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GLOSSARY OF TERMS USED IN PHARMACEUTICS

(IUPAC Recommendations 2008)

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Abstract: This Glossary of Terms in Pharmaceutics is needed by practitioners in the field of pharmaceutics as this field fulfills an important and crucial role, different from the roles of other scientific disciplines involved in the drug-making process. The glossary contains 156 definitions used in pharmaceutics. These are related to various aspects of this discipline such as: 1) physicochemical characterization of pharmaceutical preparations and the active ingredients they contain; 2) unit operations used in the practice of pharmaceutics; 3) terms related to the various dosage forms; 4) terms related to the various modes and routes of drug delivery; 5) terms used in pharmacokinetics and biopharmaceutics in general, and additional miscellaneous terms. The field of pharmaceutics itself is of multidisciplinary nature as its practitioners come from a variety of disciplines, such as chemistry or various biological sciences, thus a glossary containing authoritative definitions would be useful for them. The terms used in pharmaceutics are rarely covered by existing glossaries, and in the cases they are, their definitions are often inappropriate for the field of pharmaceutics and require new or modified definitions to better fit the new context.

GLOSSARY OF TERMS

1 absolute bioavailability
Fraction of the administered dose of a drug from a *dosage form* absorbed intact into the *systemic* circulation.
See also *bioavailability, relative availability*.

2 absorption (in pharmaceutics)
Process by which a drug moves from its site of administration to its site of action in the body.

3 active transport of drugs
Carriage of a solute across a biological membrane from low to high concentration which requires the expenditure of (metabolic) energy.
[1]

4 adjuvant
Additive with no pharmacological action, used in the *formulation* of *dosage forms*.

Note: this term is not related to adjuvant in vaccination.

5 administration of drugs, ocular route
Administration of drugs through the eye.

Note 1: Drugs used to treat eye disorders can be administered as liquid or semi-solid *dosage forms*. Solid inserts, which release the drug in slow-release pattern, are also available.
Note 2: Ocular drugs are almost always used for their local effects. Some drugs produce a local effect after they are absorbed through the cornea and conjunctiva. Some of these drugs then enter the bloodstream and may have unwanted or wanted *systemic* effects.
See also *administration.*

6 administration of drugs, oral route
Administration of drugs through the mouth.

Note 1: This is the most convenient and popular administration route.
Note 2: Per-oral products can be *powder*s, *granule*s, un*coat*ed or *coat*ed *tablet*s, *capsule*s and liquids (solutions, *emulsion*s and suspensions). Liquids for oral use may contain antimicrobial preservatives and are supplied in multi-dose or single dose containers.
See also *administration.*

7 administration of drugs, parenteral route
Administration of drugs via means not involving the alimentary canal.

Note 1: *Parenteral* routes may be employed whenever enteral routes are contraindicated or inadequate.
Note 2: Parenteral administration includes some conventional (*intravenous*, *intramuscular*, *subcutaneous*) and some special (intradermal, intraventricular etc.) routes.
Note 3: Parenteral products can be solutions, suspensions and *emulsion*s. They are presented as *sterile* products. It is commonly used to imply administration by *injection* or infusion.
See also *administration.*

8 administration of drugs, rectal route
Administration of drugs through the rectum.

Note 1: Products may be solid (*suppositories*) or liquid unit dosage preparations, or *cream*s, *ointment*s, and gels.
Note 2: This is an important way of administering a medicinal product that may not be tolerated orally, especially in pediatrics and geriatrics or when the patient has an infection of the GI tract; or when the drug is less suited for *oral* administration because of side effects, bad taste or enzymatic degradation.
Note 3: The *rectal* route has several drawbacks. These can be, in addition to psychological aversion, slow and incomplete *absorption*, and ~~it may be~~ inadequacy ~~te~~ where rapid *adsorption* and high plasma levels are required.
See also *enemas, administration.*

9 administration of drugs, respiratory route
Introduction of products to the lower *respiratory* tract in order to obtain a local or *systemic* effect.

Note: Products usually deliver the active substance in the form of *aerosol* droplets or solid particles (*powder*s). Preparations are supplied in multi-dose or single dose containers.
See also *inhalation therapy*, *administration.*

10 administration of drugs, topical route
Administration of drugs on surfaces of the body.

Note 1: *Topical* products produce pharmacological effects at or near the point of application, such as the skin, eyes, nose, throat, ears and vagina, etc.
See also *administration.*

11 administration of drugs, transdermal route
diadermic administration
percutaneous administration
transcutaneous administration
transdermic administration
Introduction of products through unbroken skin by means of a specific *drug delivery system* (such as a patch containing a semisolid *formulation* of the drug) for *systemic* and/or prolonged drug effect.
See also *administration.*

12 administration of drugs, vaginal route
Introduction of products into the vagina normally for local effect.

Note: *Vaginal* preparations may be liquids (solutions, foams), semi-solid (gels, *creams*, *ointments*), and solids (*tablet*, *capsules*).
See also *administration.*

13 adsorption (in pharmaceutics)
In pharmaceutics it means: Binding of the therapeutic substance to an insoluble adsorbent in order to extend its rate of release or elimination.

14 aerosol
1. Dispersion of solid or liquid particles (typically smaller than 50 micrometer, in gas phase. Usually, these preparations are used for applications to the skin or into accessible body cavities (lungs). Examples of active ingredients are antiseptics, antibiotics, bronchodilators, local anesthetics, corticosteroids or dermatological drugs.

2. Mixtures of small particles (solid, liquid or a mixed variety) and the carrier gas (usually air); owing to their size, these particles (usually less than and greater than in diameter) have a comparatively small settling velocity and hence exhibit some degree of stability in the earth's gravitational field. An *aerosol* may be characterized by its chemical composition, its radioactivity, the particle size distribution, the electrical charge and the optical properties. [2, 3]

15 aggregation
General term for the collection of particles into groups.
See also *coagulation, flocculation*, orthokinetic *aggregation*, perikinetic *aggregation.*
[2]

16 amorphous
Solids without definite shape or visible differentiation in structure.

Note 1: Used to describe substances that are solids but not crystals. *Amorphous* solids consist of randomly oriented molecules.
Note 2: Frequently they are more soluble than *crystalline* solids.

17 amphipathic, amphiphilic
Drug molecules, *detergents* or wetting agents that contain groups with characteristically different properties, e.g., both *hydrophil*ic and hydrophobic properties.

Note: Property of surface activity is usually due to the fact that the molecules of the substance are amphipathic or amphiphilic, meaning that each contains both a hydrophilic and a *hydrophobic* (lipophilic) group. This assumes that one of the two phases is aqueous, and the other non-aqueous. If both are non-aqueous (e.g. oil/air), molecules containing organophilic and organophobic groups may be amphipathic and surface active.
[2, 3].

18 angle of repose
Characteristic angle of slope formed with the horizontal by the side of a static conical mound of *powder*.

Note 1: Angle of repose is determined by a balance of gravitational force and the frictional forces caused by interparticulate interactions.
Note 2: A measure of cohesiveness in *powder*s. The smaller the angle of *repose* the greater the ability of the *powder* to flow. A particle will begin to slide on a slope when the angle of inclination is sufficiently large to overcome the frictional forces, and conversely the particle will not move when the angle is below that required to overcome cohesion and adhesion.
Note 3: The angle of *repose* depends on the method of measurement.

19 appertization
Process by which food is rendered free from pathogenic, toxigenic and spoilage organisms.

Note 1: A term used in the food industry.
Note 2: Appertization will not necessarily kill thermophilic spores, and thus products subjected to the process may not be *sterile*.
See also *sterilization*, *disinfection*.

20 binders
Substances that act as adhesives to bind *powder*s or *granule*s together during compression in tableting or during *granulation*.

21 bioassay
Procedure for determining the concentration or biological activity of a substance (e.g. vitamin, hormone, plant growth factor, antibiotic) by measuring its effect on an organism or tissue compared to a standard preparation.
[4, 5]

22 bioavailability
1. Relative amount of the administered dose of a drug that reaches *systemic* circulation from a certain *dosage form* in comparison to the amount absorbed by intravenous administration.

2. Ratio of the *systemic* exposure from extravascular (ev) exposure to that following intravenous (iv) exposure as described by the equation:

$$F = \frac{A_{ev}\, D_{iv}}{B_{iv}\, D_{ev}}$$

where F is the *bioavailability*, A and B are areas under the (plasma) concentration-time curve following extravascular and intravenous administration, respectively, and D_{ev} and D_{iv} are the administered extravascular and intravenous doses.

[6]

23 bioequivalence
Dosage forms containing equal doses of the same therapeutically active ingredient are said to be bioequivalent if they do not differ significantly in the *bioavailability* of the active constituent, when administered in the same dose under similar experimental conditions.

24 biological half-life of a drug
Time required to eliminate (or decompose, metabolize, etc.) 50 % of the initial amount of drug.
[7]

Note: The larger the biological *half-life,* the longer is the drug present in the body.

25 biological product
Virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries in humans.

Note: The term "analogous product" may include essentially all *biotechnology*-derived products and procedures including *gene therapy*, transgenics, and somatic cell therapy.

26 biopharmaceutics
Branch of the pharmaceutical science that deals with the fate of drugs in the living system; particularly the release of the drug from its *dosage form* into a biological medium, its passage across membranes into *systemic* circulation, metabolism and elimination, and the application of this knowledge to obtain the desired therapeutic effect.

27 biotechnology
1. Technique that uses living organisms (or component(s) of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses.
2. Newer definition refers to the industrial and pharmaceutical use of DNA, cell fusion, novel bioprocessing techniques and *gene therapy*.
3. The integration of life sciences with chemical, physical and engineering sciences in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services.
[3, 4]

28 buccal tablets
Usually small, flat and soft *tablet*s, which are designed to be placed in the side of the cheek to be directly absorbed through the mucosa for *systemic* effect.

29 bulk density
Characteristic of a *powder* rather than of individual particles and is given by the mass of *powder* occupying a known volume.

Note 1: Characteristics of importance in *tablet* production.
Note 2: The *bulk density* is always lower than the true density of its component particles.
Note 3: A *powder* can have only one true density, it can have many different bulk densities.

30 capsules

Small edible packages made usually from gelatin that can be filled with drugs to produce a unit dose, mainly for *oral* use. Hard *capsule*s consist of two pieces that fit one inside the other which are produced empty and filled in a separate operation, and soft, liquid filled *capsule*s, which are manufactured and filled in one operation.

31 carrier mediated drug transport
Transfer of a drug across a membrane by a transporter (often a protein) constituent of the cytosol membrane. Also known as *active transport* as opposed to passive *diffusion* / *absorption*.

32 coacervation
Separation of colloidal systems into two liquid phases. The phase more concentrated in colloid component is the coacervate, while the other phase is the equilibrium solution. [2]

33 coagulation
Close, tight *aggregation* (see also *flocculation*) of colloid particles, which are difficult to redisperse. Clotting: the process of changing from a liquid to a solid, said especially of blood (i.e., blood *coagulation*). Transformation of a *sol* into a gel or semisolid mass; e.g., the *coagulation* of the white of an egg by means of boiling.

Note: When a *sol* is colloidally unstable (i.e. the rate of *aggregation* is not negligible) the formation of aggregates is called *coagulation* or *flocculation*. [2, 6]

34 coating
Technological process consisting of the application of a substance which forms a layer able to control the rate of drug release or to protect the *tablet* itself (e. g. film *coating*, sugar *coating*).

Note: Sugar *coating* is used to mask bad taste without altering release profile.

35 compressed tablet
Pill prepared to a desired shape, usually in large-scale production, by means of great pressure.

Note: Most *compressed tablet*s consist of the active ingredient and a diluent (filler), *binder*, disintegrator, and *lubricant*.

36 controlled-release dosage form
Medication, which due to its special technological construction, provides for drug release having kinetics of zero order, at a sufficient rate to maintain the desired therapeutic level over an extended period of time.

Note: Also used to denote *sustained release* products in general (not necessarily limited to zero order).

37 cosolvents
Vehicles used in combination to increase the solubility of drugs (most popular is ethanol). Frequently, the solubility of a drug in a mixed solvent system is greater than can be predicted from its solubility in each solvent component separately.

38 creams

Semisolid *emulsion*s for external application. Oil-in-water *emulsion*s are most useful as water washable bases, whereas water-in-oil *emulsion*s are emollient and cleansing.[2]

39 critical micelle concentration (cmc)
Threshold detergent concentration at which the *micelle*-formation begins. This means that all effective molecules are present as monomers at a concentration below their *cmc*.

Note 1: There is a relatively narrow range of concentrations separating the limit below which virtually no *micelle*s are detected and the limit above which virtually all additional *surfactant* molecules form *micelle*s.
Note 2: Many properties of *surfactant* solutions, if plotted against the concentration, appear to change at different rates above and below this range. By extrapolating the loci of such a property above and below this range until they intersect, a value may be obtained known as the critical *micellization* concentration (*critical micelle concentration*), symbol C_M, abbreviation *cmc* (or c.m.c.). As the values obtained using different properties are not quite identical, the method by which the *cmc* is determined should be clearly stated.[3]
See also *inverted micelle*.

40 critical moisture content
A stage in the drying of solids, above which the drying rate (the plot of the loss of moisture content against time) is linear, and at which the drying rate stops to be linear, until it reaches the *equilibrium moisture content*.
[8]

41 crossover study
Type of comparative *bioavailability* study designed in such a way as to take into account differences in *bioavailability* arising from differences between patients suffering from disease, participating in the study.

Note: The differences between the subjects may be in age, stage or severity of the disease and prior drug treatment that some may have received. In such a *crossover study*, the patients are divided into two equal size groups, uniform with respect to age, body weight, sex, etc. The first group is given a specific dose of the product studied, while the second group is given a second product of proven clinical efficacy, containing the same active ingredient. After taking an appropriate number of blood samples from each individual and a washout period, the groups are reversed and the first group is given the product of proven clinical efficacy and the second is given the product being studied. This way each patient serves as his or her own control.
[9]

42 crystalline
Term that describes a solid of regular shape and the presence of three-dimensional order on the level of atomic dimensions, for a given molecule.

Note 1: *Crystallinity* may be detected by diffraction techniques, heat-of-fusion measurements, etc.
Note 2: *Crystalline* forms are preferred in pharmaceutical dosage forms, due to uniformity, reproducibility and sometimes lack of hygroscopicity.

43 deflocculation

Reversal of *coagulation* or *flocculation*, i. e. the dispersion of *aggregates* to form a colloidally stable suspension or *emulsion*.
See also *flocculation.*
[2]

44 delayed release dosage form
Pharmaceutical preparation that releases the drug(s) at a time other than promptly after administration.

Note: Typically, this is related to *enteric coated tablets*.

45 deliquescent
Substance that absorbs sufficient moisture from the atmosphere to dissolve itself.

46 depot
In the context of pharmaceutics, a depot injection, or similar mode of introduction, of a drug is a deposit to serve as source of slow release.

Note: From the French dépôt meaning deposit.

47 detergency
Property, which serves as basis for the process whereby *surfactant*s are used for the removal of foreign matter from surfaces (including dirt from clothes or body surfaces).
See also *detergents*, *solubilizing*, *surface active agent, surfactant.*

48 diffusion barrier
Obstacle such as *coating* or *embedding,* which acts as factor controlling the rate of drug release.

Note: Body fluids or membranes can also act as barriers.

49 disperse systems
Include suspensions (solid in liquid), *emulsions* (liquid in liquid) and foams (gas in liquid, or solid in solid).

Note: These systems are thermodynamically unstable and need to be stabilized by suspensifying or emulsifying agents.

50 divided granules
*Formulation*s in which individual doses of a granulated *dosage form* are separated.

51 divided powders
*Powder formulation*s in which individual doses of a powdered *dosage form* are separately wrapped.

52 dosage forms
Formulated preparations of drugs made from the pharmacologically active molecules that are rarely suitable for administration as pure substances.

Note: They can be designed for administration by all possible administration routes to achieve the desired therapeutic response.

53 dosage regimen
Dose and dosing interval of a drug.

54 drug
medicine
pharmaceutical
Substance which when absorbed into a living organism may modify one or more of its functions.

Note: The term is generally accepted for a substance taken for a therapeutic purpose, but is also commonly used for abused substances. [3]

55 drug delivery systems
Sophisticated *dosage forms*, which, by their construction, are able to modify/control the availability of the drug substance to the body by temporal or spatial considerations.

controlled release
extended release
delayed release
dosage forms
depot
embedding
gradual release
fast release or immediate release, i.e. conventional dosage forms
implants
liposomes
long-acting
matrix
prolonged action
slow release.

56 dusting powders
Usually intended for external use.

Note 1: They usually contain ingredients used for therapeutic, prophylactic or *lubricant* purposes.
Note 2: They are normally dispensed in containers with perforated lids.
Note 3: The *powder* must flow well so that it can be dusted over the required area.
Note 4: Examples are antibacterial and antifungal products.

57 effervescent tablets
Solid preparation that on contact with water breaks apart by gas (usually CO_2) evolution, resulting from the reaction of (bi)carbonate with citric or tartaric acid, in order to facilitate dissolution or dispersion of the active ingredient.

58 efflorescent
Substance that loses water to form a lower *hydrate* or becomes anhydrous spontaneously.

59 elixir
Sweet (often colored) liquid used in the compounding of drugs to be taken by mouth in order to mask an unpleasant taste.

Note: Elixirs are among the most common types of medicinal preparations taken orally in liquid form.

60 elutriation
Sedimentation method for the separation of particles into different size fractions depending on the velocity of a fluid in which the particles are *dispersed* and which flows in the opposite directions in which they settle.
[6]

61 embedding
Technological process, which consists of mixing the therapeutic substance with an *excipient* or their mixtures, typically as a *matrix dosage form*, in order to change the rate of release.

62 emulsion
Fluid *colloidal* system in which liquid droplets and/or liquid crystals are dispersed in a liquid.

Note 1: The droplets often exceed the usual limits for *colloids* in size.
Note 2: An emulsion is denoted by the symbol O/W if the continuous phase is an aqueous solution and by W/O if the continuous phase is an organic liquid (an "oil").
Note 3: More complicated emulsions such as O/W/O (i.e. oil droplets contained within aqueous droplets dispersed in a continuous oil phase) are also possible.[3]

63 encapsulation
Enclosing a drug in a (micro or nano) particle (*capsule*, *liposome*, *polymer*).

64 enemas
Solutions (aqueous or oily) or *emulsion*s or suspensions for *rectal* administration of medicaments for cleansing, diagnostic or therapeutic purposes.

65 enteric coating
Used on *tablet*s to make them resistant to gastric fluids but to disrupt or dissolve when the coated *tablet* enters the duodenum.

Note: *Enteric coating* is used for one of the following reasons:
1. To protect the drug from degradation by the acid in the stomach (e.g., erythromycin).
2. To protect the stomach from the irritant effect of the drug (e.g., aspirin).
3. To facilitate *absorption* of a drug distally to the stomach.

See also *delayed release dosage form*.

66 equilibrium moisture content (EMC)
Final stage reached after drying of a solid further, beyond the critical moisture content.

67 excipient
Vehicle for the drug.

Note: Any substance added to a medicine so that it can be formed into the proper shape and consistency.
[3]
See also *adjuvant*, *dosage forms, absorption, lubricant.*

68 extended release
See *Sustained release*.

69 flocculation
Process of contact and adhesion whereby the particles in dispersion form larger-size clusters.
See also *aggregation*, *coagulation*.
[3]

70 formulation
Summary of operations carried out to convert a pure pharmacologically active compound into a *dosage form.*
See also *drug delivery systems*, *solubilizing agents.*

71 gargle
mouthwash
Aqueous solution used for the prevention and treatment of mouth and throat infections.

Note 1: May contain antiseptics, antibacterials, analgesics and/or astringents.
Note 2: Usually diluted with water before use.

72 gastric emptying rate
Pace at which a drug leaves the stomach and enters the duodenum.

Note 1: Since most drugs are optimally absorbed from the duodenum, the onset of drug action depends on the *gastric emptying rate*.
Note 2: The *gastric emptying rate* depends on several factors, e.g. stomach content, hunger, anxiety, the nature of the drugs and body position.

73 generic(s)
Drug(s) or *formulation*(s) of drug(s) which no longer have patent protection.

Note 1: Generic or nonproprietary drugs may enter the market after the expiry of the basic patent covering the original drugs.
Note 2: Nonproprietary drugs are required to meet the same *bioequivalency* test as the original brand name drugs.

74 gene therapy
Use of products containing genetic material to treat a disease or condition, or to modify or manipulate the expression of genetic material or to alter the biological properties of living cells.

75 gradual release
See s*ustained release*.

76 granules
Powder particles, which have been aggregated to form larger irregular particles, usually of 0.5 to 2 mm diameter.

Note 1: *Granule*s are also used as intermediates in tableting. These are typically of smaller sizes.
Note 2: May also be used as independent d*osage form* for all *oral* administrations.
See also *tablet*s.

77 granulation
Process in which *powder* particles are made to aggregate to larger particles called *granule*s.

Note 1: In the majority of cases *granulation* is done in the production of *tablet*s or *capsule*s, when *granule*s are made as an intermediate product
Note 2: *Granulation* is preceded by mixing the necessary *powder*ed ingredients to assure their uniform distribution in the *granule*s.
Note 3: *Granulation* may be done by two types of methods: wet *granulation*s which utilize nontoxic volatile solvents, like water or low alcohols; or dry methods in which high pressure is applied.
See also *binders, granules.*

78 half-life
Time required by the body, tissue, or organ to metabolize, excrete or inactivate half the amount of a substance taken in.

Note: This is an important consideration in determining the proper amount and frequency of dose of drug to be administered.
See also *biological half-life.*

79 hydrate
C*rystalline* form of a compound in which water molecules are part of the crystal structure.

Note: Association of water molecule(s) can be of different strength.

80 hydrophile-lipophile balance system (HLB system)
Empirical scale (of 0 to18) used to assess *surfactant*s and emulsifying agents.

Note 1: The HLB number of a *surfactant* is obtained by dividing the percentage weight of the hydrophilic group by 5. The higher the HLB number, the more hydrophilic the *surfactant* and it favors o/w over w/o *emulsion*s.
See also *surfactant*, *emulsion*

81 hydrophilicity
Tendency of a molecule to be solvated by water.
[3]

82 hydrophobicity
Association of non-polar groups or molecules in an aqueous environment which arises from the tendency of water to exclude non-polar molecules and vice versa.
[3]

83 hygroscopicity
Tendency of a substance to absorb water from the atmosphere.

Note: A substance that absorbs moisture from the atmosphere is called hygroscopic.

84 implantation
Insertion or grafting of a biological, living, inert or radioactive material into the body.

85 implants
Small *sterile* polymeric matrices, pellets or particles for insertion or implanting into the body by surgical means or by *injection* to help achieving *sustained release*.

86 inactivation factor (IF)
Number which expresses the reduction in the numbers of a microorganism, brought about by a *sterilization* process.

Note: The IF value is specific for a microorganism and a *sterilization* process.

87 inhalation therapy
Administration of drugs directly to the *respiratory* tract, mostly by *aerosol*s.

Note 1: Since a drug is delivered directly to the site of action, lower dose is needed by this route than by other routes, e.g. the gastrointestinal or *parenteral* routes.
Note 2: The incidence and the intensity of side effects are generally lower when this route is used as compared to other routes of drug administration.

See also *administration*

88 injection
Forcing of a sterile liquid into a vessel, tissue, or organ.

Note 1: *Epidural injections* are given into the epidural space of the spinal cord.
Note 2: *Intra-articular injection*s are made into the synovial fluid, which lubricates the articulating ends of bones in a joint.
Note3: *Intrabursal injection*s are given into the bursae, which are small sacks of fluids between the tendons and bones.
Note 4. *Intracardial injection*s are given directly into the heart in emergencies.
Note 5:*Intracutaneous or intradermal injection*s are made into the skin between the inner layer (dermis) and the outer layer (epidermis)
Note 6: *Intramuscular injection*s are made by inserting the needle across the skin, subcutaneous tissue and membrane enclosing the muscle.
Note 7: *Intraspinal injection*s are made into or around the spinal cord
Note 8:*Intravascular injection*s (intra-arterial and intravenous) are made directly into the blood stream for rapid effect.
Note 9:*Intrathecal injection* is the introduction of material for *diffusion* throughout the subarachnoid space by means of lumbar puncture.
Note 10*: Ophthalmic* injections include a variety of sites in the eye.
Note 11*: Subcutaneous of hypodermic injection*s are made under the skin into the subcutaneous tissue.

89 inverted micelle
Reversible formation of association colloids from *surfactants* in non-polar solvents leads to aggregates termed inverted (or inverse, reverse or reversed) *micelles*. Such *association* is often of the type: Monomer ⇌ Dimer ⇌ Trimer ⇌ n-mer, and the phenomenon of *critical micelle concentration* (or an analogous effect) is consequently not observed. In an inverted *micelle* the polar groups of the surfactants are concentrated in the interior and the *lipophilic* groups extend towards and into the non-*polar solvent*.
[3]
See also *micelle*

90 liniment
Liquids intended for massage into the skin.

91 liposome
An artificial spherical lipid bilayer droplet formed from phospholipids having a core of water phase, small enough to form a relatively stable suspension in aqueous media and with potential use in drug delivery.
[3]

See also *drug delivery systems*.

91 loading dose
Initial, larger than usual dose of a drug given to a patient at the start of pharmacotherapy is called *loading dose*.

Note 1: The objective is to reach quickly the therapeutically beneficial plasma level. This is followed by smaller (maintenance) doses in order to maintain the plasma concentration.
Note 2: Generally, the *loading dose* is twice the size of the maintenance dose if the selected dosage time interval corresponds to the biological *half-life* of the drug.

92 long acting
see *Sustained release*.

93 lotion
Solution, emulsion or suspension to be applied to the skin.

94 lozenge
Tablet, which does not contain a disintegrant and which is sucked to dissolve in the mouth to produce either a local (e.g. antiseptic) or *systemic* (e.g. vitamins) effect.

Note: Lozenges must be palatable and slowly soluble.
See also *troche*.

95 lubricant
Used as processing aid in *tablet* manufacturing.

96 lyophilic

In colloid chemistry, denoting a *dispersed* phase having a pronounced affinity for the dispersion medium; when the *dispersed* phase is *lyophilic*, the colloid is usually a reversible one.
[2]

97 lyophobic
Denotes a *dispersed* phase having but slight affinity for the dispersion medium.

Note: When the *dispersed* phase is *lyophobic*, the colloid is usually an irreversible one.
[2]

98 matrix *formulation* (e.g. matrix *tablet*)
Specific case of drug *embedding* in insoluble *excipients* (typically in a polymer) in order to achieve *extended release*.

Note: This term also applies to a matrix built of *hydrophilic* substances, which, in contact with water, form a gel of high viscosity.
See *embedding*.

99 maximum additive concentration
Maximum concentration of a drug, which will form a clear solution with a given concentration of *surfactant*.

100 maximum safe concentration
Concentration of a drug in the plasma, above which side effects occur in a patient.

101 micelle(s)
Aggregates of colloidal dimensions (i.e. association colloids) formed reversibly from amphiphile molecules.
[3]

Note 1: A *micelle* is thus a structural unit of the *disperse* phase in an *emulsion*, suspension or a gel; a unit whose repetition in three dimensions constitutes the micellar structure of the gel; it does not denote the individual particles in free suspension or solution, or the unit structure of a crystal.
Note 2: Arrangements of groups of molecules of hydrophobic liquids in an aqueous environment, formed by surface-active agents.
[6]

See also *Critical micelle concentration*.

102 micellization
Formation of *micelles*.

103 microemulsions
Emulsions in which the *dispersed* droplets are in the micron-size range.

Note: These are essentially swollen micellar systems but it is difficult to tell the difference between a swollen *micelle* and a small *emulsion* droplet.

104 microencapsulation
Formation of microparticles *encapsulating* a drug.

Note: Such *coating* protects the drug from chemical or enzymatic attack, and may prolong the drug action
See *encapsulation*.

105 microfiltration
Pressure-driven, membrane-based separation process in which particles and dissolved macromolecules larger than 0.1 μm are rejected.

Note: Can be used for *sterilization* with 0. μm size filters. [10]

106 microsphere
Solid spherical particles in the size of microns used as *matrix dosage form*s.

107 minimum effective plasma concentration
Concentration of a drug that must be achieved in the plasma before any desired therapeutic or pharmacological effect can be obtained.

108 minimum inhibitory concentration (MIC)
Lowest concentration of an antibacterial drug necessary to inhibit the growth of a microorganism.

109 minimum therapeutic plasma concentration
See *minimum effective plasma concentration.*

110 moistening agents
Usually water or low molecular weight alcohols or compounds, used in *topical* applications and in wet *granulation*, for the production of *tablets*.

111 multicompartment formulation
Dosage form (*capsule*, *tablet*) comprising several elements (e.g. *microspheres* or *coat*ed *pellets*) differing in the rate of drug release.

112 multilayer tablet
Consists of several different layers that are compressed on top of each other, to form a single *tablet* composed of two or more layers.

Note: Mainly used for incompatible substances and for *sustained release*.

113 nanoencapsulation
Formation of *coat*ed *nanoparticles*.

114 nanoparticles
All forms of nano size particles; nano*capsule*s or nanospheres in which the drug can be *embedded* as in a *matrix* or adsorbed or *encapsulated*.

115 nebulizer
Device that disperses liquids to *aerosols*.

116 ointment
Greasy, semisolid preparation for external application, often anhydrous, containing dissolved or *dispersed* medicaments.

117 one-compartment model
Concept in *biopharmaceutics*, which assumes the distribution of the drug instantly throughout the whole body, following its release from the *dosage form*.

Note: In this model, the body is a single compartment, and drug concentration equilibrium is assumed to exist between the plasma, the other body fluids and the tissues.

118 onset of drug action
Time required to achieve the *minimum effective plasma concentration* following administration of the *dosage form*.

119 parenteral
See *administration of drugs, parenteral*.

120 paste
Ointment containing > 30 % of *powder*, *dispersed* in a fatty base.

121 pellet
a) Very small pill or pilule.
b) Implantable polymeric *matrix*.

122 pelletization

Process of agglomeration that converts fine *powders* or *granules* of bulk drugs and *excipients* into small, free-flowing, spherical or semi-spherical units, referred to as *pellets*.

Note 1: *Pellets* range typically between 0.5 to 1.5 mm in diameter.

Note 2: The most widely used *pelletization* processes in the pharmaceutical industry are extrusion / *spheronization*, solution / suspension layering, and *powder* layering.[11]

123 pharmaceutical equivalence
To be pharmaceutically equivalent, the *generic* and innovator *formulations* must (1) contain the same active ingredient; (2) contain the same active ingredient in the same *dosage form*; (3) be intended for the same route of administration; and (4) generally be labeled for the same conditions of use.

Note 1: It is not usually required that the *generic* and the reference drug contain the same *excipients*, or that the mechanism by which the active drug substance is released from the *formulation* be the same.
(*See, bioequivalence, generic, nonproprietary.*)

124 pharmaceutics
Science of preparation of drugs, *dosage forms* and *drug delivery systems* as well as pharmacokinetics, etc.

125 polymorph

Solid material that exists at least in two different molecular arrangements, i.e. distinctly different crystal species.

Note 1: The differences between *polymorphs* disappear in solution or in the vapor phase.
Note 2: Solubility, melting point, density, crystal shape, crystal structure and some other physical properties often differ from one *polymorph* to the other.

126 polymorphic transition
Transition of a solid *crystalline* phase to another phase having the same chemical composition but a different crystal structure.

Note: The transition may occur at a characteristic temperature and pressure, called the inversion point.
[3, 12]

127 polymorphism
Existence of two or more different crystal structures for the same compound.

128 powder grades
Defined for *powder*s used pharmaceutically, according to particle sizes.

Note: It is required that when the fineness of a *powder* is described by a number, all particles must pass through a *sieve* with aperture diameter in microns equal to that number.

129 powder(s)
Conventionally, the title *powder* should be restricted to *powder* mixes for internal use and alternative terms are used for other *powder*ed *formulation*s presented in this way, e.g., *dusting powder*s, which are for external use.

Note 1: The term *powder* when used to describe a *dosage form*, however, describes a *formulation* in which a drug *powder* has been mixed with other *powder*ed *excipient*s to produce the final product.

130 prodrug
Compound that undergoes bio- or chemical transformation before exhibiting its pharmacological effect.
[1]

131 prolonged action
See *sustained release*.

132 pseudopolymorph(s)
Different *crystalline* form(s) of a *solvate*d compound that differ either or both in the identity or stoichiometry of the solvating molecule.

133 relative bioavailability
Measure of the fraction of a given drug that is absorbed intact into the *systemic* circulation from a *dosage form*, relative to a recognized, clinically proven, standard *dosage form* of that drug.

134 repeat action dosage form
Tablet or *capsule* distinguished from a *sustained release dosage form*, by the fact that it releases the medicinal agents, or part of it, at any time other than promptly after administration as opposed to a slow, controlled manner.

Note: A repeat action *tablet* contains usually two doses of the drug, the first being released immediately following *peroral administration*. The second dose is released later, when the layer of *enteric coating* is dissolved.

135 sieving
Process that differentiates or separates solid particles according to their size using a meshed or perforated device.

136 slow release
See *sustained release*

137 slugging
Method by which *powder* particles are compressed into a large *tablet*, called a slug, which is subsequently dry-screened and compressed into a *tablet*.

138 sol
Colloidal dispersion of a solid in a liquid.

139 sol-gel transition
Transition of a suspension of solid, usually colloid, particles in a liquid (sol) to an apparent solid, jelly-like material (gel).
[3, 12]

140 solubilizing agents
Additives making a substance soluble or more soluble, especially in water.

141 solvate
C*rystalline* form of a compound in which one or more solvent molecule is part of the crystal structure.
See also *hydrate*.

142 spheronization
Process of making dense, spherical *pellets* by means of special spheronizing or pelletizing equipment.

143 sterility
Condition of being aseptic, or statistically free from living microorganisms and their spores.

144 sterilization
Destruction of microorganisms in or about an object, as by steam (flowing or pressurized), chemical agents (alcohol, phenol, heavy metals, ethylene oxide gas), high-velocity electron bombardment, gamma or ultraviolet light radiation.

145 sublingual *tablet*s

Usually small, flat and soft *tablets*, which are designed to be placed under the tongue to be directly absorbed through the mucosa for a *systemic* effect.

146 suppositories
D*osage form*, mainly used for the *administration* of drugs via the *rectal route*, for *systemic* or *local* effect, but application via other routes is also known, for example *vaginal* applications in the treatment of locally occurring infections. Also there are other *suppositor*y type products (bougies) for other body orifices e.g. ear, nose and urethra known but very seldom used.

Note 1: The vehicles used in *suppositories* are of two types, i.e. fatty bases and water soluble ones.
Note 2: An important requirement for *suppositories* is a melting point around 36-37 ºC. The melting range should be narrow to allow rapid solidification after preparation.

147 surface active agent
Substances that alter the conditions prevailing at an interface, causing for example, a marked decrease in the surface tension of water.

Note 1: These substances are of importance in a wide variety of fields as emulsifying agents, *detergents*, *solubilizing* agents, wetting agents, foaming and antifoaming agents, flocculants and deflocculants and in drug stability and drug *absorption*.
Note 2: All *surfactant*s are characterized by having two regions in their molecular structure: a *lyophobic* (or hydrophobic) group, such as a hydrocarbon chain, that has no affinity for water, and a *lyophilic* (or *hydrophili*c) group that has an affinity for water.
See *surfactant*.
[2]

148 surfactant
See *surface active agent*

149 sustained release
Dosage form designed to release the drug contained therein at a continuous and controlled rate for a longer period of time that can normally be achieved with its conventional, non-sustained counterpart.

Note: Consequently, peroral administration of a single dose of a *sustained release* product increases the duration of therapeutic action of the drug, beyond that achieved normally with a single dose of the corresponding non-sustained conventional counterpart.

Other terms used to describe the same concept include: “controlled release”, “extended-release” “long-acting”, “*gradual release*”, “*prolonged action*”, and “*slow release*”.

150 syrup
Liquid preparation of medicinal or flavoring substances.

Note 1: In the U.S.P. syrup is a highly concentrated solution of sugar. Other polyols, such as glycerol or sorbitol, may be present to retard crystallization of sucrose or to increase the solubility of added ingredients.
Note 2: When the *syrup* contains a medicinal substance, it is termed medicated *syrup*; although *syrup* tends (due to its very high [approximately 85 %] sucrose content) to resist mold or bacterial contamination, *syrup* may contain antimicrobial agents to prevent bacterial and mold growth.
Note 3: It is often required to add a *cosolvent* or water to the medicated *syrup* in order to dissolve the drug.

151 systemic
1. Relating to the entire organism as distinguished from any of its individual parts.
2. The opposite of local (administration or pathology).

Note 1: *Intravenous* or *transdermal administration*s are typically *systemic*.
Note 2: Eye drops, *topical cream*s or drug-eluting stents are local.

152 tablet
Solid *dosage form* containing medicinal substances with or without suitable diluents.

Note 1: It may vary in shape, size, color and weight, and may be classified according to the method of manufacture, as molded *tablet* and *compressed tablet* (Synonym: tabule).
Sea also *buccal tablet, compressed tablet, enteric-coating, lozenges, prolonged action tablet, sublingual tablet, sustained action tablet.*

153 tablet coating
Solid layer, covering pills; based typically on cellulose derivatives and may include plasticizers and pigments.
Employed usually for one or more of the following reasons:
1. Protection of the ingredients (from light or moisture)
2. Masking the bad taste of the drug.
3. Masking possible batchwise differences in the appearance of raw materials and hence allaying possible patient concern over *tablet*s of differing appearance.
4. *Coating* confers mechanical strength and facilitates handling.
5. Colored *coating* aids in the rapid identification of a product.
6. Functional film *coating* is used to impart enteric or controlled release properties to the *tablet*.
See *enteric coating*.

154 therapeutic index
Ratio of the drug dose which produces an undesired effect to the dose which causes the desired effects.

Note: It indicates the selectivity of the drug and consequently its usability.

155 transplantation

Grafting of tissues or an organ from the patient's own body or from another person's body. See also: *implantation.*

156 troche
Applied to *compressed lozenge*s. In lay language, *lozenge* and troche are used interchangeably.

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