Pharmaceutical Analytical Chemistry I

الأستاذ الدكتور جمعه الزهوري (دكتوراه صيدلة-ألمانيا 1991)

Prof.Dr.Joumaa Al- Zehouri(Ph. D Germany 1991)

Damascus university

Faculty of Pharmacy

Introduction

Pharmaceutical Analytical chemistry :

The branch of chemistry that deals with the *Separation* , *Identification* and *determination* of Drugs.

Pharmaceutical analytical chemistry I

مكرس، مخصص سيكتشف

This course is devoted to the exploration of principles of qualitative and quantitative analysis methods, expressing of the concentration ,principles of volumetric analysis, acid-base equilibria in aqueous and in non-aqueous solutions, acid –base titration and their applications in both solution with Pharmaceutical Application. Also Redox ,complexometric , precipitate titration .and Gravimetric analysis with pharmaceutical applications

3

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كيف تحصل على المحاضرات ؟

رابط المحاضرات على موقع جامعة دمشق :

http://new.damascusuniversity.edu.sy/faculties/pharm/2013-07-18-11-11-13/2013-07-18-11-22-15/174-2014-02-04-13-03-09

رابط المحاضرات على موقع جامعة الرشيد :

https://onedrive.live.com/?authkey=%21AHTRlDW3auHIvlc&id=6E6E9FDA4EA6B639%212048&cid=6E6E9FDA4EA6B639

Watson.G.D

Pharmaceutical Analysis 2.eddition

A Textbook for Pharmacy Students and Pharmaceutical Chemists

Elsevier Churchill Livingstone

الكيمياء التحليلية

الصيدلانية (١)

(التحليل الحجمي)
الجزء النظري

الدكتور:
جمعه الزهوري
استاذ في قسم الكيمياء التحليلية والغذائية

الكيمياء التحليلية الصيدلانية

(١)

((التحليل الحجمي))

الجزء العملي

الدكتور

جمعه الزهوري

Advice

- English Language (Pharmacopeias, Report,Fiels ,search …

- Computer Science (Instrumentation, pharmacy, report …)

8

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- USP-NF

- BP

- Eur.Ph

- DAB

- Japanese pharmacopo

- The International Pharmacopoeia

Arshine

ARSHINE PHARMACEUTICAL CO., LIMITED

17/F SHUN KWONG COMM BLDG 8 DES VOEUX RD WEST SHEUNG WAN CHINA.

CERTIFICATE OF ANALYSIS

DATE: DEC. 20, 2013

L/C NUMBER: 304913010275, L/C DATE: 131125, TIN: 307-200-2199

PRODUCT NAME:	DICLOFENAC SODIUM
BATCH NUMBER:	131008-5
MANUFACTURING DATE:	OCT. 10, 2013
EXPIRY DATE:	OCT. 09, 2017
QUANTITY:	1000 KGS
COUNTRY OF ORIGIN:	CHINA

ITEMS	SPECIFICATION	RESULTS
Characteristics	A white or slightly yellowish Crystalline powder	White crystalline powder
Identification	A. IR	ACCORD
	D. Test of sodium salt	CONFORM
Appearance of solution	5.0% of methanol solution 440nm, NMT 0.05	0.011
Clarity of solution	Clear	PASS
Related substances	Any Specified impurity: NMT0.2%	Not detected
	Any unspecified impurity: NMT0.1%	Not detected
	Total impurities: NMT 0.5%	Not detected
Heavy metals	NMT 10 PPM	PASS
Loss on drying	NMT 0.5% (1g, 100℃ ~ 105℃, 3 hrs)	0.14%
Assay	99.0 ~ 101.0%	100.13%
Conclusion:	It accords with BP2012. Be up to the standard.	

Brenda

Authorized Signature(s)

www.arshine.com.cn

Biochemical Factor		Mean	Range
Glucose	mM/L	3.78±0.74	2.22-6.38
Urea	mM/L	15.08±3.8	6.07-23.92
Creatinine	µM/L	86.63±26.52	17.68-167.96
Cholesterol	mM/L	1.54±0.36	0.51-2.79
Triglyceride	mM/L	0.46± 0.13	0.13- 0.84
Total Protein	g/L	78±6.9	60-97
Albumin	g/L	34.5±4.7	23-51

The CTD Triangle

NOT Part of the CTD

Regional Admin Information
Module 1

Module 2

Quality Overall Summary

Nonclinical Overview

Clinical Overview

Nonclinical Summary

Clinical Summary

The CTD

Quality
Module 3

Nonclinical Study Reports
Module 4

Clinical Study Reports
Module 5
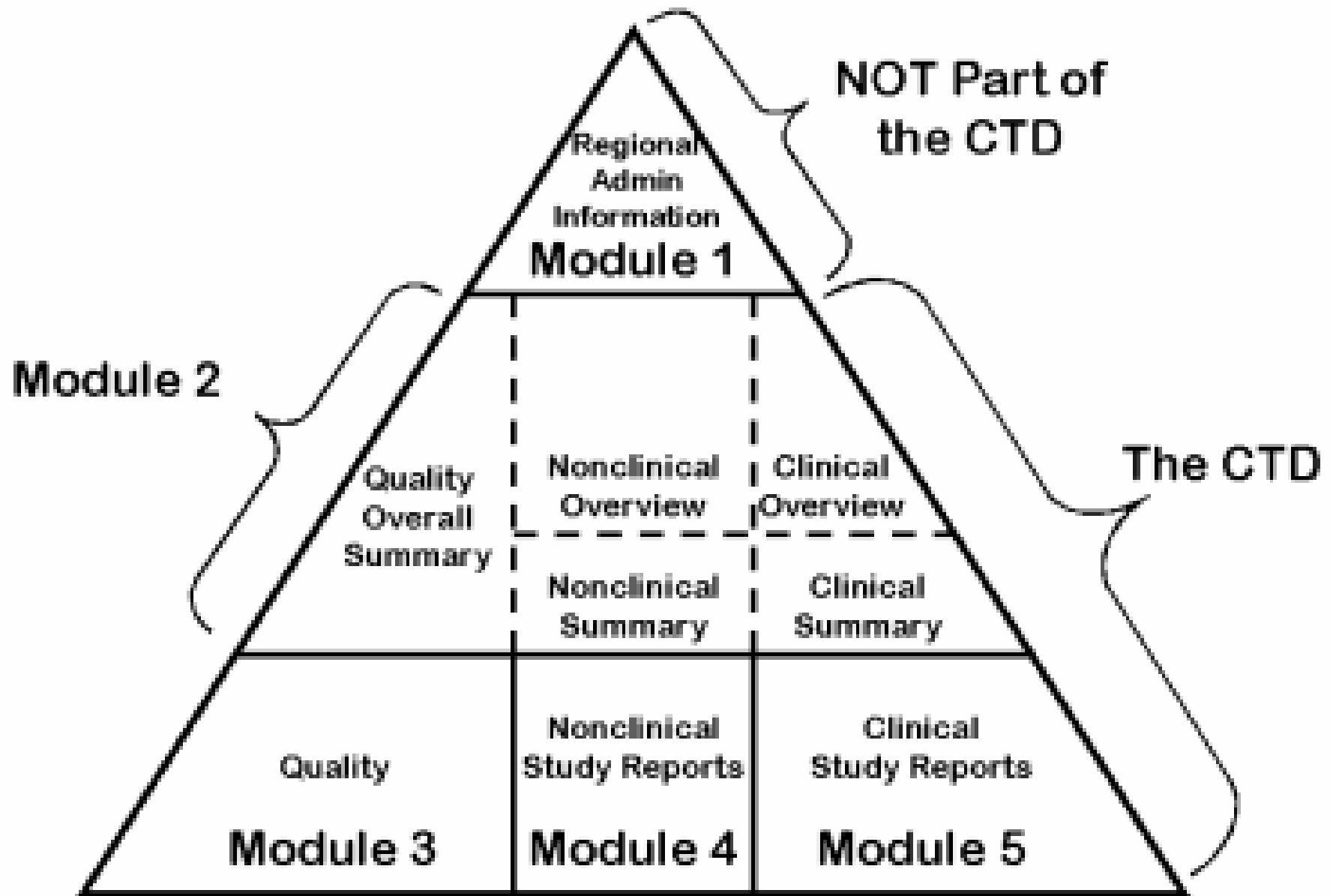
Search the internet:

- Pub Med

- Science Direct

- Google Scholar

- ….

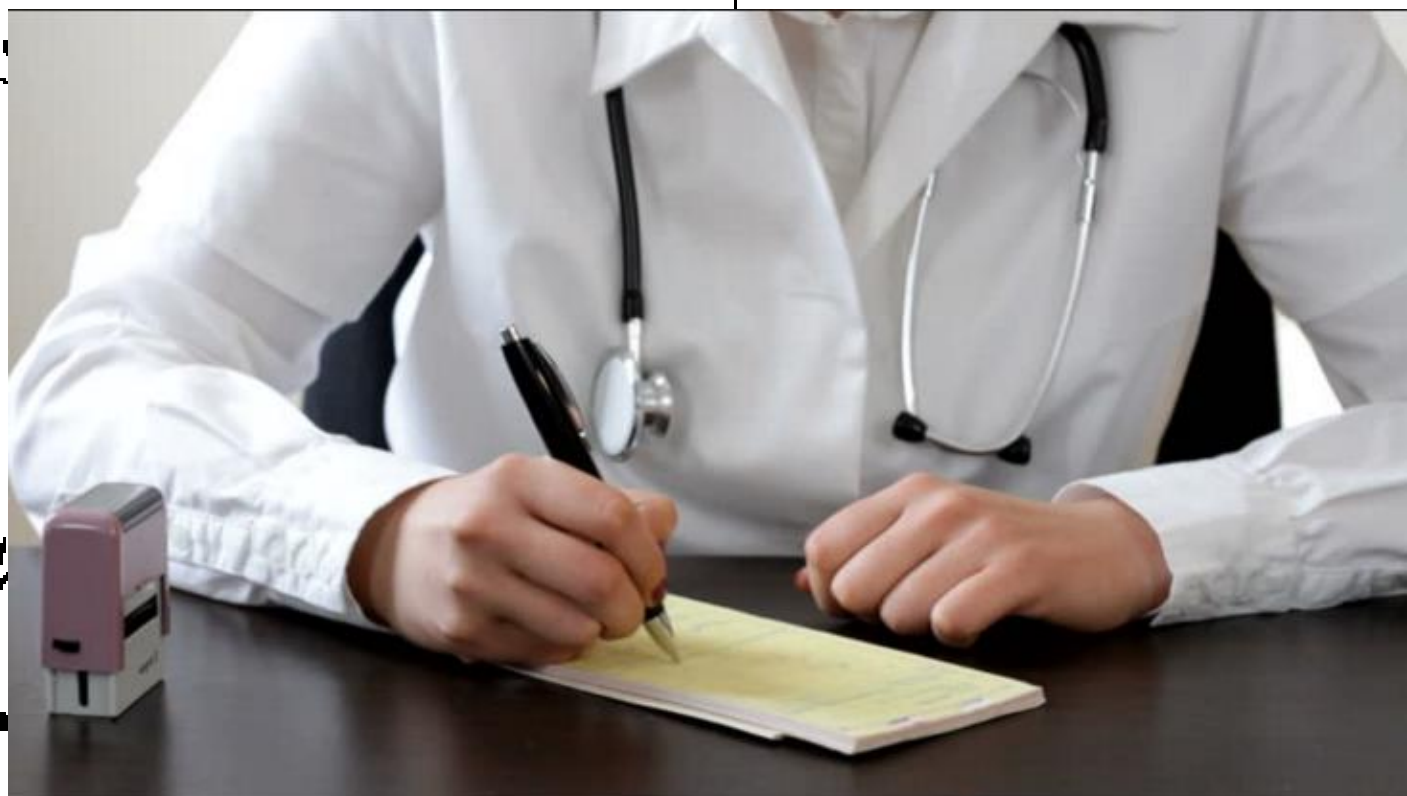- R&D of analytical method (in house)

Dr B. Who
Farmstreet 12
Kirkville
tel. 3876

R/   d

Amoxicillin 5
susp. da 100
S. 3dd 5 ml
(add

R_X **PRESCRIPTION**

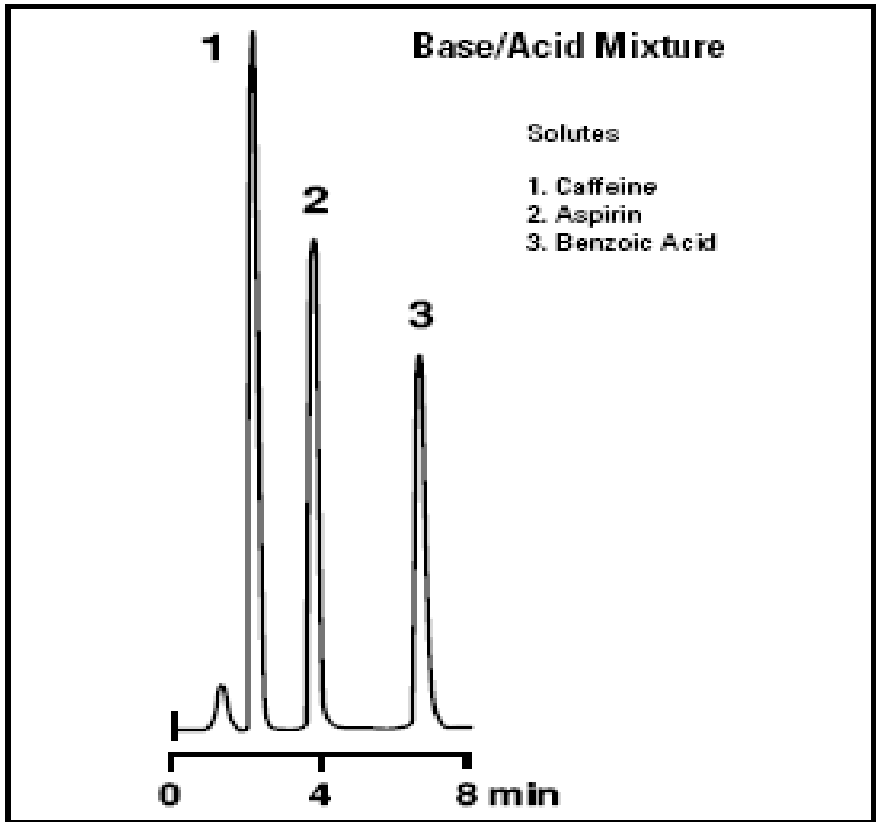NAME _____ AGE _____
ADDRESS _____ DATE _____

Ms/Mr Patient
address:
age: 5 years

Computer Science

Why Pharmacists study Pharmaceutical analytical chemistry?

& How important is the analytical method in pharmacy ?

Base/Acid Mixture

Solutes

1. Caffeine
2. Aspirin
3. Benzoic Acid

Column	Hypersil BDS C18, 5μ,150x4.6mm
Eluent	Methanol:0.05M Phosphate Buffer, pH3.5 (40:60)
Flow Rate	1.0 ml/min
Detection	UV 254nm

Solution all
New Products
Application/Methods
problems

	Quantity/1000 Tablets (g)
	500.00
	65.00
	15.00
	10.00
)	5.00
	33.00
	8.00
	1.00
ᴹ PH102)	10.00
ᴾ)	7.00
)	5.00
	2.00
	4.00
	155.00

أ.د.جمعه الزهوري

Rate $-\dfrac{dc}{dt} = K$

Integrated rate $x = Kt$

$t_{1/2} = \dfrac{a}{2k}$

t (shelf) or $t_{90}\% = \dfrac{a}{10k}$

A drug s...
by zero-...
Constant...
Calculate...
250/7= 3...

STABILITY STUDY

Zero – order rate constant independent on the amount of drug present
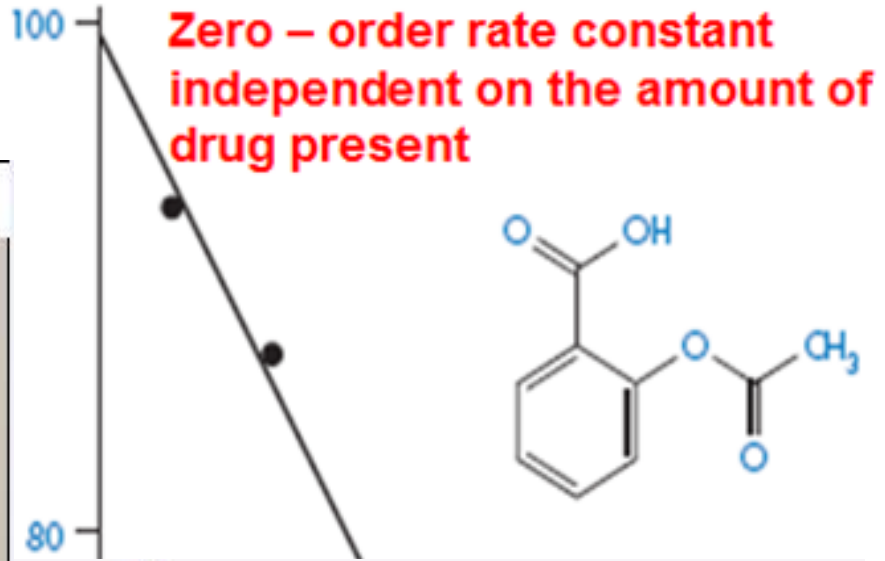
$y = \dfrac{AUC\ oral}{AUC\ injected} \times 100$

Plasma concentration of drug

Drug injected

AUC (injected)

Drug given orally

AUC (oral)

Time

Drug administered
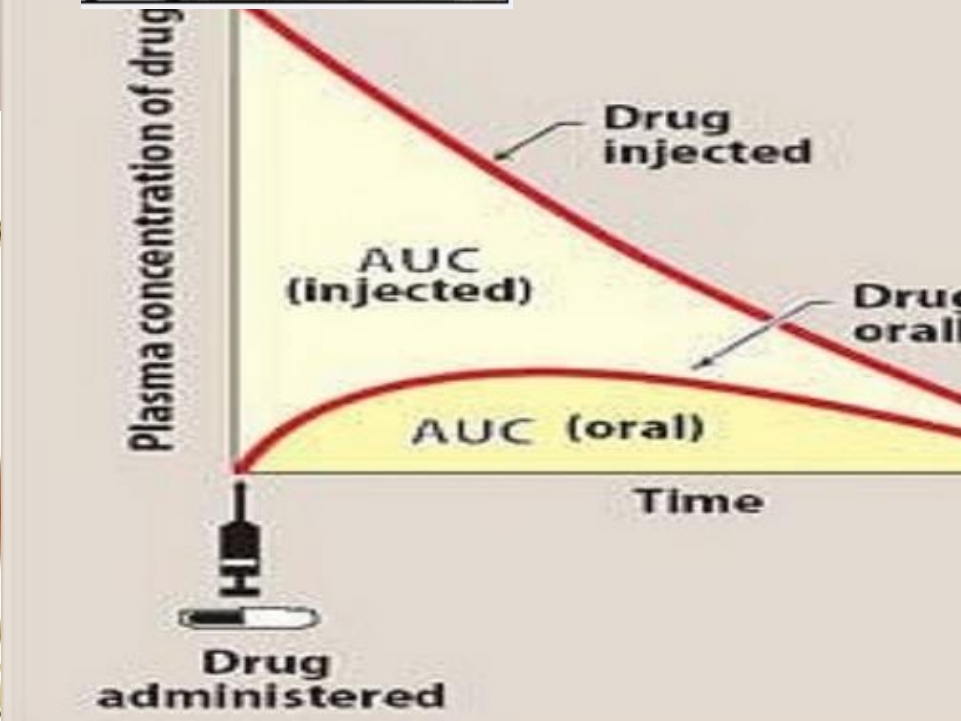
THERAPEUTIC DRUG MONITORING

An example of medicines which its individual dosage adjusted according to its level in serum, mention **antiepileptic** while the kinetic of these drug especially the relationship between it concentration in serum and his effect and the interval between toxic and therapeutic had been studied by many researchers and it was an agreement that the monitor of this drug in serum considered as the corns ton of therapy for epilepsy patients.

Generic Name
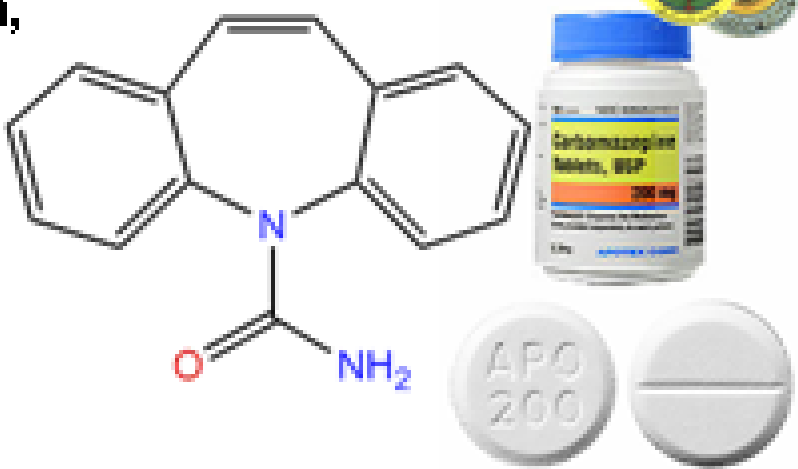
Carbamazepine : 6-10 µg/ml

Time to steady state = 2-6 d

Brand Names :

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Antiepileptics

Conclusion

Every thing is made of chemicals.
Analytical chemists determine

What ?

and

How much

20

Analysis Types

Qualitative analysis

Quantitative analysis

Volumetric analysis

Gravimetric analysis
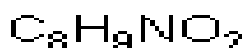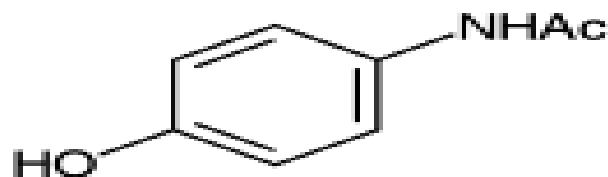
Instrumental analysis

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Qualitative analysis

- **Physical Character** (color, melting point ,pH, light absorption,…)
- **Chemical reaction** (participate, color formulation,….)
- **Instrumentation** (IR,TLC,…..)

22

Paracetamol

$$C_8H_9NO_2 \qquad 151.$$

CHARACTERS

A white, crystalline powder, sparingly soluble in water, freely soluble in alcohol, very slightly soluble in ether and in methylene chloride.

IDENTIFICATION

First identification: A, C.

Second identification: A, B, D, E.

A. Melting point (*2.2.14*): 168°C to 172°C.

B. Dissolve 50 mg in *methanol R* and dilute to 100.0 ml with the same solvent. To 1.0 ml of the solution add 0.5 ml of *0.1M hydrochloric acid* and dilute to 100.0 ml w *methanol R*. Protect the solution from bright light and immediately measure the absorbance (*2.2.25*) at the absorption maximum at 249 nm. The specific absorbance maximum is 860 to 980.
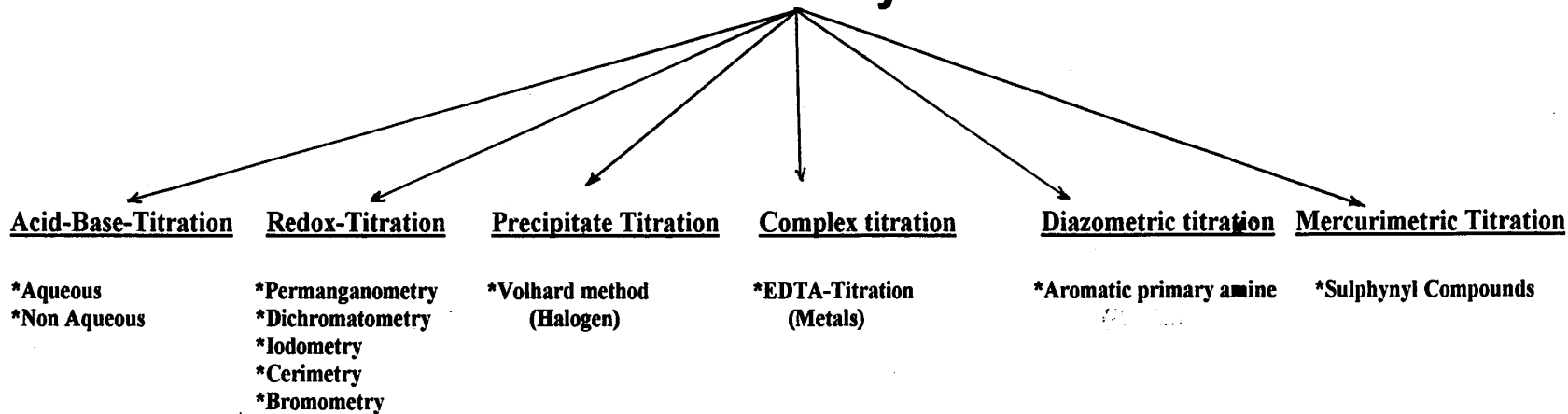
C. Examine by infrared absorption spectrophotometry (*2.2.24*), comparing with the spectrum obtained with *paracetamol CRS*. Examine the substances prepared as

D. To 0.1 g add 1 ml of *hydrochloric acid R*, heat to boiling for 3 min, add 10 ml of *water R* and cool. No precipitate is formed. Add 0.05 ml of *0.0167M potassium dichromate*. A violet colour develops which does not change to red.

E. It gives the reaction of acetyl (*2.3.1*). Heat over a naked flame.

Volumetric Analysis

Acid-Base-Titration	Redox-Titration	Precipitate Titration	Complex titration	Diazometric titration	Mercurimetric Titration
*Aqueous *Non Aqueous	*Permanganometry *Dichromatometry *Iodometry *Cerimetry *Bromometry	*Volhard method (Halogen)	*EDTA-Titration (Metals)	*Aromatic primary amine	*Sulphynyl Compounds

Instrumental Analysis

Spectrophotometric methods

* UV-Vis
*Fluorescence Spectroscopy
*IR
* MS
* NMR (H,C)
*AAS
* AES = Flame Photometry
* X-ray Spectrometry

Chromatographic methods

* TLC , PC
* HPTLC
* GC (GSC , GLC)
* HPLC ,LSC,LLC
* Ion-ExchangeChromato.
* Gel Chromatography

Electrochemical methods

* Voltametry (Polarography)
* Amperometry
* Conductometry
* Coulonmetry
* Electrogravimetry

Immunoassay methods

* RIA
* EIA
* FluorescenceImmuno assay
* PCR

Anhydrous Citric Acid

$C_6H_8O_7$ 192.1

ASSAY

Dissolve 0.550 g in 50 ml of water R. Titrate with 1M sodium hydroxide VS, using 0.5 ml of phenolphthalein solution R as indicator.

Each 1 ml of 1M sodium hydroxide VS is equivalent to 64.03 mg of C6H8O7.

26

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Lithium Carbonate Tablets (300 mg)

Li$_2$CO$_3$ 73.9   (use : Antimanic)

Assay

Weigh and powder 20 tablets. Add a quantity of the powder containing 1 g of Lithium Carbonate to 100 ml of *water*, add 50 ml of 1M *hydrochloric acid VS* and boil for 1 minute to remove the carbon dioxide. Cool and titrate the excess of acid with 1M *sodium hydroxide VS* using *methyl orange solution* as indicator. Each ml of 1M *hydrochloric acid VS* is equivalent to 36.95 mg of Li2CO3.

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Safety in the laboratory

- Lab coat
- To prepare an dilute acid solution from concentrated acid , Be caution first water then acid.
- Most of the chemicals in a laboratory are toxic, and some-such as concentratrd solutions of acids and bases –are highly corrosive.
- Avoid contact between these liquids and the skin.
- Never Perform an unauthorized experiment.
- Never bring food or beverages in to the laboratory.
- Don't smoke in the laboratory.
- Always use a bulbe to draw liquids in to pipet.
- Use fume hoods whenever toxic or noxious gases are likely to be evolved. ضار
- Be cautious in testing for odors.

28

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Solution
and the
Stoichometric calculation

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Solution and the Stoichometric calculation

- **Solution and Solvent**
- **Dielectric constant**
- **Water**
- **Molecular weight, Mole and Equivalent weight.**
- **Concentration methods (Molarity,Normality,Percentage…)**
- **Dilution**
- **Question and problems**

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Solutions

Solution is a mixture of homogenous chemical constituents, it consist of Solvent and Solute.

Solvent + Solute → Solution

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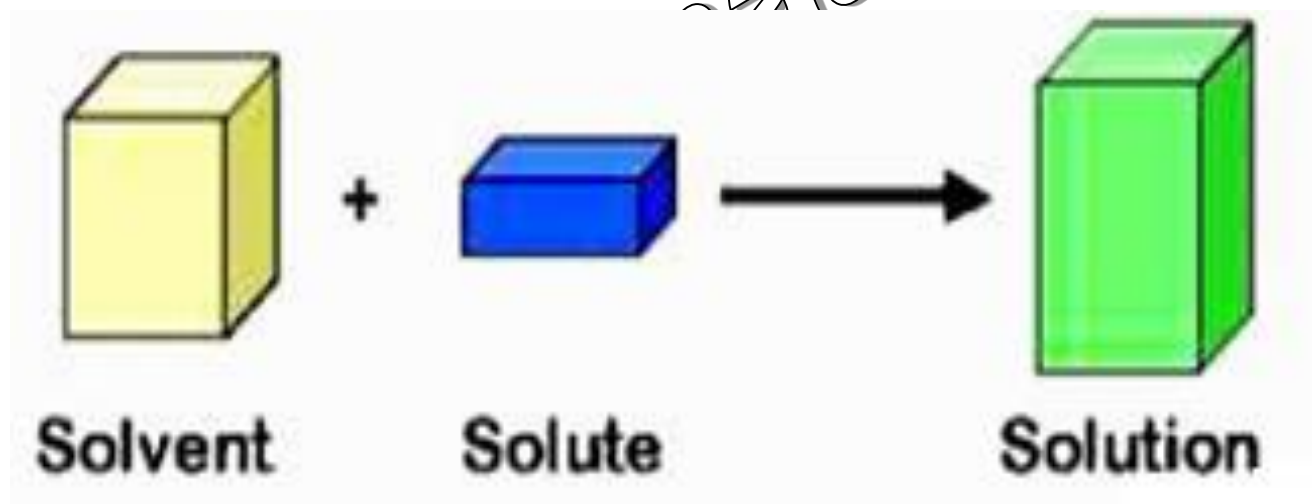
Solution

Solution = **Solvent** + **Solute**

Nonpolar
(Lipophile)

Polar
(Hydrophile)

Dipole moment

Solution Characters

Homogenous   disappear of

chemical reaction

Solubility of solute

- The solubility of solid in liquids usually increase with an increase in temperature.

- Like (solvent) dissolve Like (solute)

34

The following table indicates the meanings of the terms used in statements of approximate solubilities.

Descriptive term	Approximate volume of solvent in millilitres per gram of solute
very soluble	less than 1
freely soluble	from 1 to 10
soluble	from 10 to 30
sparingly soluble	from 30 to 100
slightly soluble	from 100 to 1000
very slightly soluble	from 1000 to 10 000
practically insoluble	more than 10 000

The term 'partly soluble' is used to describe a mixture of which only some of the components dissolve.

1. HOH CH_4

2. HOH CH_3OH

3. HOH   CHO

                         $(CHOH)_4$

                         CH_2OH

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Molecular representations

H_2O - water

CH_3CH_2OH - ethyl alcohol
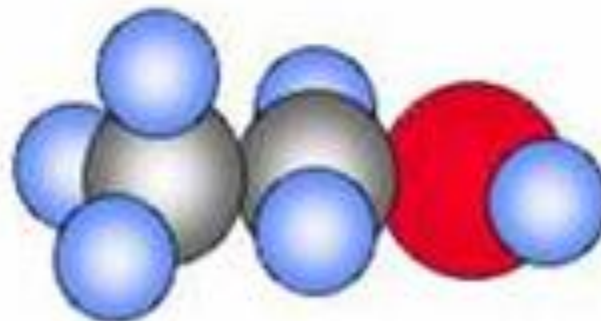
Water

- The water molecule is a bent polar molecule with a bend angel of 104.5^o

H   H

104.5o

O
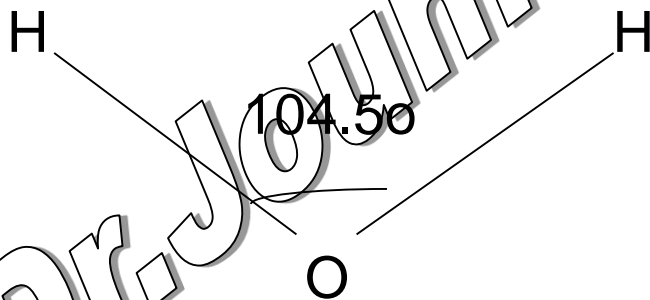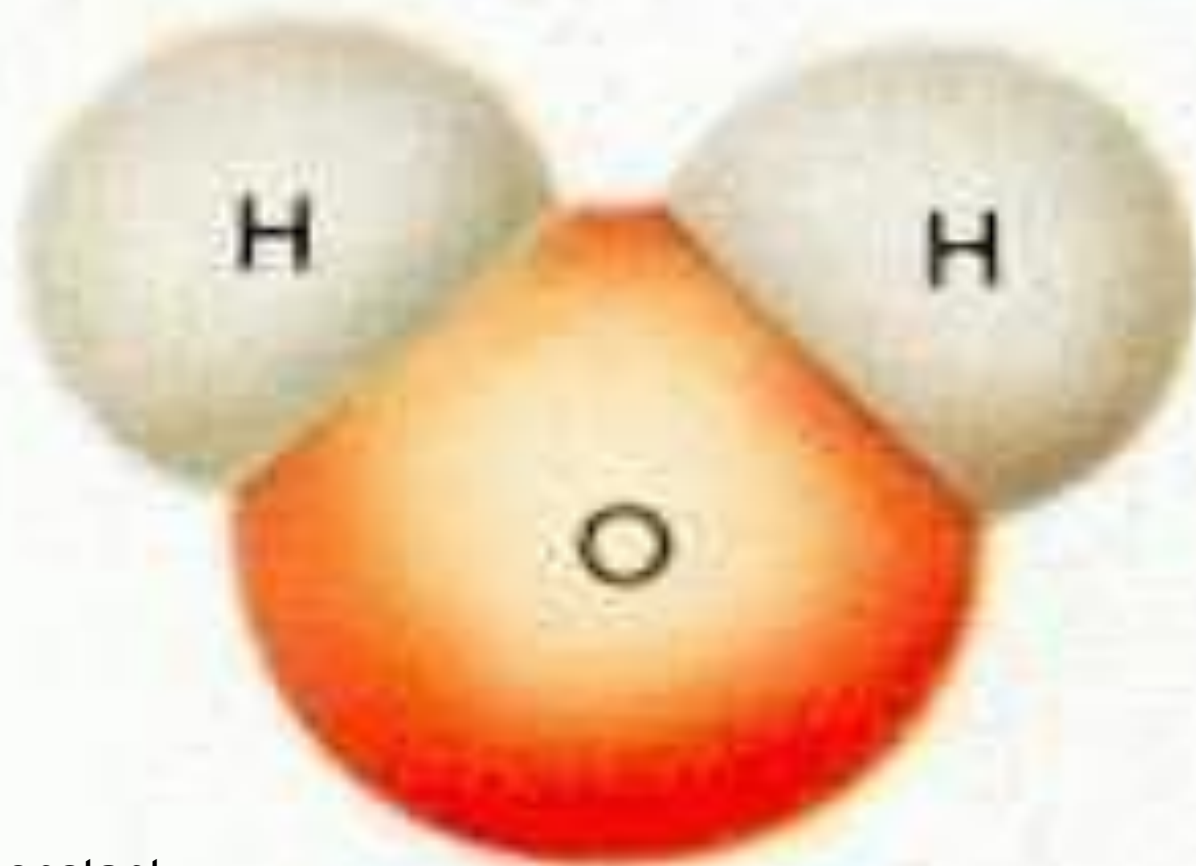
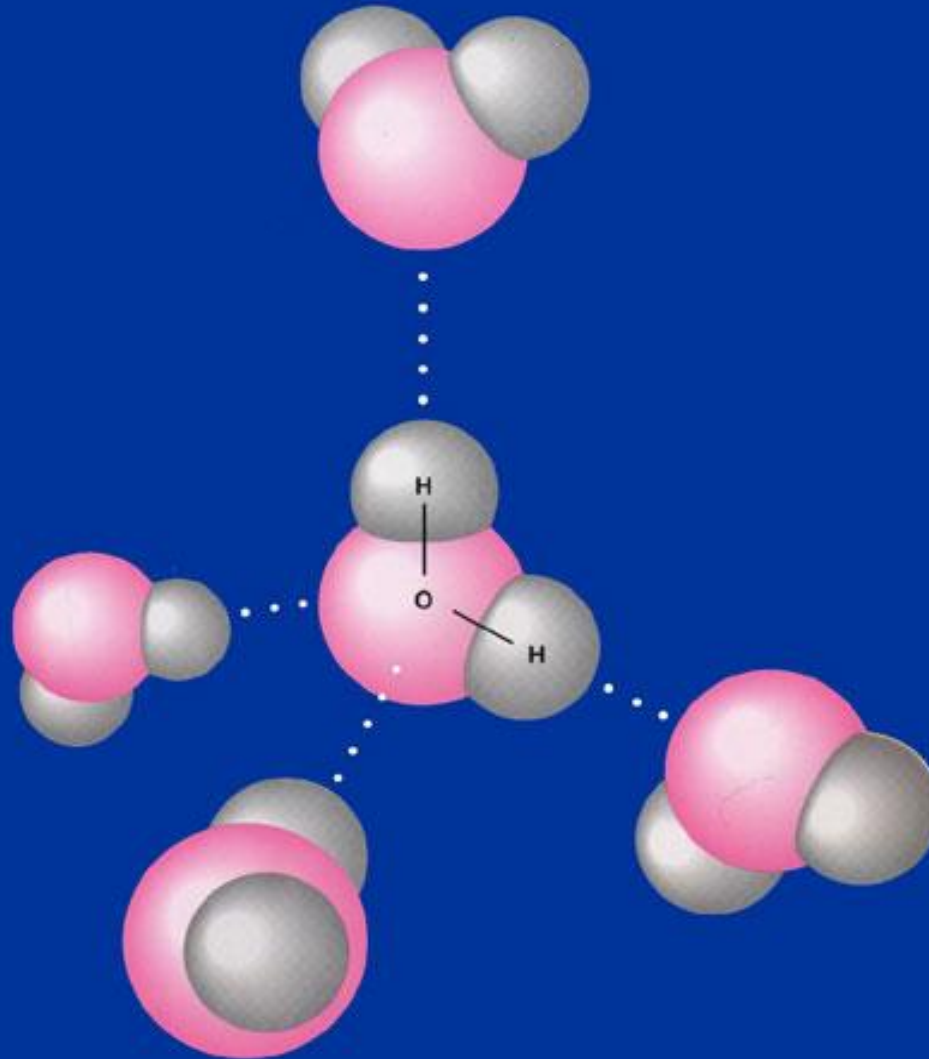Dielectric constant

$(\varepsilon) = 80 \implies$ more ability to dissolve the ionic compounds (NaCl…)

يتمتع الماء بأعلى قيمة لثابتة العزل الكهربائي

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HYDROGEN BONDS BETWEEN WATER MOLECULES

Water

Hydrogen bonds can form between any two molecules that each have hydrogen atoms directly bonded to:

N , O , or F Atoms

Water in Pharmacy

- The most common solvent of ingredient in order to make liquid dosage form , Like Syrups , drops, Ampoule ,Vials ..) or semi liquid like (ointments , creams ….) .

- In order to dissolve some dosage form like effervescent tablets and the powder in vials or suspension.

- In order to dissolve the drugs in aqueous solution.

- In bio-assay

- To prepare the buffer solution.

42

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Types of water in Pharmacy

According to British Pharmacopoeia ,we have several type of water , some of their :

1- Water for injection

2- Purified water

3- Distilled Water

4- Water for Chromatography

……

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Stoichiometric

Calculations

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Definition :

Stoichiometry **Refers to the combining ratios among molar quantities of species in chemical reaction.**

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Stoichiometric Calculations

- **Stoichometry deals with the ratios in which chemicals react.**

    - We calculate the mass of analyte in solution from its concentration and the volume.

    - we calculate the mass of product expected from the mass of reactant.

Stoichiometric Calculations

- **The mole & Chemical equations**

You need a balanced Equation and you will Work with moles

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Solution Stiochometric

What mass of $CaCO_3$ is required to react with 25 ml of 0.75 M HCl?

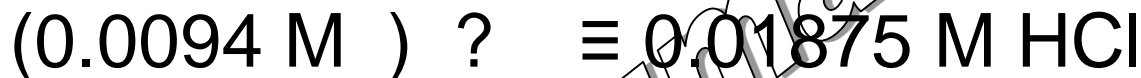$$CaCO_3 + 2HCl \longrightarrow CaCl_2 + H_2O + CO_2 \nearrow$$

Answer = 0.94 gram

Solution Stiochometric

0.75 mol ⟹ each 1000 ml cont. 0.75 M HCl

each 25 ml cont. 0.01875MHCl

Consider the chemical reaction:

1 M $CaCO_3$ ≡ 2 M HCl

(0.0094 M) ? ≡ 0.01875 M HCl

1 mol CaCO3 = 100 gram

0.0094 M = ? (0.94 gram)

Answer

49

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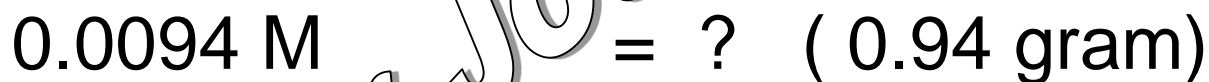
2- Mole

Definition :

Mole The amount of substance contained in
6.022 x 10^{23} particles of that substance

=Molar mass

50

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Mole

Since a mole of any substance contains the same number of atoms or molecules as a mole of any other substance, atoms will react in the same mole ratio as their atom ratio in the reaction.

Example : in the following reaction ,one silver ion reacts with one chloride ion, and so each mole of silver ion will react with one mole of chloride ion .(Each 107.87 g will react with 35.453 g)
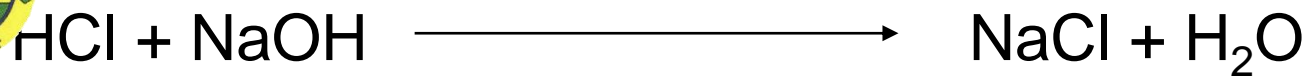
$$Ag^+ + Cl^- \longrightarrow AgCl \downarrow$$
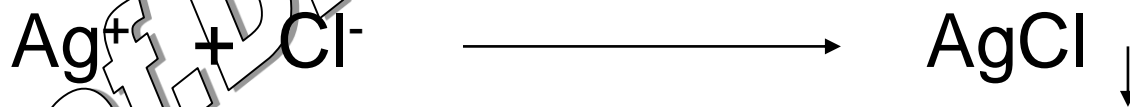
3- **Equivalent Weight (Gram)**

- **The equivalent weight is that weight of a substance in gram that will furnish one mole reacting unit. So one equivalent of an analyte reacts with one equivalent of a reagent, even if the Stoichiometry of the reaction is not one to one.**
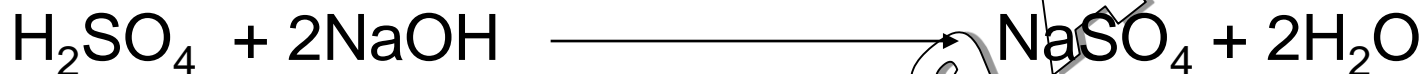
Eq =MW/z
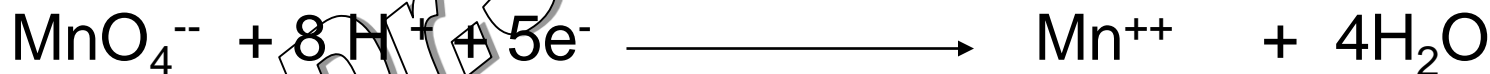
(z= no. of replacement unit in the reaction.)

52

$$HCl + NaOH \longrightarrow NaCl + H_2O$$

Eq (HCl) = 36.5/1 = 36.5 g

1 mole = 1Eq

$$H_2SO_4 + 2NaOH \longrightarrow NaSO_4 + 2H_2O$$

Eq (H_2SO4) = 98/2 = 49 g

1mole = 2 Eq

$$MnO_4^{--} + 8 H^+ + 5e^- \longrightarrow Mn^{++} + 4H_2O$$
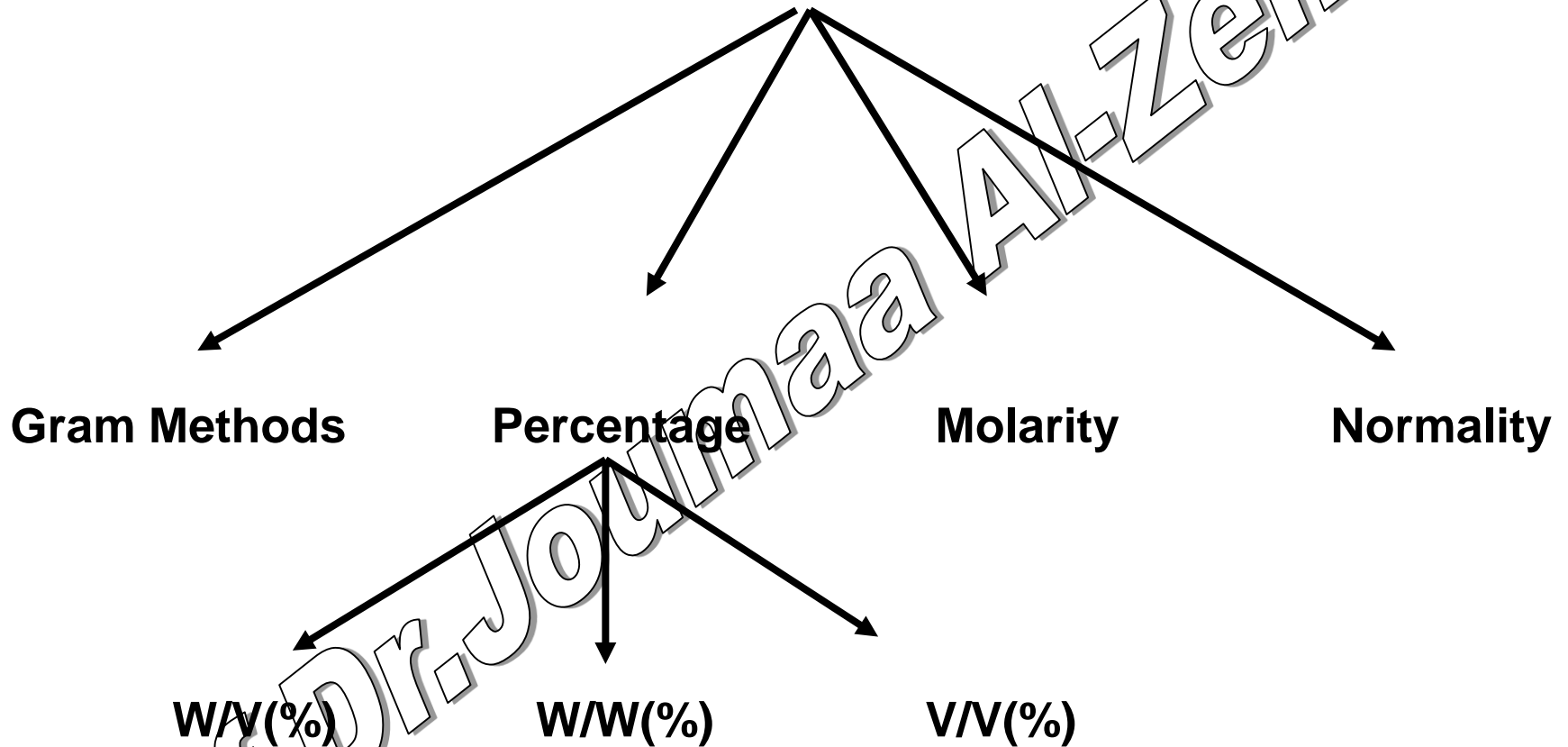
Eq ($KMnO_4$) = 158/5 = 31.6 g

1mole = 5 Eq

(Analyte)

- Analyte The species in the sample about which analytical information is sought

- Sampling The process of collecting a small part of a material whose composition is representative of the bulk of material from which it was taken

CONCENTRATION METHODS

Gram Methods   **Percentage**   **Molarity**   **Normality**

W/V(%)   **W/W(%)**   **V/V(%)**

55

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Gram method

- ## The amount of mass solute expressing in gram in one liter solution

- g /l = Mass solute(g) / Liters of Solution

- $1g = 10^3$ mg $= 10^6$ μg $=10^9$ ng $=10^{12}$pg

- $1L = 10^3$ ml $= 10^6$ μl

- The unit of volume is the liter (L), defined as one cubic decimeter.

56

Gram method

- What is the volume of solution which can be prepare in 9 g /l using 54 gram of Sodium chloride.

- Answer = 6 liters

57

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Definitions :

Weight/Volume percent (w/v) The ratio of the mass of a solute to the volume of solution in which it is dissolved , multiplied by 100 %

Weight percent (w/w) The ratio of the mass of a solute to the mass of its solution, multiplied by 100 %

Volume percent (v/v) The ratio between the volume of a liquid and the volume of its solution, multiplied by 100%

Concentration

Molarity - M

The number of moles of a material per liter of solution.

$$M = \frac{mol\ A}{L\ solution} = \frac{mmol\ A}{mL\ solution}$$

$$= \frac{\dfrac{grams\ A}{Formula\ Weight\ A}}{liters\ of\ solution}$$

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- How can you prepare 1 M NaCl solution?
  (NaCl =58.5)

58.5 g of NaCl added to 1000 ml volumetric flask and dissolve with dist. water to the volume.

60

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- A solution of AgNO3 contain in each 250 ml 1.26 gram ,What is the Molarity ?

  250 ml   cont. 1.26 gram AgNO3

  1000 ml cont.   ? (5.04 g)

  1 M AgNO$_3$ 169.9 gram

   ?   5.04 g

  (0.0297 mol/l)

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Calculation with normality

Normality - N

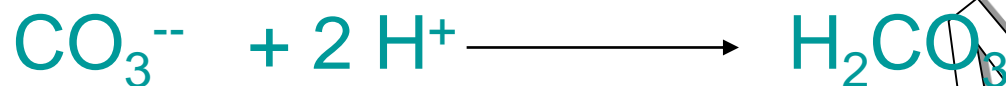Number of equivalents / liter of solution

Equivalent

Defined such that one equivalent of one material will react exactly with one equivalent of another.

This will vary based on the type of reaction and the reactants.

According to the following reaction what is the Normality of 5.3 gram / Liters of Na_2CO_3 ?

$$CO_3^{--} + 2\,H^+ \longrightarrow H_2CO_3$$

$$N = \frac{Nr\ .of\ Equivalent}{1\ liter}$$

$Na_2CO_3 = 106\,/2 = 53$ gram

$1\,E = 53$ gram

$5.3/53 = 0.1$

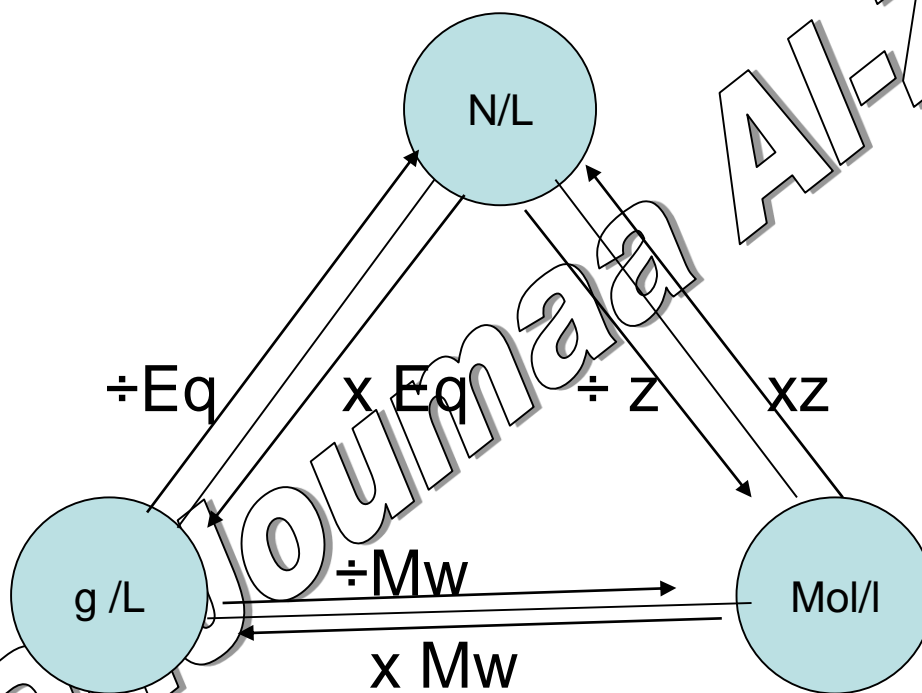$N = 0.1/1$ liter $= 0.1$ N

63

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Definitions :

Molarity, M The number of moles of a species contained in one liter of solution or the number of millimoles contained in one milliliter.

Normality, N or C_N The number of equivalent weights of a species in one liter of solution
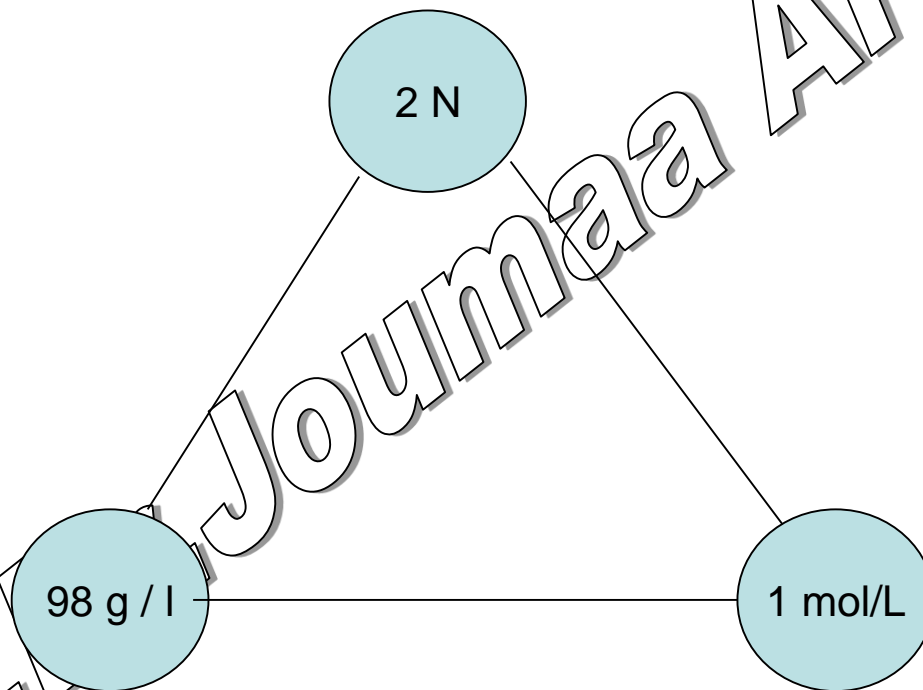
64

Converting Between Concentration Units

N/L

g /L

Mol/l

÷Eq   x Eq   ÷ z   xz

÷Mw

x Mw

(z= no. of replacement unit in the reaction.)

65

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Converting Between Concentration Units

- Example H_2SO_4 1mol/l

2 N

98 g / l

1 mol/L

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- What is the Normality of 2 Molar H_2SO_4 Solution ?

- Answer = 4

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- Calculate the concentration of 1 N NaOH Solution in gram method?

- Answer = 40 g/L

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- If the Na concentration in blood 140 mmol/L. What is the concentration in gram (Na=23) .

- Answer = 3.22 g I L

Na ↑ ➡ **Hypertension**

Na ↓ ➡ **Dehydration**

69

- If the glucose concentration in blood 100 mg/dl . What is the concentration in mmol/L (M .w = 180 g)

- Answer = 5.55 mmol/L

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Other units of concentration

Parts per million and parts per billion

   These are extensions of the % system which are used for very dilute solutions

$$ppm = \frac{wt\ solute}{wt\ solution} \times 10^6$$

$$ppb = \frac{wt\ solute}{wt\ solution} \times 10^9$$

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If 100 ml of water contain 1 mg of solute. What is the concentration in ppm &ppb?

$$\text{ppm} = \frac{\text{wt. solute}}{\text{wt. solution}} \times 10^6 = \frac{0.001}{100} \times 10^6 = 10$$

$$\text{ppb} = \frac{\text{wt. solute}}{\text{wt. solution}} \times 10^9 = \frac{0.001}{100} \times 10^9 = 10000$$

72

Definition :

Parts per million, ppm A convenient method for expressing the concentration of a solute species that exists in trace amounts. For dilute aqueous solutions, ppm is synonymous with mg solute/L solution.

For aqueous Solutions :

> ppm = mg / Liter = µg/ml
> ppb = µg/Liter = ng / ml

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Other units of concentration

p functions or **p- Values**

p is used to represent -log[ ]

$$pH = -log[H^+]$$

$$pCl = -log[Cl^-]$$

This system is useful for dealing with large concentration changes. It is also commonly used with potentiometric measurements.

Definition :

p-Values   An expression of the concentration of a solute species as its negative logarithm. The use of p-values permits expression of enormous ranges of concentration in terms of relatively small numbers.

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Dilution and Concentration

- **Dilution** : Main operation in analytical chemistry to decrease the concentration of solutions or to prepare standard series

Stock Solution (V) x C = Final (V) x C (F)

- **Stock Solution** = Solution of known concentration that are frequently prepared by the pharmacist for convenience in dispensing.

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Example: How many milliliters of 0.25 % (w/v) stock solution should be used to make 4 liters of a 0.05% (w/v) solution ?

Stock solution (V) x C = Final (V) x C (F)
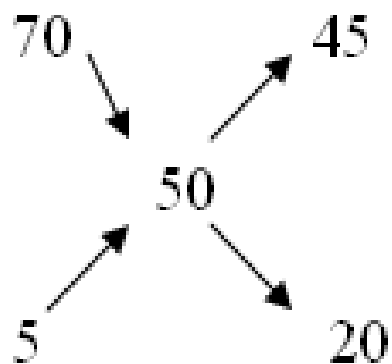
?   X 0.25 =   4000 ml X 0.05

? = 800 ml , answer

Example (2)

How can we prepare 50%(w/v) solution from 5% (w/v) and 70% (w/v) solutions.

Answer : 45 part of 70% + 20 part of 5% .

```
70              45
    ↘        ↗
        50
    ↗        ↘
5               20
```

- *Example :*

  How Many milliliter must be took from Hydrochloric acid 37% (d=1.1341) and diluted to 1 Liter with water to obtain approximately 0.1 N solution .

  Answer   8.698 ml

QUESTIONS

AND

PROBLEMS

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Example 2 :

- What is the volume of solution which can be prepare in 3% (w / v) using 27 gram of potassium permanganate?

$$3 = \frac{27}{? \text{ ml}} \times 100 = 900 \text{ ml}$$

$$\text{w/v\%} = \frac{\text{Mass Solute}}{\text{total vol}} \times 100$$

81

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Percentage weight to volume

Example (1)

How many grams of dextrose are required to prepare 4000 ml of 5% (w/v) solution ?

Answer = 200 gram.

5% = 0.05

4000 g × 0.05 = 200 g, answer.

Or, solving by dimensional analysis:

$$\frac{5 \text{ g}}{100 \text{ ml}} \times 4000 \text{ ml} = 200 \text{ g}, \text{ answer.}$$

$$5 = \frac{?}{4000} \times 100$$

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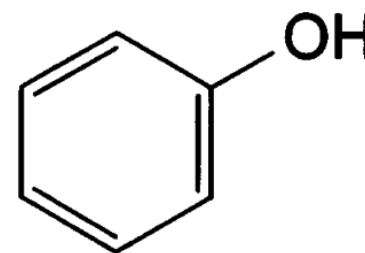
Percentage weight-in-weight

- ## Example(1)

How many grams of phenol should be used to prepare 240 g of a 5 % (w/w) solution in water ?

Answer 12 gram.

Weight of solution (g) $\times$ % (expressed as a decimal) = g of solute

240 g $\times$ 0.05 = 12 g, *answer.*

OH

Action and use
Antiseptic; antimicrobial preservative; antipruritic

$$5 = \frac{?}{240} \times 100$$

83

Percentage volume – in- volume

- Example:

If 500 ml of a 15% (v/v) solution of methyl Salicylate in alcohol are diluted to 1500. What will be the percentage (v/v).

Answer 5%.

$$\frac{1500 \ (mL)}{500 \ (mL)} = \frac{15 \ (\%)}{x \ (\%)}$$

$$x = 5\%, answer.$$

Or,

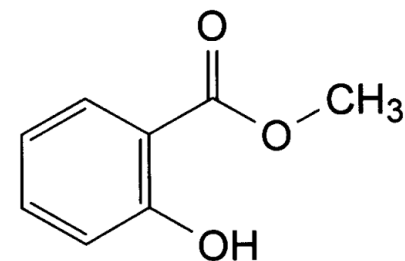$$(quantity) \times (concentration) = (quantity) \times (concentration)$$
$$500 \ (mL) \times 15 \ (\%) = 1500 \ (mL) \times x \ (\%)$$
$$x = 5\%, answer.$$

Or,

500 mL of 15% (v/v) solution contain 75 mL of methyl salicylate (active ingredient)

$$\frac{1500 \ (mL)}{75 \ (mL)} = \frac{100 \ (\%)}{x \ (\%)}$$

$$x = 5\%, answer.$$

Action and use

Counter-irritant

84

Percentage weight – in- weight

How many grams Of a drug substance should be dissolved in 240 ml of water to make a 4% (w/w) solution ?

Answer = 9.6 gr

100% − 4% = 96% (by weight) of water

240 mL of water weigh 240 g

$$\frac{96\ (\%)}{4\ (\%)} = \frac{240\ (g)}{x\ (g)}$$

x = 9.6 gr

$$4 = \frac{?}{240} \times 100$$

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Density or Specific Gravity of solution

- Describe the preparation of 1000 ml of approximately 6 M HCl from a concentrated solution that has a specific gravity of 1.18 and is 37% (w/w) HCl

(HCl=36.5)

- Answer 501.6 ml to 1000ml .

Thank you

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Q&A