IPC/UNIT-1

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ACIDS AND BASES

By the 1884 definition of Svante Arrhenius (Sweden), an acid is a material that can release a proton or hydrogen ion (H^+). Hydrogen chloride in water solution ionizes and becomes hydrogen ions and chloride ions. If that is the case, a base, or alkali, is a material that can donate a hydroxide ion (OH^-). Sodium hydroxide in water solution becomes sodium ions and hydroxide ions.

By the definition of both Thomas Lowry (England) and J.N. Brønsted (Denmark) working independently in 1923, an acid is a material that donates a proton and a base is a material that can accept a proton.

The G.N. Lewis (1923) idea of acids and bases is broader than the Lowry - Brønsted model. The Lewis definitions are: Acids are electron pair acceptors and bases are electron pair donors.

We can consider the same idea in the Lowry - Brønsted fashion. Each ionizable pair has a proton donor and a proton acceptor. Acids are paired with bases. One can accept a proton and the other can donate a proton. Each acid has a proton available (an ionizable hydrogen) and another part, called the ***conjugate base***. (That word, 'conjugate' just means that it "goes with" the other part.) When the acid ionizes, the hydrogen ion is the acid and the rest of the original acid is the conjugate base. Nitric acid, HNO_3, ***dissociates*** (splits) into a hydrogen ion and a nitrate ion. The hydrogen almost immediately joins to a water molecule to make a hydronium ion. The nitrate ion is the conjugate base of the hydrogen ion. In the second part of the reaction, water is a base (because it can accept a proton) and the hydronium ion is its conjugate acid.

$$\underset{\text{ACID}}{HNO_3} + \underset{\text{BASE}}{H_2O} \rightarrow \underset{\text{CONJUGATE BASE}}{(NO_3)^-} + \underset{\text{CONJUGATE ACID}}{(H_3O)^+}$$

PROPERTIES OF ACIDS

For the properties of acids and bases we will use the Arrhenius definitions.

Acids release a hydrogen ion into water (aqueous) solution. You will usually see the formula for an acid with the ionizable hydrogen at the beginning, such as HCl, hydrochloric acid, or $H(C_2H_3O_2)$, acetic acid.

- **Acids neutralize bases in a neutralization reaction**. An acid and a base combine to make a ***salt*** and water. A salt is any ionic compound that could be made with the anion of an acid and the cation of a base. The hydrogen ion of the acid and the hydroxide ion of the base unite to form water.
- **Acids corrode active metals**. Even gold, the least active metal, is attacked by an acid, a mixture of acids called 'aqua regia,' or 'royal liquid.' When an acid reacts with a metal, it produces a compound with the cation of the metal and the anion of the acid and hydrogen gas.
- **Acids turn blue litmus to red**. Litmus is one of a large number of organic compounds that change colors when a solution changes acidity at a particular point. Litmus is the oldest known pH indicator. It is red in acid and blue in base. The phrase, 'litmus test,' indicates that litmus has been around a long time in the English language. Litmus does not change color exactly at the neutral point between acid and base, but very close to it. Litmus is often impregnated onto paper to make 'litmus paper.'
- **Acids taste sour**. Acetic acid is the acid ingredient in vinegar

PROPERTIES OF BASES

- **Bases release a hydroxide ion into water solution**. (Or, in the Lowry - Brønsted model, cause a hydroxide ion to be released into water solution by accepting a hydrogen ion in water.)
- **Bases neutralize acids in a neutralization reaction**. The word - reaction is: Acid plus base makes water plus a salt.
Where 'Y' is the anion of acid 'HY,' and 'X' is the cation of base 'XOH,' and 'XY' is the salt in the product, the reaction is: $HY + XOH \longrightarrow HOH + XY$
- **Bases denature protein**. This accounts for the "slippery" feeling on hands when exposed to base. Strong bases that dissolve in water well, such as sodium or potassium lye are very dangerous because a great amount of the structural material of human beings is made of protein. Serious damage to flesh can be avoided by careful use of strong bases.
- **Bases turn red litmus to blue**. This is not to say that litmus is the only acid - base indicator, but that it is likely the oldest one.
- **Bases taste bitter**. There are very few food materials that are alkaline, but those that are taste bitter.

STRONG ACIDS AND STRONG BASES

The common acids that are almost one hundred percent ionized are:
HNO_3 - nitric acid

HCl - hydrochloric acid
H_2SO_4 - sulfuric acid
$HClO_4$ - perchloric acid
HBr - hydrobromic acid
HI - hydroiodic acid

Likewise, there is a short list of strong bases,

$LiOH$ - lithium hydroxide
$NaOH$ - sodium hydroxide
KOH - potassium hydroxide
$RbOH$ - rubidium hydroxide
$CsOH$ - cesium hydroxide
($Mg(OH)_2$ - magnesium hydroxide)
($Ca(OH)_2$ - calcium hydroxide)
($Sr(OH)_2$ - strontium hydroxide)

Sodium hydroxide

Sodium hydroxide (**NaOH**), also known as **lye** and **caustic soda**,[1][2] is an inorganic compound. It is a white solid and highlycaustic metallic base and alkali salt which is available in pellets, flakes, granules, and as prepared solutions at a number of different concentrations.[9] Sodium hydroxide forms an approximately 50% (by weight) saturated solution with water.[10]

Sodium hydroxide is soluble in water, ethanol and methanol.
This alkali is deliquescent and readily absorbs moisture and carbon dioxide in air.

Sodium hydroxide is used in many industries, mostly as a strong chemical base in the manufacture of pulp and paper, textiles,drinking water, soaps and detergents and as a drain cleaner.

Properties:

Physical properties:
Pure sodium hydroxide is a whitish solid, sold in pellets, flakes, and granular form, as well as in solution. It is highly soluble in water, with a lower solubility in ethanol and methanol, but is insoluble in ether and other non-polar solvents.

Similar to the hydration of sulfuric acid, dissolution of solid sodium hydroxide in water is a highly exothermic reaction in which a large amount of heat is liberated, posing a threat to safety through the possibility of splashing. The resulting solution is usually colourless and odorless with slippery feeling upon contact in common with other alkalis.

Chemical properties:

Reaction with acids:

Sodium hydroxide reacts with protic acids to produce water and the corresponding salts. For example, when sodium hydroxide reacts with hydrochloric acid, sodium chloride is formed:

$$NaOH(aq) + HCl(aq) \rightarrow NaCl(aq) + H_2O(l)$$

In general, such neutralization reactions are represented by one simple net ionic equation:

$$OH^-(aq) + H^+(aq) \rightarrow H_2O(l)$$

This type of reaction with a strong acid releases heat, and hence is exothermic. Such acid-base reactions can also be used fortitrations. However, sodium hydroxide is not used as a primary standard because it is hygroscopic and absorbs carbon dioxide from air.

Production:

Sodium hydroxide is industrially produced as a 50% solution by variations of the electrolytic chloralkali process. Chlorine gas is also produced in this process. Solid sodium hydroxide is obtained from this solution by the evaporation of water. Solid sodium hydroxide is most commonly sold as flakes, prills, and cast blocks.

Historically, sodium hydroxide was produced by treating sodium carbonate with calcium hydroxide in a metathesis reaction. (Sodium hydroxide is soluble while calcium carbonate is not.) This process was called causticizing.

$$Ca(OH)_2(aq) + Na_2CO_3(s) \rightarrow CaCO_3 \rightarrow + 2\ NaOH(aq)$$

This process was superseded by the Solvay process in the late 19th century,.

Uses:

Sodium hydroxide is a popular strong base used in industry. Around 56% of sodium hydroxide produced is used by industry, 25% of which is used in the paper industry. Sodium hydroxide is also used in the manufacture of sodium salts and detergents, pH regulation, and organic synthesis. It is used in the Bayer process of aluminium production.[11] In bulk, it is most often handled as an aqueous solution,[15]since solutions are cheaper and easier to handle.

Sodium hydroxide is used in many scenarios where it is desirable to increase the alkalinity of a mixture, or to neutralize acids.

For example, in petroleum industry, sodium hydroxide is used as an additive in drilling mud to increase alkalinity in bentonite mud systems, to increase the mud viscosity, and to neutralize any acid gas (such as hydrogen sulfide and carbon dioxide) which may be encountered in the geological formation as drilling progresses

Phosphoric acid

Phosphoric acid (also known as **orthophosphoric acid** or **phosphoric(V) acid**) is a mineral (inorganic) acid having the chemical formula H_3PO_4.
Orthophosphoric acid molecules can combine with themselves to form a variety of compounds which are also referred to as **phosphoric acids**, but in a more general way. Orthophosphoric acid refers to *phosphoric acid*, which is the IUPAC name for this compound. The prefix *ortho* is used to distinguish the acid from related phosphoric acids, called polyphosphoric acids. Orthophosphoric acid is a non-toxic acid, which, when pure, is a solid at room temperature and pressure.

Reactions

Anhydrous phosphoric acid, a white low melting solid, is obtained by dehydration of 85% phosphoric acid by heating under a vacuum.[6]
Orthophosphoric acid is a very polar molecule. It is miscible with water. The oxidation state of phosphorus (P) in ortho- and other phosphoric acids is +5; the oxidation state of all the oxygen atoms (O) is −2 and all the hydrogen atoms (H) is +1. Triprotic means that an orthophosphoric acid molecule can dissociate up to three times, giving up an H^+ each time, which typically combines with awater molecule, H_2O, as shown in these reactions:

$$H_3PO_{4(s)} + H_2O_{(l)} \rightleftharpoons H_3O^+_{(aq)} + H_2PO_4^-{}_{(aq)} \qquad K_{a1} = 7.25\times10^{-3}$$

$$H_2PO_4^-{}_{(aq)} + H_2O_{(l)} \rightleftharpoons H_3O^+_{(aq)} + HPO_4^{2-}{}_{(aq)} \qquad K_{a2} = 6.31\times10^{-8}$$

$$HPO_4^{2-}{}_{(aq)} + H_2O_{(l)} \rightleftharpoons H_3O^+_{(aq)} + PO_4^{3-}{}_{(aq)} \qquad K_{a3} = 4.80\times10^{-13}$$

Preparation

Laboratory routes

A demonstrative process consists in the oxidation of red phosphorus by nitric acid.

$$\tfrac{1}{n}\,P_n + 5\,HNO_3 \rightarrow H_2O + H_3PO_4 + 5\,NO_2$$

Uses:

Phosphoric acid is used in dentistry and orthodontics as an etching solution, to clean and roughen the surfaces of teeth where dental appliances or fillings will be placed. Phosphoric acid is also an ingredient in over-the-counter anti-nausea medications that also contain high levels of sugar (glucose and fructose). This acid is also used in many teeth whiteners to eliminate plaque that may be on the teeth before application.

Limit Tests

Definition of Limit Tests

Definition

Limit = a value or amount that is likely to be present in a substance
Test = to examine or to investigate
Impurities = a foreign matter present in a compound

Limit test is defined as quantitative or semi quantitative test designed to identify and control small quantities of impurity which is likely to be present in the substance.

Limit test is generally carried out to determine the inorganic impurities present in compound. In short, limit test is nothing but to identify the impurities present in the substance and compare it with standard.

Importance of Limit tests:

To find out the harmful amount of impurities
To find out the avoidable/unavoidable amount of impurities

Limit Test of Sulphate

Principle:

Limit test of sulphate is based on the reaction of soluble sulphate with barium chloride in presence of dilute hydrochloric acid to form barium sulphate which appears as solid particles (turbidity) in the solution.

$$SO_4^{2-} + BaCl_2 \xrightarrow{HCl} BaSO_4 + KCl$$

Procedure:

Test sample	**Standard compound**
Specific weight of compound is dissolved in water or solution is prepared as directed in the pharmacopoeia and transferred in Nessler cylinder	Take 1ml of 0.1089 % W/V solution of potassium sulphate in Nessler cylinder
Add 2ml of dilute hydrochloric acid	Add 2ml of dilute hydrochloric acid
Dilute to 45 ml in Nessler cylinder	Dilute to 45 ml in Nessler cylinder
Add 5ml of barium sulphate reagent	Add 5ml of barium sulphate reagent
Keep aside for 5 min	Keep aside for 5 min
Observe the Turbidity	Observe the Turbidity

Barium sulphate reagent contains barium chloride, sulphate free alcohol and small amount of potassium sulphate.

Observation:

The turbidity produce in sample solution should not be greater than standard solution. If turbidity produces in sample solution is less than the standard solution, the sample will pass the limit test of sulphate and vice versa.

Reasons:

Hydrochloric acid helps to make solution acidic.
Potassium sulphate is used to increase the sensitivity of the test by giving ionic concentration in the reagent
Alcohol helps to prevent super saturation.

Limit Test of Arsenic

Principle:

Limit test of Arsenic is based on the reaction of arsenic gas with hydrogen ion to form yellow stain on mercuric chloride paper in presence of reducing agents like potassium iodide. It is also called as Gutzeit test and requires special apparatus.

Arsenic, present as arsenic acid in the sample is reduced to arsenious acid by reducing agents like potassium iodide, stannous acid, zinc, hydrochloric acid, etc. Arsenious acid is further reduced to arsine (gas) by hydrogen and reacts with mercuric chloride paper to give a yellow stain.

$H_3AsO_4 + H_2SnO_2 \rightarrow H_3AsO_3 + H_2SnO_3$
Arsenic acid Arsenious acid

$H_3AsO_3 + 3H_2 \rightarrow AsH_3 + 3H_2O$
Arsenious acid Arsine

The depth of yellow stain on mercuric chloride paper will depend upon the quality of arsenic present in the sample.

Procedure:

Test solution:

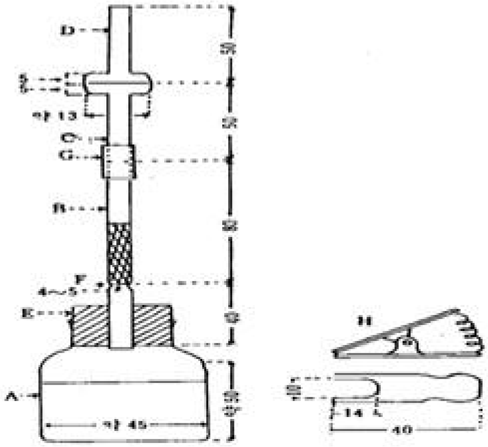
The test solution is prepared by dissolving specific amount in water and stannated HCl (arsenic free) and kept in a wide mouthed bottle.

To this solution 1 gm of KI, 5 ml of stannous chloride acid solution and 10 gm of zinc is added (all this reagents must be arsenic free)

Keep the solution aside for 40 min and stain obtained on mercuric chloride paper is compared with standard solution.

Standard solution:

A known quantity of dilute arsenic solution (1 ml) is kept in wide mouthed bottle and rest procedure is followed as described in test solution.



A : approximately 60 ml generator bottle with 40 ml indicating line.
B : glass tube with 6.5 mm inner diameter
C and D : a ground joint glass tube with 6.5 mm inner diameter and 18 mm outer diameter at the joint. Inner joint and the outer joint form a concentric circle.
E : rubber stopper
F : narrow part of the glass tube B. Glass wool is inserted up to this part.
G : rubber board (Lead acetate cotton plug)
H : clamp

Reasons:

Stannous chloride is used for complete evolution of arsine
Zinc, potassium iodide and stannous chloride is used as a reducing aget
Hydrochlorid acid is used to make the solution acidic
Lead acetate pledger or papers are used to trap any hydrogen sulphide which may be evolved along with arsine.

Limit Test of Lead

Lead is a most undesirable impurity in medical compounds and comes through use of sulphuric acid, lead lined apparatus and glass bottles use for storage of chemicals.

Principle:

Limit test of lead is based on the reaction of lead and diphenyl thiocabazone (dithizone) in alkaline solution to form lead dithizone complex which is red in color.

Dithizone is green in color in chloroform and lead-dithizone complex is red color, so the resulting color at the end of process is violet.

Procedure:

Test sample	**Standard compound**
A known quantity of sample solution is transferred in a separating funnel	A standard lead solution is prepared equivalent to the amount of lead permitted in the sample under examination
Add 6ml of ammonium citrate	Add 6ml of ammonium citrate
Add 2 ml of potassium cyanide and 2 ml of hydroxylamine hydrochloride	Add 2 ml of potassium cyanide and 2 ml of hydroxylamine hydrochloride

Add 2 drops of phenol red	Add 2 drops of phenol red
Make solution alkaline by adding ammonia solution.	Make solution alkaline by adding ammonia solution.
Extract with 5 ml of dithizone until it becomes green	Extract with 5 ml of dithizone until it becomes green
Combine dithizone extracts are shaken for 30 mins with 30 ml of nitric acid and the chloroform layer is discarded	Combine dithizone extracts are shaken for 30 mins with 30 ml of nitric acid and the chloroform layer is discarded
To the acid solution add 5 ml of standard dithizone solution	To the acid solution add 5 ml of standard dithizone solution
Add 4 ml of ammonium cyanide	Add 4 ml of ammonium cyanide
Shake for 30 mins	Shake for 30 mins
Observe the color	Observe the color

Observation:

The intensity of the color of complex, is depends on the amount of lead in the solution. The color produce in sample solution should not be greater than standard solution. If color produces in sample solution is less than the standard solution, the sample will pass the limit test of lead and vice versa.

Reasons:

Ammonium citrate, potassium cyanide, hydroxylamine hydrochloride is used to make pH optimum so interference and influence of other impurities have been eliminated.
Phenol red is used as indicator to develop the color at the end of process
Lead present as an impurities in the substance, gets separated bye extracting an alkaline solution with a dithizone extraction solution.

Limit Test of Chloride

Principle:

Limit test of chloride is based on the reaction of soluble chloride with silver nitrate in presence of dilute nitric acid to form silver chloride, which appears as solid particles (Opalescence) in the solution.

$$NaCl + AgNO_3 \xrightarrow{HNO_3} AgCl + NaNO_3$$

Procedure:

Test sample	**Standard compound**
Specific weight of compound is dissolved in water or solution is prepared as directed in the pharmacopoeia and transferred in Nessler cylinder	Take 1ml of 0.05845 % W/V solution of sodium chloride in Nessler cylinder
Add 10ml of nitric acid	Add 10ml of nitric acid

Dilute to 50ml in Nessler cylinder	Dilute to 50ml in Nessler cylinder
Add 1ml of $AgNO_3$ solution	Add 1ml of $AgNO_3$ solution
Keep aside for 5 min	Keep aside for 5 min
Observe the Opalescence/Turbidity	Observe the Opalescence/Turbidity

Observation:

The opalescence produce in sample solution should not be greater than standard solution. If opalescence produces in sample solution is less than the standard solution, the sample will pass the limit test of chloride and visa versa.

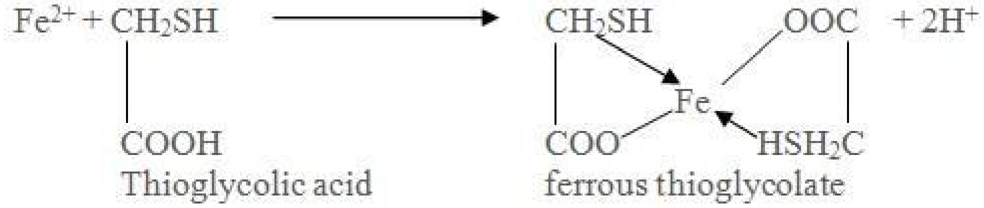
Reasons:

Nitric acid is added in the limit test of chloride to make solution acidic and helps silver chloride precipitate to make solution turbid at the end of process.

Limit Test of Iron

Principle:

Limit test of Iron is based on the reaction of iron in ammonical solution with thioglycollic acid in presence of citric acid to form iron thioglycolate which is pale pink to deep reddish purple in color.



Procedure:

Test sample	Standard compound
Sample is dissolved in specific amount of water and then volume is made up to 40 ml	2 ml of standard solution of iron diluted with water upto 40ml
Add 2 ml of 20 % w/v of citric acid (iron free)	Add 2 ml of 20 % w/v of citric acid (iron free)
Add 2 drops of thioglycollic acid	Add 2 drops of thioglycollic acid
Add ammonia to make the solution alkaline and adjust the volume to 50 ml	Add ammonia to make the solution alkaline and adjust the volume to 50 ml
Keep aside for 5 min	Keep aside for 5 min
Color developed is viewed vertically and compared with standard solution	Color developed is viewed vertically and compared with standard solution

Earlier aamonium thiocyanate reagent was used for the limit test of iron. Since thioglycolic acid is more sensitive reagent, it has replaced ammonium thiocyanate in the test.

Observation:

The purple color produce in sample solution should not be greater than standard solution. If purple color produces in sample solution is less than the standard solution, the sample will pass the limit test of iron and vice versa.

Reasons:

Citric acid helps precipitation of iron by ammonia by forming a complex with it.
Thioglycolic acid helps to oxidize iron (II) to iron (III).
Ammonia to make solution alkaline

Limit Test of Heavy Metals

Principle:

Limit test of heavy metals is based on the reaction of metallic impurities with hydrogen sulfide in acidic medium to form brownish colour solution. Metals that response to this test are lead, mercury, bismuth, arsenic, antimony, tin, cadmium, silver, copper, and molybdenum. The metallic impurities in substances are expressed as parts of lead per million parts of the substance. The usual limit as per Indian Pharmacopoeia is 20 ppm

Procedure:

The Indian Pharmacopoeia has adopted three methods for the limit test of heavy metals.

Method I: Use for the substance which gives clear colorless solution under the specific condition.

Test sample	**Standard compound**
Solution is prepared as per the monograph and 25 ml is transferred in Nessler's cylinder	Take 2 ml of standard lead solution and dilute to 25 ml with water
Adjust the pH between 3 to 4 by adding dilute acetic acid 'Sp' or dilute ammonia solution 'Sp'	Adjust the pH between 3 to 4 by adding dilute acetic acid 'Sp' or dilute ammonia solution 'Sp'
Dilute with water to 35 ml	Dilute with water to 35 ml
Add freshly prepared 10 ml of hydrogen sulphide solution	Add freshly prepared 10 ml of hydrogen sulphide solution
Dilute with water to 50 ml	Dilute with water to 50 ml
Allow to stand for five minutes	Allow to stand for five minutes
View downwards over a white surface	View downwards over a white surface

Observation:

The color produce in sample solution should not be greater than standard solution. If color produces in sample solution is less than the standard solution, the sample will pass the limit test of heavy metals and vice versa.

Method II: Use for the substance which do not give clear colorless solution under the specific condition.

Test sample	**Standard compound**
Weigh specific quantity of test substance, moisten with sulphuric acid and ignite on a low flame till completely charred Add few drops of nitric acid and heat to 500 °C Allow to cool and add 4 ml of hydrochloric acid and evaporate to dryness Moisten the residue with 10 ml of hydrochloric acid and digest for two minutes Neutralize with ammonia solution and make just acid with acetic acid	Take 2 ml of standard lead solution and dilute to 25 ml with water
Adjust the pH between 3 to 4 and filter if necessary	Adjust the pH between 3 to 4 by adding dilute acetic acid 'Sp' or dilute ammonia solution 'Sp'
Dilute with water to 35 ml	Dilute with water to 35 ml
Add freshly prepared 10 ml of hydrogen sulphide solution	Add freshly prepared 10 ml of hydrogen sulphide solution
Dilute with water to 50 ml	Dilute with water to 50 ml
Allow to stand for five minutes	Allow to stand for five minutes
View downwards over a white surface	View downwards over a white surface

Observation:

The color produce in sample solution should not be greater than standard solution. If color produces in sample solution is less than the standard solution, the sample will pass the limit test of heavy metals and vice versa.

Method III: Use for the substance which gives clear colorless solution in sodium hydroxide solution.

Test sample	**Standard compound**
Solution is prepared as per the monograph and 25 ml is transferred in Nessler's cylinder or weigh specific amount of substance and dissolve in 20 ml of water and add 5 ml of dilute sodium hydroxide solution	Take 2 ml of standard lead solution
Make up the volume to 50 ml with water	Add 5 ml of dilute sodium hydroxide solution and make up the volume to 50 ml with water
Add 5 drops of sodium sulphide solution	Add 5 drops of sodium sulphide solution
Mix and set aside for 5 min	Mix and set aside for 5 min
View downwards over a white surface	View downwards over a white surface

Observation:
The color produce in sample solution should not be greater than standard solution. If color produces in sample solution is less than the standard solution, the sample will pass the limit test of heavy metals and vice versa.

Types of Glass used in Pharmaceutical Industries

Glass

Glass is an amorphous (non-crystalline) solid which is often transparent and has widespread practical, technological, and decorative usage in things like window panes, tableware, and optoelectronics. The most familiar, and historically the oldest, types of glass are based on the chemical compound silica (silicon dioxide), the primary constituent of sand. The term *glass*, in popular usage, is often used to refer only to this type of material, which is familiar from use as window glass and in glass bottles. Of the many silica-based glasses that exist, ordinary glazing and container glass is formed from a specific type calledsoda-lime glass, composed of approximately 75% silicon dioxide (SiO_2), sodium oxide (Na_2O) from sodium carbonate(Na_2CO_3), calcium oxide, also called lime (CaO), and several minor additives

Type I Glass:

Highly Resistant Borosillicate. Although glass is considered to be a virtually inert material and is used to contain strong acids and alkalies as well as all types of solvents, it has a definite and measurable chemical reaction with some substances, notably water

silica 81% + boric oxide (B_2O_3) 12% + soda (Na_2O) 4.5% + alumina (Al_2O_3) 2.0%

Used for Buffered and Unbuffered aqueous solution.

Typical products – tubular glass vials, pre-fill syringes, cartridges and ampoules for small volume parenterals and diagnostic reagents.

Type II Glas:

Type II containers are made of commercial soda-lime glass that has been de-alkalized, or treated to remove surface alkali. The de-alkalizing process is known as "sulfur treatment" and virtually prevents "weathering" of empty bottles. The treatment offered by several glass manufacturers exposes the glass to an atmosphere containing water vapor and acidic gases, particularly sulfur dioxide at an elevated temperature.

Highly Resistant Sodalime glass.

Buffered aqueous solution below pH 7.0

Typical products - moulded glass infusion bottles

Type III Glass:

Containers are untreated and made of commercial soda-lime glass of average or better-than-average chemical resistance.

Moderately Resistant Sodalime glass.

Used for dry powder and oily solution.

Non-Parenteral Use

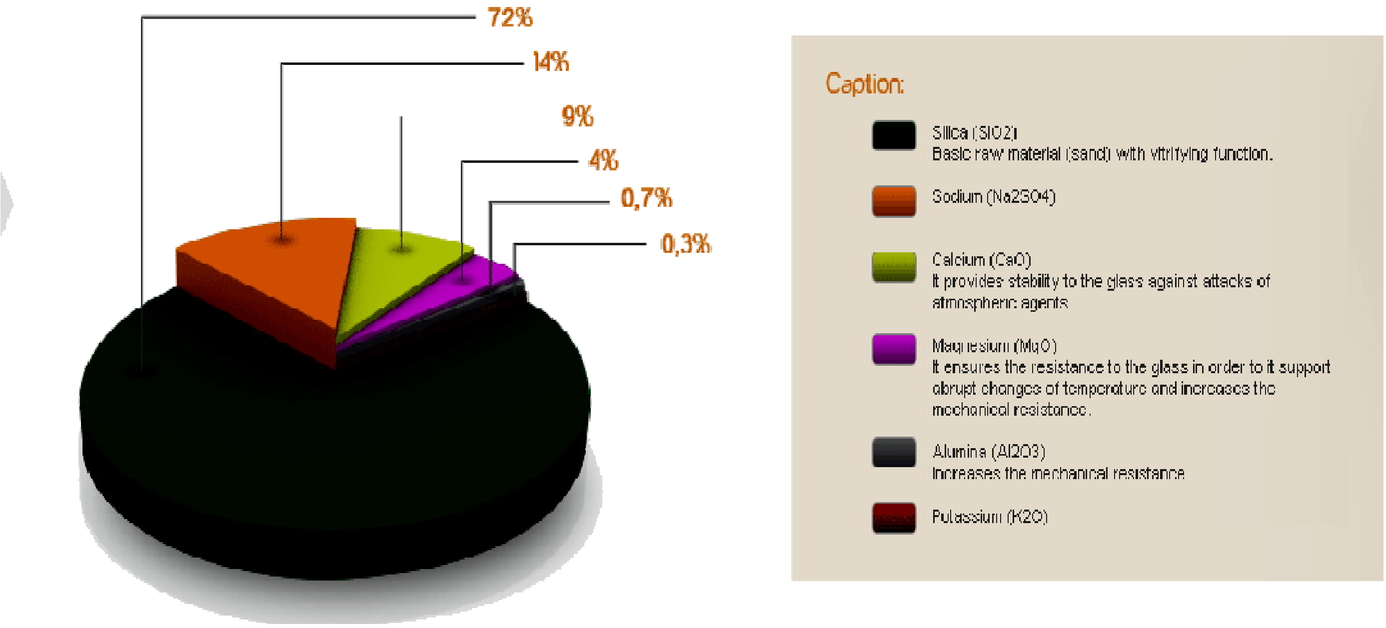
Typical products – moulded glass syrup bottles and tablet containers

Type IV Glass:

Containers made of soda-lime glass are supplied for nonparenteral products, those intended for oral or topical use.
General Purpose Sodalime glass.
silica 72% + sodium oxide (Na_2O) 14.2% + lime (CaO) 10.0% + magnesia (MgO) 2.5% + alumina (Al_2O_3) 0.6%
Not for parenteral, for tablet,liquid oral and externals.
Non-Parenteral Use

The colored glasses are produced adding pigment to the composition as selenium (Se), iron oxide and cobalt to achieve the different colors.

Glass Components



Caption:

- Silica (SiO_2)
  Basic raw material (sand) with vitrifying function.
- Sodium (Na_2SO_4)
- Calcium (CaO)
  It provides stability to the glass against attacks of atmospheric agents
- Magnesium (MgO)
  It ensures the resistance to the glass in order to it support abrupt changes of temperature and increases the mechanical resistance.
- Alumina (Al_2O_3)
  Increases the mechanical resistance
- Potassium (K_2O)

WATER FOR PHARMACEUTICAL PURPOSES

Water is the most widely used substance,raw material,or ingredient in the production,processing,and formulation of pharmaceutical articles.Control of the microbiological quality of these waters is important because proliferation of microorganisms in water may occur during the purification,storage,and distribution of this substance.If water is used in the final product,these microorganisms or their metabolic products may eventually cause adverse consequences.

TYPES OF WATER

Purified Water—

Purified Water (*USP*monograph)is used as an excipient in the production of official preparations;in pharmaceutical applications,such as cleaning of certain equipment;and in the preparation of some bulk pharmaceutical chemicals.Purified Water must meet the requirements for ionic and organic chemical purity and must be protected from microbial proliferation.It is prepared using Drinking Water as a feed water and is purified using unit operations that include deionization,distillation,ion exchange,reverse osmosis,filtration,or other suitable procedures.Purified Water systems must be validated.

Purified Water systems that produce,store,and circulate water under ambient conditions are susceptible to the establishment of tenacious biofilms of microorganisms,which can be the source of undesirable levels of viable microorganisms or endotoxins in the effluent water.These systems require frequent sanitization and microbiological monitoring to ensure water of appropriate microbiological quality at the points of use.

Water for Injection—

Water for Injection (*USP*monograph) is an excipient in the production of injections and for use in pharmaceutical applications,such as cleaning of certain equipment and preparation of some bulk pharmaceutical chemicals.The source or feed water for this article is Drinking Water,which may have been preliminarily purified but which is finally subjected to distillation or reverse osmosis.It must meet all the chemical requirements for Purified Water. It also must be protected from microbial contamination.The system used to produce,store,and distribute Water for Injection must be designed to prevent microbial contamination and the formation of microbial endotoxins,and it must be validated.

Sterile Water for Injection—

Sterile Water for Injection (*USP*monograph)is Water for Injection that is packaged and rendered sterile.Sterile Water for Injection is intended for extemporaneous prescription compounding and is distributed in sterile units.It is used as a diluent for parenteral products.It is packaged in single-dose containers not larger than 1Lin size..

SAGAR BANSAL