
# ENGLISH FOR

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# Pharmaceutical Area

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# O vocabulário que toda a Área Farmacêutica deve dominar:

**Orientação:**

1º Imprima esse documento;

2º Destaque com caneta "marca-texto" apenas as palavras que você desconhece;

3º Leia a coluna *meaning* para descobrir o significado e evite usar tradutores;

4º Construa frases com aplicação das novas palavras que você está aprendendo. Se precisar de inspiração, use o www.businessdictionary.com. Faça isso por meio da escrita e não da digitação, pois isso potencializa o armazenamento do novo conhecimento na memória de longo prazo

Bons estudos!

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*Exemplos explicados na videoaula*

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**Português – Inglês**

☑ **1 Receita: Prescription**

*"I surely am not encouraging its use without a prescription!"*

*"Certamente que eu não estou recomendando tomar sem uma receita!"*

☑ **2 Prazo de validade: Expiry date**

*"Store at room temperature, use before the expiry date indicated on the label."*

*"Conservar à temperatura ambiente e utilizar antes do prazo de validade indicado no rótulo."*

☑ **3 Dose terapêutica: Therapeutic dose**

*"It has no side effects if taken at the recommended therapeutic dose for short periods of time."*

*"Não tem efeitos colaterais se tomado na dose terapêutica recomendada por curtos períodos de tempo."*

☑ **4 Antitussígenos: Antitussives**

*“As regards mucolytics and antitussives, their regular use is not recommended.”*

*“Quanto aos mucolíticos e antitussígenos, seu uso regular não é recomendado.”*

☑ **5 Anti-histamínicos: Antihistamines**

*“Do not use antihistamines for children unless a doctor recommends them.”*

*“Não use anti-histamínicos em crianças, a menos que um médico os recomende.”*

☑ **6 Equivalência terapêutica: Therapeutic equivalence**

*“All generic pharmaceutical products must demonstrate their therapeutic equivalence with the reference products.”*

*“Todos os produtos farmacêuticos genéricos devem demonstrar sua equivalência terapêutica com os produtos de referência.”*

☑ **7 Ensaio clínico: Clinic trial**

*“The clinical trial showed that the medication was effective.”*

*“O ensaio clínico mostrou que o medicamento foi eficaz.”*

☑ **8 Substâncias regulamentadas: Controlled substances**

*“The export of controlled substances or products containing controlled substances should be subject to authorisation.”*

*“A exportação de substâncias controladas ou produtos que contenham substâncias controladas deve ser sujeita a autorização.”*

☑ **9 Nome genérico ou Denominação comum: Non-proprietary name**

*“Prescriptions usually adopt the non-proprietary name of pharmaceutical active principles.”*

*“As prescrições geralmente adotam o nome genérico dos princípios ativos farmacêuticos.”*

☑ **10 Antipirético: Antipyretics**

*“He had high fever not resolved with antipyretics followed by dizziness and dyspnea.”*

*“Apresentava febre alta não resolvida com antipiréticos, seguida de tontura e dispneia.”*

☑ **11 Pomadas: Ointments**

*“Both eye irritation and redness are helped with lubricating eye drops and eye ointments.”*

*“Tanto a irritação quanto a vermelhidão dos olhos são amenizadas com colírios e pomadas lubrificantes para os olhos.”*

☑ **12 Contraindicação: Contraindication**

*"Before beginning the treatment, a medical check-up is performed to exclude any possible contraindication."*

*"Antes de iniciar o tratamento, é realizado um check-up médico para descartar qualquer contraindicação possível."*

☑ **13 Patilha: Lozenge**

*"She offered me a lozenge when the dust irritated my throat."*

*"Ela me deu uma pastilha quando a poeira irritou minha garganta."*

☑ **14 Antidepressivo: Antidepressant**

*"For the same reason, the use of antidepressants is not indicated in his case."*

*"Pelo mesmo motivo, o uso de antidepressivos não é indicado no caso dele."*

☑ **15 Remédio Homeopático/Alopático: Homoeopathic/Allopathic medicine**

*"Homoeopathic medicines have now assumed the same standing as allopathic medicines."*

*"Os medicamentos homeopáticos já assumiram a mesma importância dos medicamentos alopáticos."*

☑ **16 Pílula do dia seguinte: Morning-after pill**

*"Some say the morning-after pill is clearly not a form of prevention; it is quite simply an early abortion."*

*"Alguns dizem que a pílula do dia seguinte claramente não é uma forma de prevenção; é simplesmente um aborto precoce."*

☑ **17 Fraldas descartáveis: Disposable nappies (UK)/Disposable diapers (USA)**

*"A common disposable nappy takes 450 years to decompose, not very friendly for the future of our planet."*

*"Uma fralda descartável comum leva 450 anos para se decompor, o que não é muito amigável para o futuro do nosso planeta."*

☑ **18 Uso profilático: Prophylactic use**

*"This is used for all acute joint diseases, with excellent results as prophylactic use."*

*"É usado para todas as doenças articulares agudas, com excelentes resultados como uso profilático."*

☑ **19 Medicamentos genéricos: Generic drugs**

*“Prices of generic drugs have soared over the past months.”*

*“Os preços dos medicamentos genéricos dispararam nos últimos meses.”*

☑ **20 Resposta imune: Immune response**

*“Depending on the host immune response, this can lead to autoinfection and hyper infection.”*

*“Dependendo da resposta imune do hospedeiro, isso pode levar à autoinfecção e hiper infecção.”*

☑ **21 Doença pandêmica: Pandemic Disease**

*“With many parents refusing to vaccinate their children, another pandemic disease may soon plague the world.”*

*“Com muitos pais se recusando a vacinar seus filhos, outra doença pandêmica pode em breve assolar o mundo.”*

☑ **22 Estudos pré-clínicos: Preclinical studies**

*“Preclinical studies were performed and received critical input from independent researchers.”*

*“Estudos pré-clínicos foram realizados e receberam contribuições críticas de pesquisadores independentes.”*

☑ **23 Inibidores da ECA: ACE inhibitors**

*“Medications such as ACE inhibitors may both effectively lower blood pressure and protect the kidneys.”*

*“Medicamentos como os inibidores da ECA podem reduzir efetivamente a pressão arterial e proteger os rins.”*

☑ **24 Enjoo de movimento (Cinetose): Motion sickness**

*“The reason that people feel disinclined towards 3D is that it makes it easy for some people to get motion sickness.”*

" A razão pela qual as pessoas não gostam do 3D é que é fácil para algumas pessoas terem enjoo de movimento."

☑ **25 Insuficiência cardíaca: Heart failure**

*“This is also used to manage heart failure or improve survival after a heart attack.”*

*“Também é usado para controlar a insuficiência cardíaca ou melhorar a sobrevida após um ataque cardíaco.”*

*Conteúdo adicional*

Agora confira um glossário bem completo com 182 palavras para profissionais da Área Farmacêutica em inglês.

A

ACCEPTANCE CRITERIA: The specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan that are necessary for making a decision to accept or reject a lot or batch of raw material, intermediate, packaging material, or active pharmaceutical ingredient. This term can also be applied to validation.

ACTUAL YIELD: The quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular API or intermediate.

ACTIVE INGREDIENT: Any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to effect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

ACTIVE PHARMACEUTICAL INGREDIENT (API): Any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body of humans or other animals. APIs include substances manufactured by processes such as (1) chemical synthesis; (2) fermentation; (3) recombinant DNA or other biotechnology methods; (4) isolation/recovery from natural sources; or (5) any combination of these processes.

ANALYTICAL METHODS VALIDATION: The process by which it is established, by laboratory studies, that the performance characteristics of the method meet the requirements for the intended analytical applications.

APPROVAL: Once a country's regulatory authority (for example, the Food and Drug Administration in the United States) approves a new drug application, the new medicine becomes available for physicians to prescribe. The manufacturing company must continue to submit periodic reports to the regulatory authority, including any cases of adverse reactions and appropriate quality control records. For some medicines, the regulatory authority may require additional studies to evaluate long-term effects.

B

BATCH: A specific quantity of an intermediate or API intended to have uniform character and quality, within specified limits, and produced according to a single manufacturing order during the same cycle of manufacture. A batch may also mean a specific quantity of material or API processed in one process or series of processes so that it could be expected to be homogenous.

BIOLOGIC ACTIVE PHARMACEUTICAL INGREDIENT: A material originating from a biological manufacturing process intended to furnish pharmacological activity or other direct effect in the cure, treatment, or prevention of disease or conditions of human beings.

BIOLOGIC PRODUCT: Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or conditions of human beings.

BRAND-NAME DRUG: A drug that is sold under the unique, trademarked name selected by the manufacturer rather than under its chemical name.

C

CALIBRATION: The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a traceable standard over an appropriate range of measurements.

CHEMICAL REACTION: A process that involves a chemical transformation of a starting material or intermediate to form a new compound (e.g., bond formation, oxidation, reduction).

CLEANING AGENT: Any material used to clean process equipment, utensils, and storage vessels. These may include soaps, detergents, surfactants, alkalis, acids, or other materials, such as organic solvents, if the solvent is specifically used for cleaning and is not a solvent used in the next processing step.

CIP: CLEAN IN PLACE is a method of cleaning installed pipe and equipment without having to dismantle or move the pipe and equipment. However, provisions should be made for partial disassembly or for personnel access for purposes of cleaning validation to facilitate inspection and sampling of inner product surfaces for possible residue or contaminates.

CLINICAL: Denotes the symptoms and course of a disease as distinguished from the laboratory findings or anatomical changes.

CLINICAL INVESTIGATOR: Experienced clinical researcher who implements a clinical study protocol with patients.

CLINICAL PHARMACOLOGIST: One who has undergone training in basic pharmacology of therapeutic agents in the prevention, treatment and control of disease in man.

CLINICAL RESPONSE: Any response by a patient to therapy. A positive response can be either complete, in which all signs or symptoms of the disease improve or partial, in which at least one half of the signs or symptoms of a disorder improve and no new signs appear.

CLINICAL TRIAL or CLINICAL STUDY: Testing in which preventive, diagnostic, or therapeutic agents are given to a human population under controlled conditions to determine the agents' safety and effectiveness. This systematic investigation tests the effects of materials or methods, according to a formal study plan (that is, a protocol), usually in subjects having a particular disease or class of diseases. These trials are conducted to satisfy the regulatory requirements to obtain marketing approval for a new drug or for a new indication for a drug previously approved for marketing. In the United States, must be under an approved investigational new drug application, under the guidance of an Institutional Review Board, and in accordance with the Food and Drug Administration's (FDA) rules on human studies and informed consent of participants. These studies are conducted in three phases: Phase I, Phase II and Phase III.

COMMISSIONING: Commissioning can be subdivided into three major activities; installation, operation and performance qualifications. It is a formal, written procedure to the planning, executing and documenting of facility validation. This process may include environmental compliance checks, verification of personnel protection equipment and qualification of containment systems as well as validation of systems related to cGMP regulations.

COMPONENT: Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

CONCURRENT VALIDATION: A subset of prospective validation in which API batches are released for distribution, based on extensive testing, before completion of process validation. Once data from additional batches produced under replicated conditions show uniformity, the process may be considered validated.

CONTAINMENT: Achieving a level of control over a raw material, intermediate, or API that provides proper protection of these materials from external contamination and cross-contamination.

CONTAMINATION: The introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or API (e.g., occurring during production, sampling, packaging or repackaging, storage or transport).

CONTINUOUS PRODUCTION: A process in which a material is continuously produced in a step or series of steps. In a continuous process, the batches of raw materials and the process parameters can be statistically, but not absolutely, correlated to the material produced in a given period of time.

CONTROLLED STUDY or CONTROLLED TRIAL: Clinical testing in which one group of subjects is used as a standard of comparison to determine the usefulness of a new medical approach. In a controlled study, doctors give the new drug being tested to one group of subjects, called the "treatment group." They give another drug, or no drug, to a second group of people under the same conditions. This group is often called the "control group." Researchers then compare the results of the two groups.

CRITICAL PROCESS PARAMETERS: Process parameters that must be controlled within established operating ranges to ensure that the API or intermediate will meet specifications for quality and purity.

CRITICAL PROCESS STEPS: Process steps that must be controlled within established operating ranges to ensure that the API or intermediate will meet specifications for quality and purity.

CROSS-CONTAMINATION: A contamination of a material or product with another material or product.

D

DEVELOPMENT REPORT: A report that summarizes the major stages of API development from early stages through large-scale manufacturing.

DOSAGE FORMULATION: The form in which a drug is produced. Pharmaceutical companies use many methods of drug delivery, including oils, gels, creams and sprays; capsules and tablets; injects; implants; suppositories; and liquids and syrups.

DOSAGE STRENGTH: Amount of active drug contained in a particular formulation; for example 50, 100, or 500 milligrams.

DOUBLE-BLIND STUDY: A scientific study in which neither the subject (patients) nor the investigators (treating physicians) know who is receiving the experimental treatment and who is receiving a placebo (a control or "sugar pill").

DRUG: As defined in Section 201(g)(1) of the Act means (a) articles that are recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; and articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

DRUG DELIVERY: The process by which a formulated drug is administered to the patient. Traditional methods have been orally or by injection. Newer methods include through the skin by application of a transdermial patch, or across the nasal membrane by administration of a specially formulated nasal spray.

DRUG INTERACTION: Modification of the effect of one drug by another in a way that diminishes, negates or enhances the effectiveness or safety of one or both drugs.

DRUG PRODUCT: A finished dosage form, for example, a tablet, capsule or solution, that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an API but is intended to be used as a placebo.

E

EFFICACY: Measure of the therapeutic effectiveness of a drug.

ELECTROPOLISHING: The electrochemical method of removing metal (usually stainless steel) from a surface. More specifically, it is the anodic dissolution of metal in the presence of an electrolyte and an

imposed current potential. This process creates a continuous film of chromium rich oxide on the affected surface. The resulting film provides the following benefits:

1. It provides an excellent passive barrier between the body of the material (i.e. internal or external pipe wall) and the contained fluid, or external environment, enhancing corrosion resistance.

2. Provides for improved cleanability and sterilization aspects.

3. Allows for improved quality control by exposing defects in welds and base material.

4. Avoids the surface tension caused when mechanical polishing is used.

ELIGIBILITY CRITERIA: Key facts about a person's health that make a patient right, or not right, for a certain research study. Examples of these facts include: a person's age, what symptoms of the illness he or she has, results of certain laboratory tests, a person's overall health, and past treatments. Both the "must-have" and the "can't-have" check lists help doctors get clear research results about whom a new drug will help, not help, or harm.

ENANTIOMERS: Compounds with the same molecular formula as the API, which differ in the spatial arrangement of atoms within the molecule and are non-superimposable mirror images.

ETHICAL DRUG: A drug that primarily sold only through physicians and pharmacists, rather through direct selling to customers. Sometimes referred to as a "prescription-only" drug.

EXPECTED YIELD: The quantity of API or intermediate or the percentage of theoretical yield anticipated at any appropriate phase of production based on data from process development or process validation.

EXPIRY/EXPIRATION DATE: The date (usually placed on the containers/labels of an API) designating the time during which the API is expected to remain within established shelf-life specifications if stored under defined conditions and alter which it should not be used.

EXTRANEOUS SUBSTANCE: An impurity arising from any source extraneous to the manufacturing process.

F

FIBER: Any particulate contaminant with a length at least three times greater than its width.

G

GANG-PRINTED LABELING: Labeling derived from a sheet of material on which more than one item of labeling is printed.

GENERIC DRUG: A broad term for chemically equivalent drugs that are available from multiple manufacturers. Commonly used to refer to products, other than then innovator's, that are sold under the universal chemical name for the drug.

GMP (cGMP): (current) Good Manufacturing Practice as put forth in various guidelines through the combined efforts of the FDA, U.S. Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) and Center for Veterinary Medicine (CVM). These guidelines, without providing specific methodology, identify the expectations of the FDA in regard to the design, construction and operation of facilities intended for the manufacturing, processing, packing or holding of API's.

GRIT: In reference to the polishing of stainless-steel pipe: Grit is one method of determining or specifying a degree of smoothness or surface roughness required. Initially a desired smoothness for the inside or outside of pipe was specified in polish numbers such as #4 or #7. However, this system of specifying surface roughness provided for too broad a range of roughness. Grit numbers have essentially replaced polish numbers in an effort at providing more specific requirements. For example: a #4 polish could vary from an 80 grit to a 150 grit finish; a #7 polish could vary from a 180 grit to a 320 grit finish. The industry is now adopting an even more specific method of determining surface roughness. The surface is specified in micro inches or microns and measured with a profilometer. The surface roughness is measured or specified as either of two arithmetic derivations: Rq – root mean square or Ra – arithmetic mean. In utilizing a quantitative measuring technique, all of the variables inherent in polishing are eliminated. An end user can now specify a specific surface roughness. For example by specifying 25 m in Ra for a surface roughness the vendor now has to determine the best way to achieve that very specific finish requirement.

I

IDENTIFIED IMPURITY: An impurity for which a structural characterization has been achieved.

IMPURITY: Any component of an API that is not the entity defined as the API.

IMPURITY PROFILE: A description of the identified and unidentified impurities present in an API.

INACTIVE INGREDIENT: Any component other than an "active ingredient".

INDICATIONS: Treatments that a drug will address. Approved indications are those that government regulators have accepted based on clinical testing. Only these indications may be marketed and offered for sale to the public, although physicians may prescribe drugs for unapproved indications according to their professional judgment.

INFORMED CONSENT: The process by which patients learn about and document their understanding of the purpose and procedures of a clinical trial and their agreement to participate in that trial.

IN-PROCESS CONTROLS: Testing and activities performed during production to monitor and, if necessary, adjust the process.

IN-PROCESS MATERIAL: Any material manufactured, blended, or derived by chemical reaction that is produced for, and used in, the preparation of an API.

INSTALLATION QUALIFICATION: Establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

INSTITUTIONAL REVIEW BOARD (IRB): A group of doctors, science experts, clergy and others who review and approve the performance of each clinical study at their institution. Each hospital doing the research must have a review board. This board makes sure that the study protects patient safety in light of the potential benefit that it may bring. IRB is the term used in the United States, but the committee is more frequently referred to as an "ethics committee" in other markets.

INTERMEDIATE: A material produced during steps in the synthesis of an API that must undergo further molecular change or processing before it becomes an API.

ISO: International Standards Organization

INVESTIGATIONAL NEW DRUG (IND) APPLICATION: The document that a sponsor (usually a drug company) must submit to the FDA before beginning testing of a new drug on humans. This IND application contains the plans for the clinical for the clinical studies and gives a complete picture of the drug, including its structural formula, animal test results, and manufacturing information. The IND application contains information resulting from several years of research and testing.

IN VITRO: Latin phrase meaning "in glass". It refers to a process, test or procedure in which something is measured, observed or produced outside a living organism after extraction from the organism. In vitro studies are carried out in animals or humans.

IN VIVO: Latin phrase meaning "in the body". Referring to a biological process or experiment occurring or carried out in the living organism. In vivo studies are carried in animals or humans.

L

LABELING: Printed materials that accompany a prescription drug when shipped in interstate commerce.

LIGAND: An agent with a strong affinity to a metal ion.

LOT: A batch, or a specific identified portion of a batch having uniform character and quality within specified limits. For an API produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that ensures its having uniform character and quality within specified limits.

LOT NUMBER (CONTROL NUMBER, or BATCH NUMBER): Any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of an API or other material can be determined.

M

MANUFACTURE, PROCESSING, PACKING, or HOLDING: All operations used to manufacture an API to include packaging and labeling operations, testing, and quality control of an API.

MOTHER LIQUOR: The residual saturated liquid that remains after crystallization. A mother liquor may contain unrecovered or unreacted starting materials, intermediates, the API and/or impurities.

N

NEW DRUG APPLICATION (NDA): A formal application to the FDA for approval to market a new drug product. When the investigational phase of a drug is completed, the manufacturer gathers together the results of all studies and submits them to the FDA in a New Drug Application. This application is reviewed in detail by a team of reviewers. The purpose of the NDA is to determine whether the drug meets the statutory standards for safety, effectiveness, labeling and manufacturing.

NEW MOLECULAR ENTITY: The designated therapeutic moiety (API) in a dosage form that has not been approved for marketing in the United States (also referred to as a new chemical entity or new drug substance). It may be a complex, simple ester, or salt of a previously approved API.

NON-FIBER-RELEASING FILTER: Any filter which, after any appropriate treatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.

O

OPERATIONAL QUALIFICATION: Operational Qualification (OQ) is the documented verification that the identified system or subsystem performs as intended throughout all operating ranges of pressure and temperature.

OVER-THE-COUNTER DRUG (also OTC drug or nonprescription drug: Any drug that can be bought without a prescription. Distribution of nonprescription drugs is unrestricted, and may be sold , for example, in grocery stores and pharmacies.

P

PASSIVATION: a process in which a diluted nitric acid solution is used to remove discoloration from weld areas as well as dissolve and flush out all iron particulates and residue. These deposits may be the result of being improperly cleaned and stored at the mill, the fab shop or the site. In the case of piping systems the process involves circulating the heated nitric acid solution for a period of time followed by a thorough flushing with potable or purified water. A test is then done to determine if free iron can be detected. When the test determines that the system is clear of any contaminants potable or purified water is flushed through the system until the pH and conductivity/resistivity of the effluent water samples are the same as that of the influent.

PERCENTAGE OF THEORETICAL YIELD: The ratio of the actual yield (at any appropriate phase of the manufacture, processing, or packing of a particular drug product) to the theoretical yield (at the same phase), stated as a percentage.

PERFORMANCE QUALIFICATION: Performance Qualification (PQ) provides documented evidence that the integrated system or process is capable of consistently producing the intended product in a high quality and safe manner.

PHARMACEUTICAL: Referring to pharmacy or medical drugs; any therapeutic product used in medicine. A pharmaceutical is a drug derived from organic or inorganic chemicals and used to treat a wide range of medical conditions.

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA): Formerly known as PMA, this is a nonprofit scientific and professional organization of more than 100 firms that discover, develop and produce prescription drugs and biological products in the United States. The Association's members produce most of the prescription drugs used in the United States and about half of the free world's supply of prescription drugs.

PHARMACODYNAMICS: The study of drug action primarily in terms of drug structure, site of action, and the biochemical and physiological consequences of the action.

PHARMACOECONOMICS: Studies focusing on the total impact of the product or services on the health system. Pharmacoeconomics relies upon several economic methodologies, including cost-benefit, cost-effectiveness and cost-utility analysis.

PHARMACOKINETICS: The study of how the body handles a drug, with particular emphasis on the time required for absorption, duration of action, distribution through the body and method of excretion.

PHARMACOLOGY: The science that deals with the study of drugs in all aspects, including drugs' mechanisms of action.

PHASE I CLINICAL TRIALS: Small studies involving healthy volunteers to assess drug tolerability (safety), metabolism, structure-activity relationships, and mechanism of action in humans.

PHASE II CLINICAL TRIALS: Tests designed to determine, under controlled conditions, whether or not a drug has therapeutic benefit (efficacy) with individuals having the target disease (patients) and document eventual short-term side effects (adverse reactions) and risks associated with the drug.

PHASE III CLINICAL TRIALS: Larger studies to gain confirmatory efficacy and safety data in a broad base of patients. The compound is given to patients according to a protocol that reflects the way the compound is expected to used when it is on the market. These expanded studies generally include hundreds of site locations and involve thousands of patients.

PHASE IIIB CLINICAL TRIALS: Trials that come after the new drug application is filed, but before the product is approved for marketing. The goal of these studies is to provide additional data for marketing support and the ultimate product launch, including conducting country-specific studies to support local needs.

PHASE IV HUMAN TESTING OR POST-MARKETING SURVEILLANCE: Tests conducted after marketing to obtain additional data regarding product safety and efficacy over the life of a drug. The pharmaceutical is on the market and generating revenue during this period.

PHYSICAL MANIPULATION: A process other than a chemical reaction that may change the purity or the physical properties of the material, including but not limited to crystallization, recrystallization, gel filtration, chromatography, milling, drying, or blending.

PILOT SCALE: The manufacture of an API on a reduced scale by processes representative of and simulating those to be applied on a larger commercial manufacturing scale.

PLACEBO: Inactive agent without therapeutic value used in controlled studies to determine the efficacy of the potential therapeutic agent against which it is being compared. The placebo is made to look exactly like the therapeutic agent.

POLISHING (As it pertains to sanitary stainless steel piping): The process of resolving the roughness of the outside and/or the inside wall of stainless steel pipe by one of two methods:

1. grit polishing – a manual method of using an abrasive pad (sandpaper) with varying, specified degrees of fineness to achieve a specified degree of smoothness.

2. electropolish – an electrochemical method of removing metal from a surface. (For further definition regarding surface roughness, grit determination and their correlation see "grit".)

POLYMORPHISM: The occurrence of different crystalline forms of the same API.

POTENTIAL IMPURITY: An impurity that, from theoretical considerations, may arise from or during manufacture. It may or may not actually appear in the API.

PRECLINICAL RESEARCH: Group of studies that test a drug on animals and other nonhuman test systems. This testing is conducted to gain more data about the pharmaceutical's efficacy and safety before tests on humans can begin.

PRIMACY REFERENCE STANDARD: A particular portion, lot or batch of an API or intermediate that has been shown by an extensive set of analytical tests to be of the highest purity. This standard may be purchased from a recognized source or may be prepared by independent synthesis or by further purification of existing production material.

PROCESS PERFORMANCE QUALIFICATION: Establishing confidence that the process is effective and reproducible.

PROCESS VALIDATION: Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics.

PRODUCT PERFORMANCE QUALIFICATION: Establishing confidence through appropriate testing that the finished product produced by a specified process meets all release requirements for functionality and safety.

PROPHYLACTIC TREATMENT: Preventative treatment or precautions to avoid disease; treatment intended to preserve health and prevent the spread of disease.

PROPRIETARY MEDICINES: Over-the-counter (nonprescription) medicines sold under a trademark and advertised to the general public.

PROSPECTIVE VALIDATION: Establishing documented evidence that a system does what it purports to do prior to the commercial distribution of a new API or an existing API made by a new or modified process.

PROTOCOL: Written documentation establishing strict and detailed guidelines and requirements for the proper execution of an activity designed to verify the proper installation or operation of a specific component, segment or system of a new or existing facility.

PURIFICATION PROCEDURE: A process, such as crystallization, distillation, or chromatography, intended to improve the purity of an API or intermediate.

Q

QUALIFICATION: The action of proving that any equipment or process works correctly and consistently and produces the expected results. Qualification is part of, but not limited to, a validation process, i.e., installation qualification (1Q), operation qualification (OQ), and performance qualification (PQ).

QUALIFICATION PROTOCOL: A Qualification Protocol (QP) is a written plan or procedure stating in sufficient detail how qualification will be achieved.

Included are specific qualification requirements for each equipment item, each system requirement, and product requirement. Each protocol should 26/08/2020 Terminology & Definitions in Pharmaceuticals : Pharmaceutical Guidelines stipulate test parameters as well as decision points on what constitutes acceptable test results. The written protocols should be based on the associated qualification procedures and should be step-by-step instructions to be used in the field to qualify equipment, instruments, materials, systems and subsystems, and should include data sheets to record critical data.

QUALITY ASSURANCE (QA): The sum total of the organized activities performed with the intent to ensure that all APIs are of the quality required for their intended use.

QUALITY CONTROL (QC) Unit: Any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

QUARANTINE: The status of materials isolated physically or by other effective means pending a decision on their subsequent use.

R

Ra (CLA): arithmetic mean roughness value. The arithmetical average of all absolute distances of the roughness profile R from the center line within the measuring length lm.

Rq (RMS): root mean square roughness value. (An alternative to Ra.) The RMS value of a profile calculated over a single sampling length, but can be expressed as the mean result of 5 consecutive sampling lengths.

raNGE FOR CRITICAL PROCESS PARAMETER: The range for each process parameter generally developed on laboratory-, pilot-, or plant-scale batches that encompasses values that are capable of producing intermediates and APIs having acceptable quality attributes.

RAW MATERIAL: Any ingredient intended for use in the production of APIs. These may include starting materials, process aids, solvents, and reagents.

REAGENT: A substance, other than a starting material or solvent, that is used in the manufacture of an API or intermediate.

RECOVERY: Any treatment of materials by a process intended to make them suitable for further use.

REPEATING A CHEMICAL REACTION: Adding fresh reagents or solvents to unreacted or base material and repeating a chemical reaction from its beginning. This excludes those situations where a chemical reaction is continued or extended in the same vessel with the addition of more solvent, to ensure completion of a reaction or increase the yield and/or purity of the API (e.g., continuation of a hydrogenation step).

REPRESENTATIVE SAMPLE: A sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

REPROCESSING: Introducing an intermediate or API that does not conform to standards or specifications, back into the process and repeating one or more steps that are part of the established manufacturing process (e.g., recrystallization using the same solvent).

RETEST DATE: The date when the API should be re-examined to ensure that it is still suitable for use.

RETEST PERIOD: The period of time during which the API can be considered to remain within specifications, and therefore acceptable for use in the manufacture of a given drug product, provided that it has been stored under defined conditions. After this period, the API should be retested for compliance with specifications before use.

RETROSPECTIVE CONCURRENT DRUG USE EVALUATION: One of three forms of evaluation of prescribing patterns to specifically determine the appropriateness of drug therapy. Retrospective drug use evaluation is conducted after the therapy has been completed. There are two other forms of drug use evaluation: concurrent (during the course of drug therapy) and prospective (before or at the time of despensing).

RETROSPECTIVE VALIDATION: Establishing documented evidence that a system does what it purports to do based on a review and analysis of historic information. It is normally conducted on an API already being commercially distributed and is based on accumulated production, testing, and control data.

REWORKING: Subjecting an intermediate or API that does not conform to standards or specifications, to one or more processing steps that are different from the established manufacturing process (e.g., recrystallizing with a different solvent).

RISK-BENEFIT RATIO: Relation between the risks and benefits of a given treatment or procedure. Institutional review boards located where the study is to take place determine whether the risks in a study are reasonable with respect to the potential benefits. The patient also decides if it is reasonable, in light of the risk-benefit ratio, to take part in the study.

RX: An abbreviation of the Latin word "recipere" which means "to take". The symbol is used at the beginning of a medical prescription.

S

SIDE EFFECT: Secondary and usually adverse effect, as from a drug or other treatment. For example, nausea is a side effect of some anticancer drugs.

SINGLE-BLIND STUDY: A study in which one party (either the patient or investigator) is unaware of what medication the patient is taking.

SOLVENT: Any liquid used as a vehicle for the preparation of solutions or suspensions in the synthesis of an API or intermediate.

STARTING MATERIAL: A material used in the synthesis of an API, which is incorporated as an element into the structure of an intermediate and/or of the API. Starting materials are normally commercially available and of defined chemical and physical properties and structure.

STRENGTH: (i) The concentration of the drug substance ( for example, weight/weight, weight/volume, or unit dose/volume basis) and/or, (ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

STUDY ARM: Patients in clinical trials are assigne to one part or segment of a study – a study "arm". One arm receives a different treatment from another.

SYSTEM QUALIFICATION: System Qualification (SQ) consists of the IQ/OQ documentation pertaining to all equipment, instruments, materials and subsystems within a specific system or unit operation, generally identified by a single Piping & Instrument Flow Diagram (P&ID).

T

THERAPEUTIC CATEGORY: Group of drugs intended to treat or cure a particular disease or related diseases. Several of these categories are antibiotics (drugs that prevent, inhibit or destroy

microorganisms), cardiovascular (drugs that treat diseases of the heart and blood vessels), hypnotics (drugs that induce sleep), and nonsteroidal anti-inflammatory drugs or NSAIDs (drugs used to treat pain, fever and swelling).

THEORETICAL YIELD: The quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular API or intermediate, based upon the quantity of components to be used, in the absence of any loss or error in actual production.

TOXIC IMPURITY: Impurities having significant undesirable biological activity.

TOXICOLOGY: Scientific discipline concerning the identification and effects of poisons and the treatment of poisoned individual.

TOXICOLOGY SAFETY AND TESTING: Group of tests to determine the potential risk of a compound to man and the environment. These studies involve the use of animals, tissue cultures and other test systems to examine dose level, frequency of administration, and duration on the dose-response pattern of the compound and its toxic side effects. Most toxicology and safety testing is conducted before its human introduction.

TRX: A measure of total prescriptions (new and refills) issued in a given time period.

U

UNIDENTIFIED IMPURITY: An impurity that is defined solely by qualitative analytical properties (e.g., chromatographic retention time).

V

VALIDATION: The procedure for establishing documented evidence that a specific system or facility is constructed and operates according to a predetermined set of specifications and guidelines.

VALIDATION PROTOCOL: A written plan stating how validation will be conducted while identifying specific acceptance criteria. For example, the protocol for a typical manufacturing process identifies processing equipment, critical process parameters/operating ranges, product characteristics, sampling and test data to be collected, number of validation runs, and acceptable test results.

W

WORKING STANDARD: An API, intermediate or other substance of established quality and purity, as shown by comparison to a primary reference standard, used as a reference for routine laboratory analysis.

OTHER DEFINITIONS :

AIRBORNE PARTICULATE COUNT (also referred to as TOTAL PARTICULATE COUNT)—Particles detected are 0.5 µm and larger. When a number of particles is specified, it is the maximum allowable number of particles per cubic meter of air (or per cubic foot of air).

AIRBORNE VIABLE PARTICULATE COUNT (also referred to as TOTAL AIRBORNE AEROBIC MICROBIAL COUNT)—When a number of microorganisms is specified, it is the maximum number of colony-forming units (cfu) per cubic meter of air (or per cubic foot of air) that is associated with a Cleanliness Class of controlled environment based on the Airborne Particulate Count.

ASEPTIC PROCESSING —A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package (containers/closures or packaging material for medical devices) and the transfer of the product into the container and its closure under microbiologic critically controlled conditions.

AIR SAMPLER —Devices or equipment used to sample a measured amount of air in a specified time to quantitate the particulate or microbiological status of air in the controlled environment.

AIR CHANGES —The frequency per unit of time (minutes, hours, etc.) that the air within a controlled environment is replaced. The air can be recirculated partially or totally replaced.

ACTION LEVELS —Microbiological levels in the controlled environment, specified in the standard operating procedures, which when exceeded should trigger an investigation and a corrective action based on the investigation.

ALERT LEVELS —Microbial levels, specified in the standard operating procedures, which when exceeded should result in an investigation to ensure that the process is still within control. Alert levels are specific for a given facility and are established on the basis of a baseline developed under an environmental monitoring program. These Alert levels can be modified depending on the trend analysis done in the monitoring program. Alert levels are always lower than Action levels.

BIOBURDEN —Total number of microorganisms detected in or on an article.

CLEAN ROOM —A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate Cleanliness Class. In addition, the concentration of microorganisms in the environment is monitored; each Cleanliness Class defined is also assigned a microbial level for air, surface, and personnel gear.

CLEAN ZONE —A defined space in which the concentration of airborne particles and microorganisms are controlled to meet specific Cleanliness Class levels.

CONTROLLED ENVIRONMENT —Any area in an aseptic process system for which airborne particulate and microorganism levels are controlled to specific levels, appropriate to the activities conducted within that environment.

COMMISSIONING OF A CONTROLLED ENVIRONMENT —Certification by engineering and quality control that the environment has been built according to the specifications of the desired cleanliness class and that, under conditions likely to be encountered under normal operating conditions (or worstcase conditions), it is capable of delivering an aseptic process. Commissioning includes media-fill runs and results of the environmental monitoring program.

CORRECTIVE ACTION —Actions to be performed that are in standard operating procedures and that are triggered when certain conditions are exceeded.

ENVIRONMENTAL ISOLATES —Microorganisms that have been isolated from the environmental monitoring program.

ENVIRONMENTAL MONITORING PROGRAM —Documented program, implemented through standard operating procedures, that describes in detail the procedures and methods used for monitoring particulates as well as microorganisms in controlled environments (air, surface, personnel gear). The program includes sampling sites, frequency of sampling, and investigative and corrective actions that should be followed if Alert or Action levels are exceeded. The methodology used for trend analysis is also described.

EQUIPMENT LAYOUT —Graphical representation of an aseptic processing system that denotes the relationship between and among equipment and personnel. This layout is used in the Risk Assessment Analysis to determine sampling site and frequency of sampling based on potential for microbiological contamination of the product/container/closure system. Changes must be assessed by responsible managers, since unauthorized changes in the layout for equipment or personnel stations could result in increase in the potential for contamination of the product/container/closure system.

FEDERAL STANDARD 209E — "Airborne Particulate Cleanliness Classes in Clean Rooms and Clean Zones" is a standard approved by the Commissioner, Federal Supply Services, General Service Administration, for the use of "All Federal Agencies." The Standard establishes classes of air cleanliness based on specified concentration of airborne particulates. These classes of air cleanliness have been developed, in general, for the electronic industry "super-clean" controlled environments. In the pharmaceutical industry, the Federal Standard 209E is used to specify the construction of controlled environment. Class 100, Class 10,000, and Class 100,000 are generally represented in an aseptic processing system. If the classification system is applied on the basis of particles equal to or greater than 0.5 µm, these classes are now represented in the SI system by Class M3.5, M5.5, and M6.5, respectively.

FILTER INTEGRITY —Testing that ensures that a filter functional performance is satisfactory [e.g., dioctyl phthalate (DOP) and bubble point test].

MATERIAL FLOW —The flow of material and personnel entering controlled environments should follow a specified and documented pathway that has been chosen to reduce or minimize the potential for microbial contamination of the product/closure/container systems. Deviation from the prescribed flow could result in increase in potential for microbial contamination. Material/personnel flow can be changed, but the consequences of the changes from a microbiological point of view should be assessed by responsible managers and must be authorized and documented.

MEDIA GROWTH PROMOTION —Procedure that references Growth Promotion under Sterility Tests á71ñ to demonstrate that media used in the microbiological environmental monitoring program, or in media-fill runs, are capable of supporting growth of indicator microorganisms and of environmental isolates from samples obtained through the monitoring program or their corresponding ATCC strains.

MEDIA FILL —Microbiological simulation of an aseptic process by the use of growth media processed in a manner similar to the processing of the product and with the same container/closure system being used.

OUT-OF-SPECIFICATION EVENT —Temporary or continuous event when one or more of the requirements included in standard operating procedures for controlled environments are not fulfilled.

PRODUCT CONTACT AREAS —Areas and surfaces in a controlled environment that are in direct contact with either products, containers, or closures and the microbiological status of which can result in potential microbial contamination of the product/container/closure system. Once identified, these areas should be tested more frequently than non-product-contact areas or surfaces.

RISK ASSESSMENT ANALYSIS —Analysis of the identification of contamination potentials in controlled environments that establish priorities in terms of severity and frequency and that will develop methods and procedures that will eliminate, reduce, minimize, or mitigate their potential for microbial contamination of the product/container/closure system.

SAMPLING PLAN —A documented plan that describes the procedures and methods for sampling a controlled environment; identifies the sampling sites, the sampling frequency, and number of samples; and describes the method of analysis and how to interpret the results.

SAMPLING SITES —Documented geographical location, within a controlled environment, where sampling for microbiological evaluation is taken. In general, sampling sites are selected because of their potential for product/container/closure contacts.

STANDARD OPERATING PROCEDURES— Written procedures describing operations, testing, sampling, interpretation of results, and corrective actions that relate to the operations that are taking place in a controlled environment and auxiliary environments. Deviations from standard operating procedures should be noted and approved by responsible managers.

STERILE FIELD —In aseptic processing or in other controlled environments, it is the space at the level of or above open product containers, closures, or product itself, where the potential for microbial contamination is highest.

STERILITY —Within the strictest definition of sterility, an article is deemed sterile when there is complete absence of viable microorganisms. Absolute sterility cannot be practically demonstrated without testing every article in a batch. Sterility is defined in probabilistic terms, where the likelihood of a contaminated article is acceptably remote.

SWABS —Devices provided that are used to sample irregular as well as regular surfaces for determination of microbial status. The swab, generally composed of a stick with an absorbent extremity, is moistened before sampling and used to sample a specified unit area of a surface. The swab is then rinsed in sterile saline or other suitable menstruum and the contents plated on nutrient agar plates to obtain an estimate of the viable microbial load on that surface.

TREND ANALYSIS —Data from a routine microbial environmental monitoring program that can be related to time, shift, facility, etc. This information is periodically evaluated to establish the status or pattern of that program to ascertain whether it is under adequate control. A trend analysis is used to facilitate decision-making for requalification of a controlled environment or for maintenance and sanitization schedules.

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