Prüfungsfragenkatalog für
Grundlagen der AST Präformulierung
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Stand: Juni 2020

Termin: 24.06.2020

1. The Noyes-Whitney equation allows to estimate drug dissolution. What parameter will likely change if we change the particle shape for our test substance? What parameter might change if we use a different polymorph?
2. Two substances have similar absorption behavior in UV / VIS spectra. What do we need to do in the laboratory do determine the amounts of both with high precision still using UV / VIS spectroscopy?
3. By the addition of a specific salt to a solution containing macromolecules, a cloud point formation is absent. When there was no salt present, a cloud point was observed. Therefore one can conclude that this salt results in a salting -> in
4. For an unknown substance, which of the following methods can be used to identify different polymorphic forms?
5. In the determination of a calibration curve for a UV / VIS experiment, the absorption values as function of concentration are determined. At high concentrations, the adsorption is constant rather than changing. Why is there no change visible? What do we need to do to access concentration information from such high concentrations in a UV / VIS absorption experiment?
6. How does the solubility in terms of mM/m^3 change as the molecular weight of a solute decreases? -> the solubility increases
7. Is the description of solubility by Hansen or this of Hildebrand less accurate for most of the substances we are interested in pharmaceutics? -> Hildebrand
8. Within a medication the amount of drug is reduced due to the occurence of a chemical reaction of first order. Assuming this is the only reason for the expiration, it can be assumed that x % or more of the initial material has changed. How large is x? -> 10
9. An amorphous solid state in general dissolves differently compared to its crystalline counterpart. What statement is wrong? -> The energy required to dissolve a molecule from the amorphous state is higher compared to those from a crystalline state.
10. In the United States pharmacopeia, the solubility is classified from very soluble down to practically insoluble. From which quantities this classification is derived?
11. During a shear rate increases no decrease and increase in the apparent viscosity takes place. Such a behavior is associated with a so-called … fluid.
12. Using a permeation assay of low complexity, it can be assumed that the estimate for human intestinal absorption from this assay will be: (better, worse, …)
13. Nematic and smectic phases are liquid crystalline phases. -> TRUE
14. Does the water/octanol partition ratio predict the solubility in the gastric juice?
15. A substance which is solid and does not posses long range order is ….
16. When the cmc in a solution is exceeded and we add more surfactant molecules, then the surface tension ….
17. Which of the following radiation is best suited to determine the unit cells dimensions of a crystalline drug?
18. When the amount of a solute added to a solution this results in precipitation and settling od some material fraction. Reaching equilibrium conditions, the particle free solution is then, ….
19. The Bragg equation is a simple formula to understand the occurrence of high diffraction intensities at given diffraction angles. If a net plane distance (d1) is measured at a diffraction angle and another (d2) is measured at a larger angle, what does this mean for the net plane distances?
20. The process, by which a molecule attaches to a surface is typically referred to adsorption. -> TRUE
21. In intrinsic dissolution experiments, the pure drug is tested for the time it takes to go from the solid to the solution. To access information on the materials intrinsic dissolution rate, we need to know the surface area during the experiment. How is the information on the surface area obtained during the experiments?

Termin: 29.05.2020

1. A substance, which is solid and does not prosses long range oder is,…
2. In the determination of a calibration curve for a UV / VIS experiment, the absorption values as function of concentration are determined. At high concentrations, the adsorption is constant rather than changing. Why is

there no change visible? What do we need to do to access concentration information from such high concentrations in a UV / VIS absorption experiment?
3. All liquid crystalline phases are smectic.
4. Two substances have similar absorption behavior in UV / VIS spectra. What can we do in the laboratory to determine the amounts of both with high precision?
5. Within a medication the amount of drug is reduced due to the occurrence of a chemical reaction of first order. Assuming this ist he only reason fort he expiration, it can be assumed that more than x % of the initial material has changed. How large is x?
6. In intrinsic dissolution experiments, the pure drug is tested for the time it takes to go from the solid to the solution. To access information on the rate, we need to know the surface area during the experiment. How is this done?
7. By the addition of a specific salt to a solution containing macromolecules, a cloud point formation is present. When there was nos alt present, a cloud point was not observed. Therefore one can conclude that this salt results in a salting….
8. What can we learn from the mathematical modelling of a dissolution profile?
9. Using a permeation assay of low complexity, it can be assumed that the estimate for human intestinal absorption from this assay will be: …
10. The process, by which a molecule attaches to a surface is typically referred to absorption.
11. Which oft he following radation is best suited to determine the unit cells dimensions of a drug?
12. How does the solubility in terms of mM/m^3 change as the molecular weight of a solute decreases?
13. In the United states pharmacopoeia, the solubility is classified from very soluble down to practically insoluble. From which quantitis is this classification derived? It indicates how much solvent molecules are required to dissolve one drug molecule
14. During a shear rate increases no decrease and increase in the viscosity is apparent. Such a behavior is associated with a so-called … fluid.
15. The Bragg equation is a simple formula to understand the occurrence of diffraction intensities at given angles. If a net plane distance (d1) is measured at a diffraction angle and another (d2) is measured at a larger angle, what does this mean?
16. An amorphous solid state in general dissolves differently compared to ist crystalline counterpart. What statement is wrong? – answer: The energy required to dissolve a molecule from the amorphous state is higher compared to those from a crystalline state.
17. Which of the following methods can be directly used to identify the polymorphic form?
18. Is the description of Hansen or this of Hildebrand mor accurate for most of the substances we are interested in pharmaceutics? -> Hansen
19. We have two particles types of different size. When we compared these, one can tell that the larger particle type does result in the solubility being: -> lower
20. When the amount of a solute added to a solution this results in precipitation of some fraction. Reaching equilibrium conditions, the particle free solution is,…
21. Does the water/octanol partition ratio predict the solubility in the gastric juice?
22. When the cmc in a solution is exceeded and we add more surfactant molecules, then the surface tension,… -> remains constant

Termin: 04.06.2019 -> Die unterstrichenen Begriffe/Sätze sind die Lösung.

1. Computed tomography data collection → on which linear _____coefficient? -absorption
2. BET-Theory: Adsorption of gas molecules at solids
3. For a material that does not increase its weight (or moisture) when stored at high humidity is a non-hygroscopic material.
4. A smectic phase is associated with a liquid crystalline phase.
5. One of the thermal analysis techniques is based on the measurement of weight loss heating. The technique is named by the acronym TGA which stands for thermal gravimetrical analysis.
6. The preformulation studies involve chemical, physical and mechanical properties in order to choose what other ingredients should be used in the preparation and to develop a stable, safe and effective dosage form.
7. pH of the body:
   - Stomach pH: smaller 7
   - Skin pH: smaller 7
   - Bloods pH: larger 7
   - Saliva typically pH: equal 7
   - pH intestine region: larger 7
8. pKa of 9.0. Such a pKa means that it behaves like a weak acid.

9. Assuming that the pKa is larger than the pH it means that the level of ionization is larger than 50%.
10. Within a medication the amount of drug is reduced due to the occurrence of chemical reactions. As the shelf life is not reached yet it can be assumed that less than X% of the drug changed. X=10%
11. By the addition of a specific salt to a solution containing proteins a cloud point formation is absent, but which was present at the very same thermodynamic conditions before. Therefore, one can conclude that this salt results in a salting *in.*
12. As the share rate increases a decrease in the viscosity is apparent. Such a behavior is associated with a so-called shear thinning.
13. The Bragg equation is a simple form to understand the appearance of diffraction intensities at given angles. If a net-plane distance (d1) is measured at a small angle and another (d2) is measured at large angle, this means that..? – d1 is larger than d2
14. Polymorphism-statements:
    - Different polymorphs posses different solubilities
    - Each polymorph requires an individual registration
    - Compact capabilities differ for each polymorph
15. An amorphous solid state in general dissolves different to its crystalline counterpart. The reason is:
    - The energy required to dissolve a molecule from the amorphous state is lower.
16. When preparing a tablet, it is important that the materials involved show plastic deformation.
17. Using permeation assays is a good way to estimate for human intestinal adsorption. Hereby an increase in assay complexity typically results in the correction being: -better
18. For the investigation of thermal properties often a differential scanning calorimeter is used.
19. The process in which vacant surface sites are occupied by molecules is named adsorption.
20. The arrangement of atoms in a unit cell can be experimentally determined. Therefore, experiments are performed which use electromagnetic radiation. The wavelength best suited for this purpose is in the regions of x-ray.
21. When the amount of surfactant molecules reaches the maximum at the water-air interface, the so called “cmc” is reached. Hereby cmc is the abbreviation for the critical micelle concentration.
22. In the pharmaceutical science, buffers are often used. The reason/s for this is/are:
    - pH value remains in a certain range over the course of the experiment.
    - Buffer solution tries to mimic/simulate the living organism.
23. How does the solubility in terms of mM/m^3 change as the molecular weight of a solute decreases? – the solubility increases
24. In the United States Pharmacopeia, the solubility is classified from very soluble down to practically insoluble. From which quantities their classifications are derived?
    - It indicates how much solvent molecules are required to dissolve one drug molecule.
25. When a medication is administered intravenously, how high is its bio-availability per definition? Numbers from 0-100%? – 100%
26. The underlying process for a substance or a solid form to dissolve is based on diffusion. Which following statements are correct?
    - The viscosity of the surrounding medium affects dissolution rates.
    - Using a sufficient large amount of dissolution medium is terms of achieving sink conditions, the dissolution will not be significantly limited by a reduction of the concentration gradient over the course of the experiment.
    - The Noyes-Whitney equation provide information on the amount of mass dissolved over time rather than providing information on the change in concentration in the surrounding over time.

Termin: 25.04.2017 – 17 Fragen

1. Distribution Faktor Log __
2. Definition preformulation: chemical, physical, mechanical
3. Allopurinol hat einen pKa von 9 und ist (Antwortmöglichkeiten):
   -very strong acid
   -strong acid
   -weak acid
4. Shear thinning
5. Solubility abhängig von (Antwortmöglichkeiten):
   -temperature
   -pressure
   -pH

- …

6. Seeding: einmal große Kerne, einmal kleine Kerne, eine Reaktion ist schneller als die andere. Wieso? (Antwortmöglichkeiten):
   -polymorphic structure
   -temperature was low
   -surface area larger
7. Additioning salt to…. ->salt in oder salt out
8. PH Werte von:
   Saliva, Blood, intestinal, skin, stomach
9. Pka > pH. Was bedeutet das? (Antwortmöglichkeiten): >50% =50% <50%
10. D1 kleiner Winkel, d2 großer Winkel. D1 ist _____ als d2. - Antwort zum reinschreiben. (smaller, bigger, smaller equal, bigger equal)
11. Preformulation in which stage? Which number? (Antwort: candidate drug screening, 2)
12. Diffusion Aussagen zum ankreuzen
13. Solubility parameter

Termin: 07.04.2017

1. Paracetamol pKa = pH der Umgebung → wv. % ist ionisiert
2. partitioning coefficient, bezeichnung durch: log P
3. X-ray defraction: mit welchen Parametern kann man netplane berechnen
   angle +?
4. Bioverfügbarkeit bei intravenöser Medikation (100)
5. Unterschied Dissoziationsgeschwindigkeit Reaktion erster und nullter Ordnung
   wenn nach 33min bei beiden 53% des Medikaments gelöst worden sind
6. shelf life, wieviel % des Wirkstoff müssen noch mindestens übrig sein
7. in welcher der 7 Entwicklungsphasen eines Medikaments wird die Präformulierung vollzogen (2. => candidate drug screening)
8. Verwendungszweck eines Puffers in der (pharmazeutischen) Chemie
9. Definition Präformulierung: mechanische, chemische & physikalische Stabilität
10. US Pharmacopedia: durch welche Faktoren wird die solubility definiert
11. welche(r) Faktor(en) beinflussen Löslichkeit (mol/V)
    (Auswahlmöglichkeiten: Druck, pKa, pH, solvent class, temperature)
12. Aspirin pKa 3,49 → strong acid
13. shear stress ↑ & viscosity ↓ → shear thinning
14. Cloud point formation: salting ____
15. mM/m3 Molekulargewicht sinkt Einfluss auf Dissoziation (?) Antwortmöglichkeiten: bleibt gleich, wird schlechter, wird besser