredited activity 7. Students individually respond to a written assessment of the topics reviewed in steps 2 and 3. | <p>Accreditation, certification.</p> <p>Criteria for the performance, application and interpretation of analytical methods.</p> <p>*Interpretation of results of analytical methods (see reference).</p> <p>*Analytical quality control and method validation guide for pesticide residue analysis (see reference).</p> <p>*NOM-177-SSA1-2013.</p> <p>*Technical Guide for Analytical Measurements (see reference).</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Repetto, M, Fundamental Toxicology (4^a ed.). ▪ Huerta, S. Environmental, clinical and everyday toxicology. Basis and Case Studies (2022). ▪ Klassen, C. (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.). ▪ Compendium of newspaper articles on cases of intoxication prepared by the teacher. ▪ Albert, L. A. (2014). Curso básico de toxicología ambiental. Mexico City: Editorial Limusa S.A. de C.V. ▪ Albert, L. (2015). Toxic Mexico: chemical emergencies. ▪ Caméan, A. (2006). Food Toxicology. Spain. ▪ Electronic booklet of validation exercises. Laboratory practice. |

| | | | | |
|--|--|--|--|---|
| | | | | <ul style="list-style-type: none"> ▪ Guide for the validation and verification of quantitative examination procedures used by the clinical laboratory. |
|--|--|--|--|---|

Stage 4: Regulatory framework.

Competency Element: Interpret the result of a toxicological analysis considering reference values or the regulatory maximum residual limit to evaluate compliance with the regulations applicable to the assigned analyte.

| Evidence of student learning | Performance criteria | Learning activities | Content | Resources |
|---|---|---|--|--|
| Evidence 9 Interprets validation and sample analysis results. | <ul style="list-style-type: none"> - Works as part of a team. - Interprets the pre-analytical and analytical stage of sample analysis. - Performs calculations to assess compliance with performance criteria. - Interpret the validation results with the acceptance criteria established in the guide. - Interprets quality control during sample analysis. - Interprets the result obtained and compliance with regulations. | <ul style="list-style-type: none"> - The professor explains the acceptance and quality control criteria used in toxicological analyses. - The professor explains the mathematical calculations required for the evaluation of the different validation parameters according to the different regulatory frameworks of application. - Students perform validation exercises and interpret acceptance criteria. - The teacher gives feedback to the student on the exercises performed. - Accredited activity 8. Students individually respond to a written assessment of the topics reviewed in steps 1 through 4. | <p>The sample for toxicological analysis.</p> <p>Variables influencing analytical results.</p> <p>Quality assurance standards for toxicological analysis.</p> <p>Results report.</p> | <ul style="list-style-type: none"> ▪ MS Teams platform. ▪ Electronic exercise booklet. ▪ Electronic spreadsheet. ▪ R statistical software. |

7. Integral evaluation of processes and products:

| EVIDENCE | | % |
|------------------------------|---|------------|
| Evidence 1 | Documentary research report on the first phase of the toxic phenomenon. | 2 |
| Evidence 2 | Comparative table of toxicokinetics. | 2 |
| Evidence 3 | Comparative table of the mechanisms of toxicity. | 2 |
| Weighting activities 1 and 2 | First-order and zero-order kinetics laboratory practice exercise. | 2 |
| Evidence 4 | Toxic risk analysis investigation report. | 2 |
| Accredited activity 3 | Written evaluation of stage 1. | 15 |
| Evidence 5 | Comparative table of the regulatory framework applicable to different fields of toxicology. | 2 |
| Accredited activity 4 | Research report on the analysis of poisoning cases in application areas. | 2 |
| Evidence 6 | Proposal for sample collection, transport and storage for toxicological analysis. | 2 |
| Evidence 7 | Interpretation of presumptive and confirmatory analysis. | 2 |
| Accredited activity 5 | Presumptive analysis in different matrices. | 2 |
| Accredited activity 6 | Laboratory practice of quantification of toxic substances in different matrices. | 2 |
| Evidence 8 | Comparative table of the different validation parameters, indicators and acceptance criteria. | 2 |
| Accredited activity 7 | Written evaluation of stage 2 AND 3. | 15 |
| Evidence 9 | Interprets validation and sample analysis results. | 2 |
| Accredited activity 8 | Written evaluation of stages 1 to 4. | 24 |
| | CIP | 20 |
| TOTAL | | 100 |

8. Course integrative project/product:

Proposal for conducting a toxicological analysis in compliance with the applicable regulatory framework, considering the validation and interpretation of results.

9. Sources of support and consultation:

- Huerta, S. Environmental, clinical and daily toxicology. Basis and case studies (2022).
- 2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (Text with EEA relevance) (notified under document number C(2002) 3044).
- Albert, L. A. (2014). Curso básico de toxicología ambiental. Mexico City: Editorial Limusa S.A. de C.V.
- Albert, L. A., & Jacott, M. (2015). Toxic Mexico: chemical emergencies. Mexico City: Siglo XXI Editores.
- Caméan, A. M., & Repetto, M. (2006). Food Toxicology. Spain: Díaz de Santos.
- Flanagan, R. J., Taylor, A., & Watson, I. (2008). Fundamentals of Analytical Toxicology. Great Britain: John Wiley & Sons Ltd.
- Guide for metrological traceability of values assigned to calibrators and control materials used by the clinical laboratory/January 2009 Issue date 2009-01-16, effective date 2009-01-21, revision 01.
- Guide for the validation and verification of quantitative examination procedures used by the clinical laboratory/March 2008. Date of issue 2008-04-15, effective date 2008-07-01, revision 00.
- Technical Guide on Traceability and Uncertainty in GC and HPLC/April 2008 Date of issue 2008-04-30, effective date 2008-05-15, revision 01. CENAM.
- Technical Guide on Traceability and Uncertainty in Chemical Measurements using Atomic Absorption and Inductively Coupled Plasma Atomic Emission Spectrophotometry/April 2008 Issue date 2008-04-30, effective date 2008-05-15, revision 01.
- Klassen, C., & Watkins, J. (2015). Casarett & Doull's Essentials of Toxicology (3^a ed.): McGraw-Hill Education.
- MOOC Learning Toxicology through Open Educational Resources. (2018). Retrieved from <http://moodle.toxoer.com/>.
- NOM-127-SSA1-1994, Environmental health. Water for human use and consumption. Permissible quality limits and treatments to which water must be subjected for its potabilization (Modification of the year 2000).
- Repetto, M., & Repetto, G. (2009). Toxicología fundamental (4^a ed.). Ediciones Díaz de Santos, S.A.
- Official Mexican Standard NOM-004-ZOO-1994, fat, liver, muscle and kidney in poultry, cattle, goats, deer, horses, sheep and pigs. Toxic residues. Maximum permissible limits and sampling procedures.
- NORMA Oficial Mexicana NOM-047-SSA1-2011, Salud ambiental-Índices biológicos de exposición para el personal ocupacionalmente expuesto a sustancias químicas.
- Peters, F. T., & Maurer, H. H. (2002). Bioanalytical method validation and its implications for forensic and clinical toxicology - A review. Accreditation and Quality Assurance, 7(11), 441-449. doi:10.1007/s00769-002-0516-5.

- Redalyc (2018). Sistema de Información Científica Redalyc Red de Revistas Científicas de América Latina y el Caribe, España y Portugal. Retrieved from <http://www.redalyc.org/revista.oa?id=919>.
- Repetto, G., Moreno, I. M., Peso, A. d., Repetto, M., & Cameán, A. M. (2001). The search for toxicological information: a practical learning module. *Revista de Toxicología*, 18(2), 92-98.
- Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification as regards maximum residue limits in foodstuffs of animal origin (Text with EEA relevance).
- Repetto, M., & Repetto, G. (2009). *Toxicología fundamental* (4^a ed.): Ediciones Díaz de Santos, S.A.
- SANTE/11813/2017 Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed.
- Scientific Working Group for Forensic Toxicology (SWGTOX) Standard Practices for Method Validation in Forensic Toxicology (2013). *Journal of Analytical Toxicology*, 37(7), 452-474. doi:10.1093/jat/bkt054.
- The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics (1998) EuraChem.
- The Role of and the Place of Method Validation in the Quality Assurance and Quality Control (QA/QC) System. *Critical Reviews in Analytical Chemistry*, 37:173-190, 2007 .