

Reagents for Pharma Industry

Chapter 6

Identification, Limit Tests, Assays, Volumetry, Waste Water Analysis



PanReac 
AppliChem
ITW Reagents



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About Us

The Origin

ITW Illinois Tool Works Inc. (NYSE: ITW) is a global industry company that delivers specialized expertise, innovative thinking and value-added products to meet critical customer needs in a variety of industries.

ITW, with approximately 14.8 billion dollars in global revenues, operates 7 major segments with businesses in 55 countries that employ approximately 48,000 employees. The company has a broad portfolio of more than 18,000 global patents and patent applications.

The ITW Reagents Division

In 2010, the ITW Reagents division was born from the integration of the companies Panreac Química SLU (Spain) and Nova Chimica Srl (Italy), and later AppliChem GmbH (Germany). The division offers the highest quality and innovative products for analysis, research and production applications.

ITW Reagents markets its products worldwide through an extensive distribution network to more than 80 countries under the PanReac AppliChem brand. It has two production plants in Darmstadt (Germany) and Barcelona (Spain).



We are Everywhere

We can say that almost all products subject to human manipulation have undergone chemical analysis that guarantees their physical and chemical properties. Food, agrifood, medicines, cosmetics... and so many other products are subjected to chemical analysis. Our reagents can be found in any quality control and research laboratory.



Our range of Laboratory Chemicals include:

Analytical reagents
Reagents for volumetric analysis
Reagents and solvents for general applications
Reagents and solvents for HPLC
Reagents and solvents for GC
Reagents for metallic traces analysis
Analytical standards
Reagents and solvents for specific applications
Products for clinical diagnosis
Products for microbiology

Our range of Laboratory Biochemicals cover:

Cell Biology / Cell Culture
Protein Biochemistry and Electrophoresis
Nucleic Acid Biochemistry
General Biochemicals and Biological Buffers
Special Biochemicals

Service & Benefits

Exceptional know-how and a wide range of chemicals and biochemicals for a great diversity of applications.

European production committed to corporate social responsibility (CSR).

Efficient global distribution network to export our products worldwide to more than 80 countries.

Qualified management team fully committed to our business project.

Excellence

Our products are strictly controlled in our laboratories and meet the highest quality requirements. A multi-site Integrated Management System for Quality, Environment and Safety is implemented in all activities and processes.

ISO 9001:2015

ISO 14001:2015

OHSAS 18001:2007



Reagents for Pharma Industry

Chapter 6

Introduction

The **Pharmaceutical Industry** discovers, develops, produces, and markets drugs or **pharmaceutical drugs** for use as medications.

Pharmaceutical companies may deal in **generic** or **brand medications** and medical devices.

They are subject to a variety of **laws** and **regulations** that govern the patenting, testing, safety, efficacy and marketing of drugs.

The pharmaceutical industry is largely driven by **scientific discovery** and **development**, in conjunction with **toxicological** and **clinical experience**.



Major differences exist between **large organizations** which engage in a broad range of drug discovery and development, manufacturing and quality control, marketing and sales and **smaller organizations** which focus on a specific aspect.



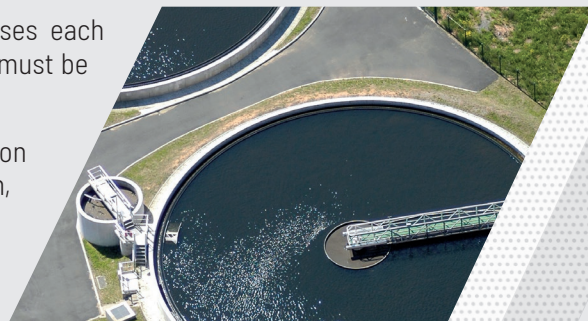
Most multinational pharmaceutical companies are involved in all these activities; however, they may specialize in one aspect based upon local market factors. Academic, public and private organizations perform scientific **research to discover and develop new drugs**. The biotechnology industry is becoming a major contributor to innovative pharmaceutical research. Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to explore the potential of new drug substances.

Active drug substances (APIs, Active Principle Ingredient) and **inert materials** (Excipients) are combined **during pharmaceutical manufacturing** to produce dosage forms of medicinal products (e.g. tablets, capsules, liquids, powders, creams and ointments). Drugs may be categorized by their manufacturing process and therapeutic benefits.



The different pharmaceutical manufacturing processes each have their own **environmental issues** and the wastes must be treated and controlled. **For example:**

- During **fermentation process**, the spent fermentation broth contains sugars, starches, proteins, nitrogen, phosphates and other nutrients with high biochemical oxygen demand (BOD), chemical oxygen demand (COD) and total suspended solids (TSS) with pH values ranging from 4 to 8.
- Also, wastes from **chemical synthesis** are complex due to the variety of hazardous materials, reactions and unit operations. These waste waters are high in BOD, COD and TSS, with varying acidity or alkalinity and pH values ranging from 1 to 11.



The **analysis laboratories** play a fundamental role in the pharmaceutical industries. **They are key pieces in:**



- Discovery and improvement of a **drug**.
- Development and optimization of **manufacturing processes**.
- **Quality control** of raw materials, intermediates and finished products.
- Quality control of **wastes**.

!

Depending on the type of analysis in which they are involved, **different types of laboratories** can be distinguished within the same pharmaceutical company. Besides, the **type of analysis** and the techniques used may be different (as shown on the next page).

In any case, the methods of analysis must be strictly validated and follow the requirements set by the **Pharmacopoeias** (Ph. Eur., USP, etc.) both in the analysis protocols and in the quality of the reagents to be used.

Our **portfolio** includes a wide range of products such as solvents, acids, bases and salts indicated for general analytical applications that **fulfil the requirements indicated in the Pharmacopoeias** (Ph. Eur. or USP) for the reagents to be used for analytical purposes.



Types of Laboratories versus Methods of Analysis

Facility		R&D Centre		Manufacturing Plant Quality Control		
Laboratory		New molecules / Improvements of existing products	Analytical development	Raw Material (excipients & APIs)	In-process (intermediate product)	Final product
Methods of analysis	Chapter					
Amino acid analysis	5			●	●	●
Approximate pH of solutions	1		●	●	●	●
Assays	6		●	●	●	●
Atomic Absorption spectroscopy	2		●	●		
Biological assays	3		●	●		
Biological tests	3			●		●
Clarity and opalescence of liquids	1		●	●		●
Conductivity	1		●	●		
Degree of Coloration of Liquids	1		●	●		
Dissolution Test	1					●
Electrophoresis	5	●	●	●	●	●
Gas Chromatography	4	●	●	●		●
ICP	2		●	●		
Identification	6		●	●		●
IR	2	●	●	●		●
Limit tests	6		●	●		
Liquid Chromatography	4	●	●	●		●
Potentiometric determination of pH	1		●	●	●	●
Thin Layer Chromatography	4	●	●	●		
UV	2	●	●	●		
Synthesis*	7	●				
Volumetry	6		●	●	●	●

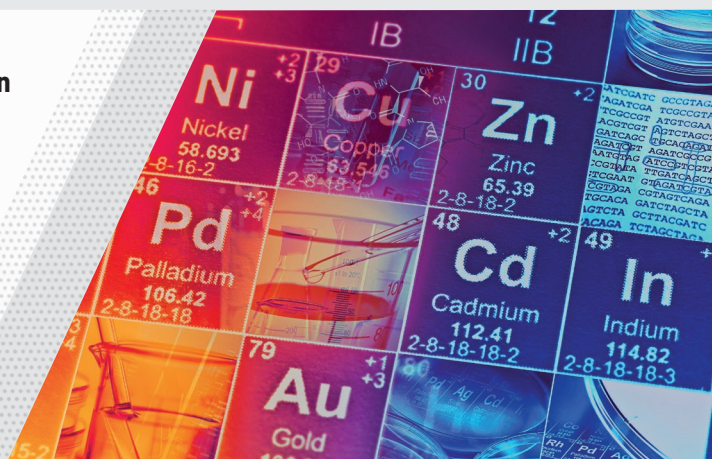
*not a method of analysis but reagents and solvents involved in synthesis procedures.

In the following sections we will describe the most common methods of analysis indicated in the pharmacopoeias and offer the most appropriate reagents for each method.



Identification

The tests indicated in the **identification** section in each pharmacopoeia monograph are not intended to fully confirm the chemical structure or composition of the product, but to confirm, with an acceptable degree of assurance, that the article conforms to the description on the label and to establish whether it is the article named in the pharmacopoeia.



The Identification test for a particular article may consist of one or more procedures. When a compendial Identification test is undertaken, all requirements of all specified procedures in the test must be met to satisfy the requirements of the test. Failure of an article to meet all the requirements of a prescribed Identification test indicates that the article is mislabeled and/or adulterated.

Certain monographs have subdivisions entitled 'First identification' and 'Second identification'. The test or tests constituting the 'First identification' may be used in all circumstances. The 'Second identification' tests may be used in pharmacies provided it can be demonstrated that the substance or preparation is fully traceable to a batch certified to comply with all the other requirements of the monograph.

Both European Pharmacopoeia and USP describe General Identification Tests.

Ph. Eur. in chapter 2.3.:

- Identification reactions of ions and functional groups
- Identification of fatty oils by thin-layer chromatography
- Identification of phenothiazines by thin-layer chromatography

USP in chapter <191> :

- Chemical Identification Tests
- Instrumental Identification Tests

Here we focus in chemical identification tests and identification reactions of ions and functional groups.

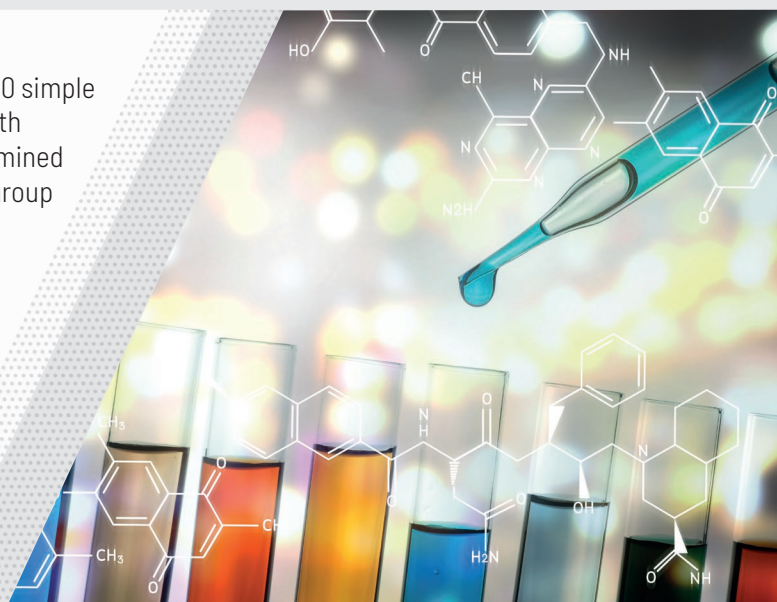
You will find information about TLC and other instrumental techniques in chapters 2 and 4 of our series of brochures "Reagents for Pharma Industry".



Identification reactions of ions and functional groups (Ph. Eur.) and Chemical Identification Tests (USP)

These identifications consist of about 40 simple tests, each of which aims to identify, with some certainty, that the substance examined contains the specific ion or functional group that gives name to the test.

The tests share the common characteristic that they can be performed on the laboratory bench without the use of analytical equipment. They are based on analytical/chemical principles such as **precipitation** and **color** reactions.



Reagents, Solvents and Volumetric solutions to perform Identification tests

Any acids, bases, or other reagents used in these identification tests should not interfere with the results. In the table below you will find the reagents we can offer to perform them, which **meet the requirements indicated in the Pharmacopoeias** to be used for analytical purposes. We use the denomination "Reag. Ph. Eur.", "Reag. USP" or "Reag. USP, Ph. Eur." to indicate that the reagent meets the specifications of the general chapters of the corresponding pharmacopoeia.

Product name	Code	For identification of
Acetic Acid glacial (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131008	Bicarbonates, Bromides, Calcium, Carbonates, Cobalt, Lead, Manganese, Nitrites, Oxalates, Potassium, Salicylates, Zinc
Acetic Anhydride (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131147	Citrates
Acetone (Reag. Ph. Eur.) for analysis, ACS, ISO	131007	Nitrates
Amidosulfuric Acid (Reag. USP, Ph. Eur.) for analysis, ACS	131056	Citrates
Ammonia 25% (as NH₃) (Reag. USP, Ph. Eur.) for analysis	121129	Acetates, Acetyl, Aluminium, Bromides, Chlorates, Chlorates, Chlorides, Citrates, Copper, Iodides, Lactates, Magnesium, Phosphates (ortho), Silver, Sodium, Xanthines
Ammonium Acetate (Reag. USP, Ph. Eur.) for analysis, ACS	131114	Lead
Ammonium Carbonate (Reag. USP, Ph. Eur.) for analysis, ACS	131119	Magnesium, Sodium
Ammonium Chloride (Reag. USP) for analysis, ACS, ISO	131121	Lithium, Magnesium
Ammonium Chloride (USP, BP, Ph. Eur.) pure, pharma grade	141121	Aluminium, Calcium, Magnesium, Zinc

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Product name	Code	For identification of
Ammonium Molybdate 4-hydrate (Reag. Ph. Eur.) for analysis, ACS, ISO	131134	Phosphates (ortho)
Ammonium Sulfate (Reag. Ph. Eur.) for analysis, ACS, ISO	131140	Lactates
Ammonium Thiocyanate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131143	Iron (ferric)
Ammonium meta-Vanadate (Reag. USP, Ph. Eur.) for analysis, ACS	132352	Phosphates (ortho)
Barium Chloride 2-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131182	Sulfates
Barium Hydroxide 8-hydrate (Reag. Ph. Eur.) for analysis, ISO	131188	Bicarbonates, Carbonates
Bromine Water saturated solution (Reag. Ph. Eur.)	171072	Lactates
Calcium Chloride 2-hydrate powder (Reag. USP) for analysis, ACS	131232	Oxalates
Chloroform stabilized with ethanol (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131252	Calcium, Iodides
Cobalt(II) Nitrate 6-hydrate (Reag. Ph. Eur.) for analysis, ACS	131258	Barbiturates, non-nitrogen substituted
Copper(II) Sulfate 5-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131270	Hypophosphites
Diethyl Ether stabilized with ~ 6 ppm of BHT (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	132770	Benzoates, Iron, Peroxides
1,5-Diphenylcarbazide (Reag. Ph. Eur.) for analysis	123577	Chlorides
Ethanol 96% v/v (USP, BP, Ph.Eur.) pure, pharma grade	141085	Calcium, Esters
Formaldehyde 37-38% w/w stabilized with methanol (Reag. USP) for analysis, ACS	131328	Silver
Fuchsin Basic (C.I. 42510) for clinical diagnosis	251332	Bromides
Hydrochloric Acid 37% (Reag. USP) for analysis, ACS, ISO	131020	Oxalates, Silver, Sulfates, Thiosulfates

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Product name	Code	For identification of
Hydrochloric Acid 37% (USP-NF, BP, Ph. Eur.) pure, pharma grade	141020	Alkaloids, Benzoates, Bicarbonates, Bismuth, Bromides, Carbonates, Esters, Iron, Salicylates, Silver, Sulfates, Xanthines
Hydrochloric Acid 0.1 mol/l (0.1N) volumetric solution	181023	Ammonium
Hydrochloric Acid 3 mol/l (3N) volumetric solution	182057	Calcium, Cobalt, Iron, Lead, Sulfites, Zinc
Hydrogen Peroxide 33% w/v (110 vol.) stabilized (USP, BP, Ph. Eur.) pure, pharma grade	141077	Xanthines
Hydroxylammonium Chloride (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131914	Esters
Iodine 0.01 mol/l (0.02N) volumetric solution	181969	Acetyl
Iodine 0.05 mol/l (0.1N) (Reag. USP, Ph. Eur.) volumetric solution	181772	Acetates, Sulfates
Iron(III) Chloride 6-hydrate pure	141358	Benzoates, Esters, Salicylates
Iron(II) Sulfate 7-hydrate (Reag. USP) for analysis, ACS	131362	Nitrates
Iron(II) Sulfate 7-hydrate (USP, BP, Ph. Eur.) pure, pharma grade	141362	Tartrates
Isoamyl Alcohol (Reag. Ph. Eur.) for analysis, ACS	131079	Iron
Lanthanum(III) Nitrate 6-hydrate (Reag. Ph. Eur.) for analysis	122669	Acetates and Acetyl
Lead(II) Acetate 3-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131466	Sulfates
Magnesium Oxide light (BP, Ph. Eur.) pure, pharma grade	141276	Ammonium salts
Mercury(II) Chloride (Reag. USP) for analysis, ACS	131419	Hypophosphites
Methanol (Reag. Ph. Eur.) for analysis, ACS, ISO	131091	Esters
Methyl Red (C.I. 13020) (Reag. USP, Ph. Eur.) for analysis, ACS	131617	Ammonium salts
Nitric Acid 69% (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131037	Bismuth, Bromides, Chlorides, Iodides, Phosphates (ortho), Silver, Sulfates
Nitric Acid 2 mol/l (2N) volumetric solution	182112	Lead, Mercury, Phosphates (ortho)
Oxalic Acid 2-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131041	Acetates, Permanganates
Phenolphthalein solution 1% (Reag. USP, Ph. Eur.) for volumetric analysis	281327	Bicarbonates, Carbonates
ortho-Phosphoric Acid 85% (USP-NF, BP, Ph. Eur.) pure, pharma grade	141032	Acetyl
Potassium Bromide (BP, USP, Ph. Eur.) pure, pharma grade	141489	Tartrates
Potassium Carbonate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131490	Sodium
Potassium Chloride (Reag. USP) for analysis, ACS, ISO	131494	Cobalt
Potassium Dichromate (Reag. USP) for analysis, ACS, ISO	131500	Peroxides

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Product name	Code	For identification of
Potassium Dichromate (Reag. Ph. Eur.) standard for volumetry, ISO	241500	Chlorides, Iodides
Potassium Hexacyanoferrate(II) 3-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131505	Calcium, Copper, Iron, Zinc
Potassium Hexacyanoferrate(III) (Reag. USP, Ph. Eur.) for analysis, ACS	131503	Iron
Potassium Hydroxide 85% pellets (USP-NF, BP, Ph. Eur.) pure, pharma grade	141515	Esters
Potassium Iodide (Reag. USP) for analysis, ACS, ISO	131542	Mercury
Potassium Iodide (USP, BP, Ph. Eur.) pure, pharma grade	141542	Lead
Potassium Permanganate (USP, BP, Ph. Eur.) pure, pharma grade	141527	Citrates
Potassium Permanganate 0.02 mol/l (0.1N) (Reag. USP) volumetric solution	181529	Nitrates, Oxalates
Potassium Sodium Tartrate 4-hydrate (Reag. Ph. Eur.) for analysis, ACS, ISO	131729	Antimony
Potassium Thiocyanate (Reag. Ph. Eur.) for analysis, ACS, ISO	131534	Iron
Pyridine (Reag. USP, Ph. Eur.) for analysis, ACS	131457	Citrates
Resorcinol (USP, BP, Ph. Eur.) pure, pharma grade	141603	Tartrates
Silver Nitrate (Reag. USP) for analysis, ACS, ISO	131459	Bromides, Chlorates, Chlorides, Iodides, Phosphates (ortho)
Silver Nitrate (BP, Ph. Eur.) pure, pharma grade	141459	Bromides, Chlorates, Chlorides, Iodides, Phosphates (ortho)
Silver Nitrate 0.1 mol/l (0.1N) (Reag. USP) volumetric solution	186983	Phosphates (ortho), Pyrophosphates
Sodium Acetate 3-hydrate (Reag. USP) for analysis, ACS, ISO	131632	Zinc
Sodium Carbonate anhydrous (Reag. USP, Ph. Eur.) for analysis, ACS	131648	Calcium, Lithium, Potassium



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Product name	Code	For identification of
Sodium Hexanitrocobaltate(III) (Reag. Ph. Eur.) for analysis, ACS	131663	Ammonium salts, Potassium
di-Sodium Hydrogen Phosphate 7-hydrate (Reag. USP) for analysis, ACS	132656	Magnesium
di-Sodium Hydrogen Phosphate 12-hydrate (USP, BP, Ph. Eur.) pure, pharma grade	141678	Magnesium
Sodium Hydroxide pellets (Reag. USP) for analysis, ACS, ISO	131687	Lithium
Sodium Hydroxide pellets (USP-NF, BP, Ph. Eur.) pure, pharma grade	141687	Aluminium, Ammonium salts and salts of volatile bases, Antimony, Barbiturates, non-nitrogen substituted, Calcium, Lead, Mercury, Nitrates, Tartrates, Zinc
Sodium Hydroxide 1 mol/l (1N) (Reag. USP) volumetric solution	182415	Aluminium, Iron, Lead, Mercury
Sodium Nitrite (Reag. Ph. Eur.) for analysis, ACS	131703	Amines, primary aromatic
Sodium Pentacyanonitrosoferrate(III) 2-hydrate (Reag. Ph. Eur.) for analysis, ACS	131705	Citrates, Lactates
Sodium meta-Periodate (Reag. USP, Ph. Eur.) for analysis, ACS	131700	Tartrates
Sodium Sulfite anhydrous (BP, Ph. Eur.) pharma grade	191717	Bromides
Sulfuric Acid 96% (Reag. Ph. Eur.) for analysis, ISO	131058	Benzoates, Chlorates, Chlorides, Citrates, Hypophosphites, Iodides, Lactates, Nitrates, Permanganates, Peroxides, Silicates, Tartrates
Sulfuric Acid 0.5 mol/l (1N) volumetric solution	181059	Tartrates
Sulfuric Acid 1 mol/l (2N) volumetric solution	182105	Barium, Lead, Lithium
Thioacetamide (Reag. Ph. Eur.) for analysis, ACS	134887	Aluminium
Tin(II) Chloride 2-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS	131303	Sulfates
Water, Purified (BP, Ph. Eur.) pure, pharma grade	141074	For general use



Limit tests

Limit tests are general procedures for a group of impurities for use where limits of these impurities are specified in the individual monographs. The limit tests are provided to demonstrate that the content of the impurity does not exceed the limit given. For this purpose, a solution of a sample is **compared to a standard** containing the impurity at the product limit and both test and standard must be prepared simultaneously at the same conditions. These tests do not give quantitative results, only qualitative "pass/fail" results based on the specified limit.



Visual methods such as **opalescence** and **color** comparison or **instrumental methods** of analysis (atomic absorption spectroscopy, spectrophotometry, chromatography, etc.) are used for comparative tests. The table below shows some examples of limit tests described in the pharmacopeias and the technique used to perform them.

Limit Test	Visual comparison		Instrumental Technique					Volumetry
	Color	Opalescence	AAS	UV-Vis	ICP	TLC	GC	
Alkaline impurities in fatty oils								•
Aluminium			•					
Ammonium	•							
Arsenic	•			•				
Calcium		•						
Chlorides		•						
Composition of fatty acids							•	
Determination of metal catalyst or metal reagent residues			•		•			
N,N-Dimethylaniline							•	
Elemental impurities					•			
Ethylene oxide and dioxan							•	
Fluorides	•							
Foreign oils in fatty oils						•		
Free formaldehyde	•			•				
Heavy metals	•		•		•			
Identification and control of residual solvents							•	
Iron	•							
Lead	•		•					
Magnesium and alkaline-earth metals	•							•
Mercury			•					•
Nickel			•					
Phosphates	•							
Potassium		•						
Readily carbonizable substances	•							
Selenium				•				
Sterols in fatty oils						•	•	
Sulfates		•						

Assays

The general chapter of the European Pharmacopoeia "Assays" and "Other tests and assays" in the USP describe some procedures for **quantitative** tests that are used when the limits of these tests are specified in the individual monographs. Some of these assays are evaluated by **volumetric analyses** such as acid-base, oxidation-reduction (redox) or complexometric titrations, Karl Fischer or using the Kjeldahl method. Others use instrumental techniques such as **spectroscopy, chromatography**, etc.



The following table shows some examples of assays that appear in the general chapters of Ph. Eur. and USP and the technique used to perform them.

Assay	Instrumental Technique						Volumetry
	AAS	UV-Vis	IR	HPLC	GC	Others	
Acetic acid in synthetic peptides				●			
Acid value							●
Acid-neutralizing capacity							●
Alginates assay							●
Aluminium in adsorbed vaccines							●
Anisidine value		●					
Antimicrobial agents				●	●		
Calcium in adsorbed vaccines	●						
Carbon monoxide/dioxide in gases			●				
Complexometric titrations							●
Ester value							●
Hexosamines in polysaccharide vaccines		●					
Hydroxyl value							●
Iodine value							●
Methanesulfonyl chloride in methanesulfonic acid					●		
Methyl, ethyl and isopropyl sulfonates					●		
Methylpentoses in polysaccharide vaccines		●					
Nitrogen by sulfuric acid digestion							●
Nitrogen monoxide and nitrogen dioxide in gases						●	
Nitrous oxide in gases			●				
O-Acetyl in polysaccharide vaccines		●					
Oxidizing substances							●
Peroxide value							●
Phenol in immunosera and vaccines		●					
Phosphorus in polysaccharide vaccines		●					
Primary aromatic amino-nitrogen							●
Protein in polysaccharide vaccines		●					
Ribose in polysaccharide vaccines		●					
Saponification value							●
Sialic acid in polysaccharide vaccines		●					
Sulfur dioxide							●
Total protein		●					●
Unsaponifiable matter							●
Water						●	●
Zinc		●					

Reagents, Solvents and Volumetric solutions to perform Limit tests and Assays

We offer reagents and solvents used to perform Limits test and Assays, which meet the requirements to be used as reagents according to pharmacopoeias, using the denomination "Reag. Ph. Eur", "Reag. USP" or "Reag. USP, Ph. Eur." to indicate that the reagent meets the specifications of the general chapters of the corresponding pharmacopoeia.

For spectroscopy or chromatography techniques, we recommend that you read our brochure series **"Reagents for Pharma Industry" chapter 2** (UV-Vis, AAS and ICP) and **chapter 4** (TLC, HPLC and GC).

Product name	Code	Limit test	Assay
Acetic Acid glacial (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131008	Aluminium, Calcium, Heavy metals, Mercury	Anisidine value, Hydroxyl value, Iodine value, Oxidizing substances, Peroxide value
Acetic Anhydride (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131147		Hydroxyl value
Acetone (Reag. Ph. Eur.) for analysis, ACS, ISO	131007	Alkaline impurities in fatty oils	
Albumin Fraction V (pH 7.0)	A1391		Protein
Amidosulfuric Acid (Reag. USP, Ph. Eur.) for analysis, ACS	131056	Free formaldehyde	
Ammonia 25% (as NH₃) (Reag. USP, Ph. Eur.) for analysis	121129	Alkaline-earth metals, Heavy metals, Lead, Magnesium, Mercury, Selenium	Bismuth, Zinc
Ammonium Acetate (Reag. USP, Ph. Eur.) for analysis, ACS	131114	Aluminium	
Ammonium Chloride (USP, BP, Ph. Eur.) pure, pharma grade	141121	Alkaline-earth metals, Magnesium	
di-Ammonium Hydrogen Citrate (Reag. USP, Ph. Eur.) for analysis, ACS	131120		Zinc
Ammonium Iron(III) Sulfate 12-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131365	Iron	
Ammonium di-Hydrogen Phosphate (Reag. Ph. Eur.) for analysis, ACS	131126	Nickel in hydrogenated vegetable oils	
di-Ammonium Oxalate 1-hydrate (Reag. Ph. Eur.) for analysis, ACS	131136	Calcium	
Ammonium Thiocyanate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131143	Iron	
AQUAMETRIC Composite 2 for volumetric analysis	285813		Water
AQUAMETRIC Composite 5 for volumetric analysis	285812		Water
AQUAMETRIC Coulomat A for Karl Fischer coulometric analysis	286181		Water
AQUAMETRIC Coulomat AG for Karl Fischer coulometric analysis	286180		Water
AQUAMETRIC Coulomat CG for Karl Fischer coulometric analysis	287192		Water
AQUAMETRIC Solvent for volumetric analysis	285817		Water

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Product name	Code	Limit test	Assay
AQUAMETRIC Titrant 2 for volumetric analysis	285816		Water
AQUAMETRIC Titrant 5 for volumetric analysis	285815		Water
Barium Chloride 2-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131182	Sulfates	Alginate
N,O-Bis-(trimethylsilyl)-trifluoroacetamide (Reag. Ph. Eur.) for GC	355588	Sterols in fatty oils	
Boric Acid (USP-NF, BP, Ph. Eur.) pure, pharma grade	141015		Protein
Bradford - Solution for Protein Determination	A6932		Protein
Bromophenol Blue (Reag. Ph. Eur.) for analysis, ACS	131165	Alkaline impurities in fatty oils	Sulfur dioxide
1-Butanol (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131082		Hydroxyl value
Butylhydroxytoluene (BP, Ph. Eur.) pure, pharma grade	142825	Composition of fatty acids in oils rich in omega-3	
Calconcarboxylic Acid (Reag. Ph. Eur.) for analysis	123575	Calcium	
Chloroform stabilized with ethanol (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131252	Aluminium, Free formaldehyde, Lead, Magnesium, Mercury	Iodine value, Peroxide value, Zinc
Citric Acid 1-hydrate (Reag. USP) for analysis, ACS, ISO	131018	Lead	
Copper(II) Sulfate 5-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131270	Lead, Mercury	Nitrogen, Protein
Crystal Violet (C.I. 42555) (Reag. Ph. Eur.) for analysis, ACS	131762		Hydroxyl value
Cyclohexane for UV, IR, HPLC, ACS	361250	Selenium	
Cyclohexane (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131250	N,N-Dimethylaniline	Hydroxyl value, Iodine value
L-Cysteine Hydrochloride 1-hydrate (Ph. Eur., USP) pure, pharma grade	A1702		Methylpentoses
Dichloromethane stabilized with ~ 20 ppm of amylene (Reag. Ph. Eur.) for analysis, ACS, ISO	131254	Sterols in fatty oils	
Diethyl Ether stabilized with ~ 6 ppm of BHT (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	132770	Foreign oils in fatty oils	Unsaponifiable matter
N,N-Dimethylacetamide for Headspace GC	753145	Ethylene oxide and dioxan	
4-(Dimethylamino) Benzaldehyde (Reag. Ph. Eur.) for analysis, ACS	131293		Hexosamines

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Product name	Code	Limit test	Assay
1,4-Dioxan stabilized with ~ 25 ppm of BHT (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131296	Ethylene oxide and dioxan	
EDTA Disodium Salt 0.01 mol/l (0.01M) volumetric solution	181671	Alkaline-earth metals, Magnesium	
EDTA Disodium Salt 0.1 mol/l (0.1M) volumetric solution	181670	Aluminium, Calcium, Lead, Magnesium	Bismuth, Zinc
Eriochrome Black T (C.I. 14645) (Reag. Ph. Eur.) for analysis, ACS	131439	Alkaline-earth metals, Magnesium	
Ethanol absolute (USP, BP, Ph.Eur.) pharma grade	191086	Sterols in fatty oils	Zinc
Ethanol 96% v/v (USP, BP, Ph.Eur.) pure, pharma grade	141085	Alkaline impurities in fatty oils, Aluminium	Acid value, Hexosamines, Hydroxyl value, Nitrogen, Unsaponifiable matter
Ethyl Acetate (Reag. Ph. Eur.) for analysis, ACS, ISO	131318	Total cholesterol in oils rich in omega-3 acids	
Ethylene Glycol (Reag. USP, Ph. Eur.) for analysis	121316	Ethylene glycol and diethylene glycol in ethoxylated substances (Ph. Eur.)	Ethylene glycol and diethylene glycol in ethoxylated substances (USP)
Formaldehyde 37-38% w/w stabilized with methanol (USP, BP, Ph. Eur.) pure, pharma grade	141328	Free formaldehyde	
D(+)-Glucose anhydrous (USP, BP, Ph. Eur.) pure, pharma grade	141341		Nitrogen, Protein
n-Heptane (Reag. Ph. Eur.) for analysis	122062	Composition of fatty acids	
Hexamethylenetetramine (Reag. Ph. Eur.) for analysis, ACS	131346	Lead	Zinc
Hydrochloric Acid 37% (max. 0.0000005% Hg) (Reag. USP) for analysis, ACS, ISO	471020	Mercury	
Hydrochloric Acid 37% (Reag. USP) for analysis, ACS, ISO	131020	Sulfates	
Hydrochloric Acid 37% (USP-NF, BP, Ph. Eur.) pure, pharma grade	141020	Aluminium, Arsenic, Calcium, Heavy metals	Hexosamines, Sulfur dioxide
Hydrochloric Acid 0.01 mol/l (0.01N) volumetric solution	182884	Alkaline impurities in fatty oils	Nitrogen
Hydrochloric Acid 0.02 mol/l (0.02N) volumetric solution	183458	Chlorides	
Hydrochloric Acid 0.1 mol/l (0.1N) volumetric solution	181023	N,N-Dimethylaniline, Selenium	Alginates, O-Acetyl
Hydrochloric Acid 0.25 mol/l (0.25N) volumetric solution	182318		Zinc
Hydrochloric Acid 0.5 mol/l (0.5N) volumetric solution	181022		Saponification value
Hydrochloric Acid 1 mol/l (1N) volumetric solution	181021		Acid-neutralizing capacity
Hydrochloric Acid 1 mol/l (1N) (Reag. Ph.Eur.) volumetric solution	186985	N,N-Dimethylaniline, Free formaldehyde	Hexosamines
Hydrochloric Acid 3 mol/l (3N) volumetric solution	182057	Lead, Sulfates	
Hydrochloric Acid 4 mol/l (4N) volumetric solution	182552		O-Acetyl

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Product name	Code	Limit test	Assay
Hydrogen Peroxide 33% w/v (110 vol.) (Reag. USP) for analysis, ACS, ISO	131077	Arsenic, Lead, Mercury	
Hydrogen Peroxide 33% w/v (110 vol.) stabilized (USP, BP, Ph. Eur.) pure, pharma grade	141077	Heavy metals	
Hydroxylammonium Chloride (max. 0.000001% Hg) (Reag. USP) for analysis, ACS, ISO	471914	Mercury	
Hydroxylammonium Chloride (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131914	Alkaline-earth metals, Lead, Magnesium, Selenium	
Iron(III) Chloride 6-hydrate pure	141358	Free formaldehyde	O-Acetyl, Ribose
Isoamyl Alcohol (Reag. Ph. Eur.) for analysis, ACS	131079		Sialic acid
Isooctane (Reag. Ph. Eur.) for analysis, ACS	132064	N,N-Dimethylaniline	Anisidine value, Peroxide value
Karl Fischer Water Standard 1.0 mg/g (Reag. Ph. Eur.)	395459		Water
Karl Fischer Water Standard 10 mg/g (Reag. Ph. Eur.)	395458		Water
Lead(II) Acetate 3-hydrate (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131466	Arsenic	
Light liquid Paraffin (USP-NF, BP, Ph. Eur.) pure, pharma grade	146257	Foreign oils in fatty oils	
Magnesium Nitrate 6-hydrate (Reag. Ph. Eur.) for analysis, ACS	131402	Nickel in hydrogenated vegetable oils	
Magnesium Oxide light (BP, Ph. Eur.) pure, pharma grade	141276	Heavy metals	
Magnesium Sulfate 7-hydrate (USP, BP, Ph. Eur.) pure, pharma grade	141404	Heavy metals	
Mercury(II) Chloride (Reag. USP) for analysis, ACS	131419	Lead	
Methanol (Reag. Ph. Eur.) for analysis, ACS, ISO	131091	Composition of fatty acids	
Methanol dry (max. 0.005% water) (Reag. Ph. Eur.), ACS, ISO	481091	Composition of fatty acids	Water
Methylene Blue (C.I. 52015) (Reag. Ph. Eur.) for analysis	121170		Nitrogen, Protein
Methyl Orange (C.I. 13025) (Reag. Ph. Eur.) for analysis, ACS	131431	Aluminium	
Methyl Orange solution 0.1% (Reag. Ph. Eur.) for volumetric analysis	281432	Aluminium	
4-Methyl-2-Pentanone (Reag. Ph. Eur.) for analysis, ACS	131430	Lead in sugars, Nickel in polyols	
Methyl Red (C.I. 13020) (Reag. USP, Ph. Eur.) for analysis, ACS	131617		Nitrogen, Protein
Nitric Acid 69% (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131037	Aluminium, Chlorides, Mercury, Selenium	Bismuth
Perchloric Acid 0.1 mol/l (0.1N) in acetic acid (Reag. USP, Ph. Eur.) volumetric solution	181046		Hydroxyl value

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Product name	Code	Limit test	Assay
Petroleum Ether 50-70°C (Reag. Ph. Eur.) for analysis	121862	Foreign oils in fatty oils	
Petroleum Ether 100-120°C (Reag. Ph. Eur.) for analysis	124809		Acid value
Phenol crystalline (USP, BP, Ph. Eur.) pure, pharma grade	144852		Phenol
Phenolphthalein (Reag. USP, Ph. Eur.) for analysis, ACS	131325	Fluorides, Heavy metals, Mercury	
Phenolphthalein solution 0.1 % (Reag. Ph. Eur.) for volumetric analysis	283090	Fluorides, Heavy metals	Unsaponifiable matter
Phenolphthalein solution 1% (Reag. USP, Ph. Eur.) for volumetric analysis	281327	Heavy metals, Mercury	Acid value, Alginates, Hydroxyl value, Saponification value
Phenol Red for analysis, ACS	131615	Lead	
di-Phosphorus Pentoxide (Reag. Ph. Eur.) for analysis, ACS, ISO	131154		Carbon monoxide
Potassium Bromide (BP, USP, Ph. Eur.) pure, pharma grade	141489		Primary aromatic amino-nitrogen
Potassium Cyanide (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131491	Lead	
Potassium Hexacyanoferrate(III) (Reag. USP, Ph. Eur.) for analysis, ACS	131503		Phenol
Potassium di-Hydrogen Phosphate (USP-NF, BP, Ph. Eur.) pure, pharma grade	141509		Phosphorus
Potassium Hydroxide 85% pellets (USP-NF, BP, Ph. Eur.) pure, pharma grade	141515	Composition of fatty acids	Carbon monoxide, Protein, Unsaponifiable matter
Potassium Hydroxide 0.1 mol/l (0.1N) volumetric solution	181521		Acid value
Potassium Hydroxide 0.5 mol/l (0.5N) in ethanol (Reag. USP, Ph.Eur.) volumetric solution	181519	Foreign oils in fatty oils	Hydroxyl value, Saponification value
Potassium Iodide (Reag. USP) for analysis, ACS, ISO	131542		Iodine value, Peroxide value
Potassium Iodide (USP, BP, Ph. Eur.) pure, pharma grade	141542	Arsenic	Carbon monoxide, Iodine value, Oxidizing substances, Peroxide value

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Product name	Code	Limit test	Assay
Potassium Sodium Tartrate 4-hydrate (Reag. Ph. Eur.) for analysis, ACS, ISO	131729		Protein
Potassium Sulfate (Reag. Ph. Eur.) for analysis, ACS, ISO	131532		Nitrogen, Protein
2-Propanol (Reag. USP, Ph. Eur.) for analysis, ACS, ISO	131090	Arsenic	
Purified Water (BP, Ph. Eur.) pure, pharma grade	141074	For general use	For general use
Pyridine (Reag. USP, Ph. Eur.) for analysis, ACS	131457		Hydroxyl value
Pyridine dry (max. 0.01% water) (Reag. Ph. Eur.), ACS	481457	Sterols in fatty oils	
Resorcinol (USP, BP, Ph. Eur.) pure, pharma grade	141603		Sialic acid
Selenium metal powder pure	141625		Nitrogen, Protein
Silver Nitrate (BP, Ph. Eur.) pure, pharma grade	141459	Chlorides	
di-Sodium tetra-Borate 10-hydrate (USP-NF, BP, Ph. Eur.) pure, pharma grade	141644	Magnesium	
Sodium Carbonate anhydrous (Reag. USP, Ph. Eur.) for analysis, ACS	131648		Hexosamines, Protein
Sodium Chloride (USP, BP, Ph. Eur., JP) pure, pharma grade	141659	Alkaline-earth metals, Magnesium	Protein
tri-Sodium Citrate 2-hydrate (USP, BP, Ph. Eur.) pure, pharma grade	141655		Protein
Sodium Hydrogen Carbonate (USP, BP, Ph. Eur.) pure, pharma grade	141638		Protein
Sodium Hydroxide pellets (USP-NF, BP, Ph. Eur.) pure, pharma grade	141687	Aluminium, Ammonium, Arsenic, Calcium, Magnesium	Hexosamines, Nitrogen, Protein
Sodium Hydroxide solution 40% w/w for the determination of nitrogen	171220		Nitrogen, Protein
Sodium Hydroxide 0.01 mol/l (0.01N) volumetric solution	181845		Nitrogen, Protein
Sodium Hydroxide 0.1 mol/l (0.1N) standard volumetric solution	181694	Fluorides	Acid value, Protein, Sulfur dioxide
Sodium Hydroxide 0.1 mol/l (0.1N) in ethanol volumetric solution	182284		Unsaponifiable matter
Sodium Hydroxide 0.25 mol/l (0.25N) standard volumetric solution	182155		Alginates
Sodium Hydroxide 0.5 mol/l (0.5N) volumetric solution	181692		Protein
Sodium Hydroxide 1 mol/l (1N) (Reag. Ph.Eur.) volumetric solution	186982	N,N-Dimethylaniline	
Sodium Hydroxide 1 mol/l (1N) (Reag. USP) volumetric solution	182415	N,N-Dimethylaniline, Mercury	
Sodium tetra-Phenylborate (Reag. Ph. Eur.) for analysis, ACS	132440	Potassium	
Sodium Tartrate 2-hydrate (Reag. Ph. Eur.) for analysis	121719		Protein

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Product name	Code	Limit test	Assay
Sodium Tartrate 2-hydrate (Reag. Ph. Eur.) standard for volumetry, ACS	241719		Water
Sodium Thiosulfate 0.1 mol/l (0.1N) (Reag. Ph. Eur.) standard volumetric solution	186987		Iodine value, Peroxide value
Sodium Thiosulfate 0.1 mol/l (0.1N) (Reag. USP) standard volumetric solution	181723		Iodine value
Starch from Potato soluble (Reag. USP, Ph. Eur.) for analysis	121096		Carbon monoxide, Iodine value, Oxidizing substances, Peroxide value
Starch solution 1% (Reag. Ph. Eur.) for volumetric analysis	283146		Carbon monoxide, Iodine value, Oxidizing substances, Peroxide value
Sulfuric Acid 95-98% (max. 0.0000005% Hg) (Reag. USP) for analysis, ACS, ISO	471058	Mercury	
Sulfuric Acid 96% (Reag. USP, Ph. Eur.) for analysis, ISO	131058	Aluminium, Arsenic, Fluorides, Heavy metals, Lead, Readily carbonizable substances, Residue on ignition, Sulfated ash	Methylpentoses, Nitrogen, Phosphorus, Protein
Sulfuric Acid 0.01 mol/l (0.02N) volumetric solution	182102	Sulfates	
Sulfuric Acid 0.5 mol/l (1N) volumetric solution	181059	Mercury	
Sulfuric Acid 1 mol/l (2N) volumetric solution	182105	Arsenic, Iron	
Thioacetamide (Reag. Ph. Eur.) for analysis, ACS	134887	Heavy metals	
Thioglycollic Acid (Reag. Ph. Eur.) for analysis	124142	Iron	
Thymolphthalein for analysis (Reag. Ph. Eur.), ACS	131739		Hexosamines
Tin(II) Chloride 2-hydrate (max. 0.000005% Hg) (Reag. USP) for analysis, ACS	471303	Mercury	
Trichloroacetic Acid (Reag. USP, Ph. Eur.) for analysis, ACS	131067		Protein, Zinc
Tween® 20 (USP-NF, BP, Ph. Eur.) pure, pharma grade	142312	Free formaldehyde	
Xylenol Orange Tetrasodium Salt (Reag. Ph. Eur.) for analysis, ACS	132617	Lead	Bismuth, Zinc
Zinc Sulfate 0.1 mol/l (0.1M) volumetric solution	181789	Alkaline-earth metals, Aluminium, Magnesium	

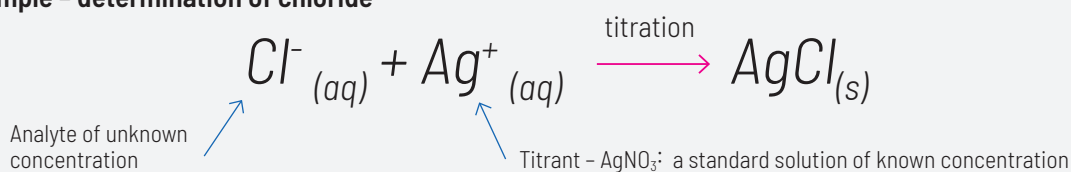


Volumetry

Volumetry (also called **titrimetry** and volumetric analysis) is a common laboratory method of quantitative chemical analysis to determine the concentration of an identified analyte (a substance to be analyzed). A reagent, called the **titrant** or **volumetric solution**, is prepared as a **standard solution** of known concentration. The titrant reacts with a solution of analyte to determine the analyte's concentration.

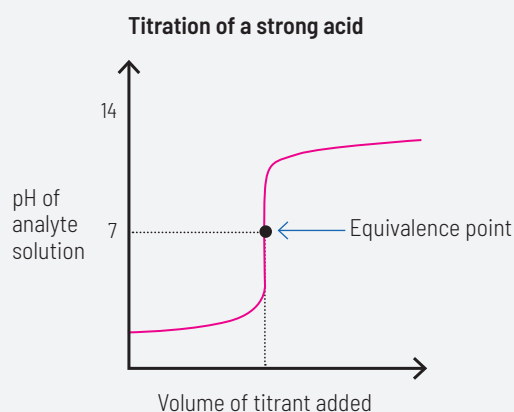


Example – determination of chloride



The concentration of volumetric solutions is indicated in terms of molarity. Molarity expresses, as the number of moles, the amount of substance dissolved in 1 L of solution. A solution which contains x moles of substance per liter is said to be x M. It can also be expressed as Normality N, the number of equivalents per liter (moles of reactive units per liter).

The completion of the reaction is called the **equivalence point** and it occurs when the added titrant is chemically equivalent to the analyte in the sample. Knowing the volume of titrant added allows us to determine the concentration of the unknown analyte.



The experimental point at which the completion of the reaction is marked by some signal is called the **end point**. The end point is detected by a **color change of an indicator** or by electrical measurement (potentiometry) of the reacting mixture. Indicators are reagents used with volumetric solutions to show the end point of the titration through visual color change. The ideal indicator changes color at an end point as close as possible to the equivalence point.

Volumetric solutions and indicators required in the tests and assays of the pharmacopoeia monographs have to meet the specifications indicated in the general chapter "Reagents" of the European Pharmacopoeia (Ph. Eur.) or in the chapter "Reagents, Indicators and Solutions" of the United States Pharmacopoeia (USP).

Volumetric Solutions

The European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopeia (USP) indicate how to prepare and standardize volumetric solutions in their chapters "Volumetric Solutions" (4.2.2) and "Reagents, Indicators and Solutions" (Volumetric Solutions), respectively.

The pharmaceutical industry needs these solutions for the quality control of both raw materials and the final product.

We use the denomination "Reag. Ph. Eur.", "Reag. USP" or "Reag. USP, Ph. Eur." when the volumetric solution is standardized according to the general chapters of the pharmacopoeias.

- **Ready-to-use solutions**, optimizing time and reducing risks from toxic substances.
- **Standardization** according to European Pharmacopoeia and/or USP indicated on the product label.
- **NIST-traceable**.
- The **factor** of the solutions is adjusted to **1.000** with a precision of **±0.1%**, providing more accurate measurements.
- **Stable** for at least **36 months** in most cases.



For routine use of large amounts of prepared solutions and specially designed to optimize the preservation of the solutions, we have our **10 L Sol-Pack** package. Sol-Pack consists of a collapsible polyethylene bag and an outer cardboard box, forming a light, practical and easily disposable pack. It incorporates a tap, which allows convenient dosing down to the last drop.



1 L plastic bottle that can adapt to automatic titrators available on the market.

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Volumetric solutions used in pharmacopoeia Assays (quantitative) and also for Identification and Limit tests (qualitative), and their standardization method.

Volumetric solution	Concentration	Standardized against	Indicator	Ph. Eur.*	USP*	Code	Package
Acetic Acid	1 mol/l (1N)	Sodium Hydroxide 1 M	Phenolphthalein		TS	181009.1211	1000 ml
Ammonium Iron (II) Sulfate	0.1 mol/l (0.1N)	Potassium Permanganate 0.1 N	-			181369.1611	1000 ml
Ammonium Thiocyanate	0.1 mol/l (0.1N)	Silver Nitrate 0.1 M	Ferric Ammonium Sulfate	X		181144.1211	1000 ml
Benzethonium Chloride	0.004 mol/l (0.004M)	SDS 0.004 M	Dimidium Bromide, Disulphine Blue mixed Indicator			183141.1611	1000 ml
Bromine (Bromate-Bromide)	0.05 mol/l (0.1N)	Sodium Thiosulfate 0.1N	Starch		X	182000.1211	1000 ml
Cerium(IV) Sulfate	0.1 mol/l (0.1N)	Sodium Oxalate	-		X	181249.1611	1000 ml
						181249.1612	2.5 L
						181671.1211	1000 ml
						181671.1212	2.5 L
EDTA Disodium Salt	0.01 mol/l (0.01M)	Zinc Oxide	Eriochrome Black T			181671.1315	10 L
						182120.1211	1000 ml
						182120.1214	5 L
EDTA Disodium Salt	0.05 mol/l (0.05M)	Zinc Oxide	Eriochrome Black T			182120.1315	10 L
						181670.1211	1000 ml
						181670.1214	5 L
EDTA Disodium Salt	0.1 mol/l (0.1M)	Zinc Oxide	Eriochrome Black T			181670.1315	10 L
						182884.1211	1000 ml
						183458.1211	1000 ml
Hydrochloric Acid	0.01 mol/l (0.01N)	Tris (Tromethanol, THAM)	Methyl Red			182107.1211	1000 ml
Hydrochloric Acid	0.02 mol/l (0.02N)	Tris (Tromethanol, THAM)	Methyl Red			181023.1211	1000 ml
Hydrochloric Acid	0.05 mol/l (0.05N)	Tris (Tromethanol, THAM)	Methyl Red			181023.1212	2.5 L
Hydrochloric Acid	0.1 mol/l (0.1N)	Tris (Tromethanol, THAM)	Methyl Red			181023.1214	5 L
						181023.0715	10 L
						181023.1315	10 L
						181022.1211	1000 ml
Hydrochloric Acid	0.5 mol/l (0.5N)	Tris (Tromethanol, THAM)	Methyl Red			181022.1214	5 L
						181022.1315	10 L
						181021.1211	1000 ml
Hydrochloric Acid	1 mol/l (1N)	Tris (Tromethanol, THAM)	Methyl Red			181021.1214	5 L
						181021.1315	10 L
						181021.0716	25 L
						186985.1211	1000 ml
Hydrochloric Acid	1 mol/l (1N)	Sodium Carbonate	Methyl Orange			182108.1211	1000 ml
Hydrochloric Acid	2 mol/l (2N)	Tris (Tromethanol, THAM)	Methyl Red	R	TS	182108.0716	25 L
						182057.1211	1000 ml
Hydrochloric Acid	3 mol/l (3N)	Tris (Tromethanol, THAM)	Methyl Red	R	TS	182057.1315	10 L
Hydrochloric Acid	4 mol/l (4N)	Tris (Tromethanol, THAM)	Methyl Red		TS	182552.1211	1000 ml
						182552.1214	5 L
Hydrochloric Acid	5 mol/l (5N)	Tris (Tromethanol, THAM)	Methyl Red		TS	182109.1211	1000 ml
						182109.1211	5 L
						182109.1215	10 L
Hydrochloric Acid	6 mol/l (6N)			R	TS	182883.1211	1000 ml
Iodine	0.01 mol/l (0.02N)	Sodium Thiosulfate 0.1N	Starch			181969.1610	500 ml
						181969.1611	1000 ml

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Volumetric solution	Concentration	Standardized against	Indicator	Ph. Eur.*	USP*	Code	Package
Iodine	0.025 mol/l (0.05N)	Sodium Thiosulfate 0.1N	Starch		X	182161.1611	1000 ml
Iodine	0.05 mol/l (0.1N)	Sodium Thiosulfate 0.1 M	Starch	X	X	181772.1611 181772.1612	1000 ml 2.5 L
Iodine	0.5 mol/l (1N)	Sodium Thiosulfate 0.1 M	Starch	X		182162.1611	1000 ml
Lanthanum Nitrate	0.1 mol/l (0.1N)	EDTA Disodium Salt 0.1 M	Xylenol Orange			187042.1211	1000 ml
Nitric Acid	1 mol/l (1N)	Tris (Tromethanol, THAM)	Methyl Red			181039.1611	1000 ml
Nitric Acid	2 mol/l (2N)	Tris (Tromethanol, THAM)	Methyl Red		TS	182112.1611	1000 ml
Oxalic Acid	0.05 mol/l (0.1N)	Potassium Permanganate 0.1 N			X	181043.1211	1000 ml
Perchloric Acid	0.1 mol/l (0.1N) in acetic acid	Potassium Hydrogen Phthalate	Crystal Violet	X	X	181046.1611 181046.1612	1000 ml 2.5 L
Perchloric Acid	0.1 mol/l (0.1N) in 1,4-dioxan	Potassium Hydrogen Phthalate	Crystal Violet		X	181047.1611	1000 ml
Potassium Dichromate	1/60 mol/l (0.1N)	Sodium Thiosulfate 0.1 M	Starch		X	181502.1611	1000 ml
Potassium Hydroxide	0.1 mol/l (0.1N) in ethanol	Hydrochloric Acid 0.1 M	Phenolphthalein		X	182146.1611	1000 ml
Potassium Hydroxide	0.1 mol/l (0.1N) in methanol	Hydrochloric Acid 0.1 M	Phenolphthalein		X	182147.1211	1000 ml
Potassium Hydroxide	0.1 mol/l (0.1N)	Hydrochloric Acid 0.1 M	Bromophenol Blue			181521.1211	1000 ml
Potassium Hydroxide	0.5 mol/l (0.5N) in ethanol	Hydrochloric Acid 0.5 M	Phenolphthalein		X	181519.1611	1000 ml
Potassium Hydroxide	1 mol/l (1N)	Hydrochloric Acid 1 M	Bromophenol Blue			181517.1211 181517.1214	1000 ml 5 L
Potassium Permanganate	0.02 mol/l (0.1N)	Sodium Thiosulfate 0.1 M	Starch	X		186986.1611	1000 ml
Potassium Permanganate	0.02 mol/l (0.1N)	Sodium Oxalate	-		X	181529.1611 181529.1612	1000 ml 2.5 L
Potassium Thiocyanate	0.1 mol/l (0.1N)	Silver Nitrate 0.1 M	Ferric Ammonium Sulfate		X	181535.1211	1000 ml
Silver Nitrate	0.05 mol/l (0.05N)	Sodium Chloride	Potassium Chromate			182115.1211	1000 ml
Silver Nitrate	0.1 mol/l (0.1N)	Sodium Chloride	Eosin		X	186983.1211	1000 ml
Silver Nitrate	0.1 mol/l (0.1N)	Sodium Chloride	Potassium Chromate			181464.1211 181464.1212 181464.1315	1000 ml 2.5 L 10 L
Sodium Hydroxide	0.01 mol/l (0.01N)	Hydrochloric Acid 0.01 M	Bromophenol Blue			181845.1211	1000 ml
Sodium Hydroxide	0.02 mol/l (0.02N)	Hydrochloric Acid 0.1 M	Bromophenol Blue		TS	183397.1211	1000 ml
Sodium Hydroxide	0.1 mol/l (0.1N) in ethanol	Hydrochloric Acid 0.1 M	Phenolphthalein			182284.1611	1000 ml
Sodium Hydroxide	0.1 mol/l (0.1N)	Hydrochloric Acid 0.1 M	Bromophenol Blue			181693.1211 181693.1214 181693.1315	1000 ml 5 L 10 L
Sodium Hydroxide	0.1 mol/l (0.1N)	Potassium Hydrogen Phthalate	Phenolphthalein	X	X	181694.1211 181694.1315	1000 ml 10 L
Sodium Hydroxide	0.5 mol/l (0.5N)	Hydrochloric Acid 0.5 M	Bromophenol Blue	X	X	181692.1211 181692.1315	1000 ml 10 L

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Reagents for Pharma Industry

Chapter 6

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Volumetric solution	Concentration	Standardized against	Indicator	Ph. Eur.*	USP*	Code	Package
Sodium Hydroxide	1 mol/l (1N)	Hydrochloric Acid 1 M	Phenolphthalein			186982.1211	1000 ml
						186982.0715	10 L
Sodium Hydroxide	1 mol/l (1N)	Potassium Hydrogen Phthalate	Phenolphthalein	X	X	182415.1211	1000 ml
						182415.1315	10 L
Sodium Hydroxide	1 mol/l (1N)	Hydrochloric Acid 1 M	Bromophenol Blue			181691.1211	1000 ml
						181691.1212	2.5 L
						181691.1214	5 L
						181691.1315	10 L
Sodium Hydroxide	2 mol/l (2N)	Hydrochloric Acid 1 M	Bromophenol Blue	R	TS	182158.1211	1000 ml
Sodium Hydroxide	4 mol/l (4N)	Hydrochloric Acid 1 M	Bromophenol Blue	R		183466.1211	1000 ml
Sodium Hydroxide	5 mol/l (5N)	Hydrochloric Acid 1 M	Bromophenol Blue		TS	182159.1211	1000 ml
						182159.1214	5 L
Sodium Hydroxide	10 mol/l (10N)	Hydrochloric Acid 1 M	Bromophenol Blue		TS	183508.1211	1000 ml
						183508.1214	5 L
Sodium Thiosulfate	0.01 mol/l (0.01N)	Potassium Dichromate	Starch	X		182577.1211	1000 ml
Sodium Thiosulfate	0.1 mol/l (0.1N)	Potassium Bromate 0.033 M	Starch	X		186987.1211	1000 ml
Sodium Thiosulfate	0.1 mol/l (0.1N)	Potassium Dichromate	Starch		X	181723.1211	1000 ml
						181723.1212	2.5 L
						181723.1315	10 L
Sulfuric Acid	0.01 mol/l (0.02N)	Tris (Tromethanol, THAM)	Methyl Red			182102.1211	1000 ml
Sulfuric Acid	0.025 mol/l (0.05N)	Tris (Tromethanol, THAM)	Methyl Red			182103.1211	1000 ml
Sulfuric Acid	0.1 mol/l (0.2N)	Tris (Tromethanol, THAM)	Methyl Red		TS	182011.1211	1000 ml
Sulfuric Acid	0.25 mol/l (0.5N)	Tris (Tromethanol, THAM)	Methyl Red			181060.1211	1000 ml
						181060.1212	2.5 L
						181060.1315	10 L
Sulfuric Acid	0.5 mol/l (1N)	Tris (Tromethanol, THAM)	Methyl Red			181059.1211	1000 ml
						181059.1212	2.5 L
						181059.1214	5 L
						181059.1315	10 L
						181059.0716	25 L
Sulfuric Acid	1 mol/l (2N)	Tris (Tromethanol, THAM)	Methyl Red		TS	182105.1208	100 ml
						182105.1211	1000 ml
						182105.1214	5 L
Zinc Sulfate	0.05 mol/l (0.05M)	EDTA Disodium Salt 0.1 M	Eriochrome Black T			182163.1211	1000 ml
Zinc Sulfate	0.1 mol/l (0.1M)	EDTA Disodium Salt 0.1 M	Eriochrome Black T			181789.1211	1000 ml

* Marked with:

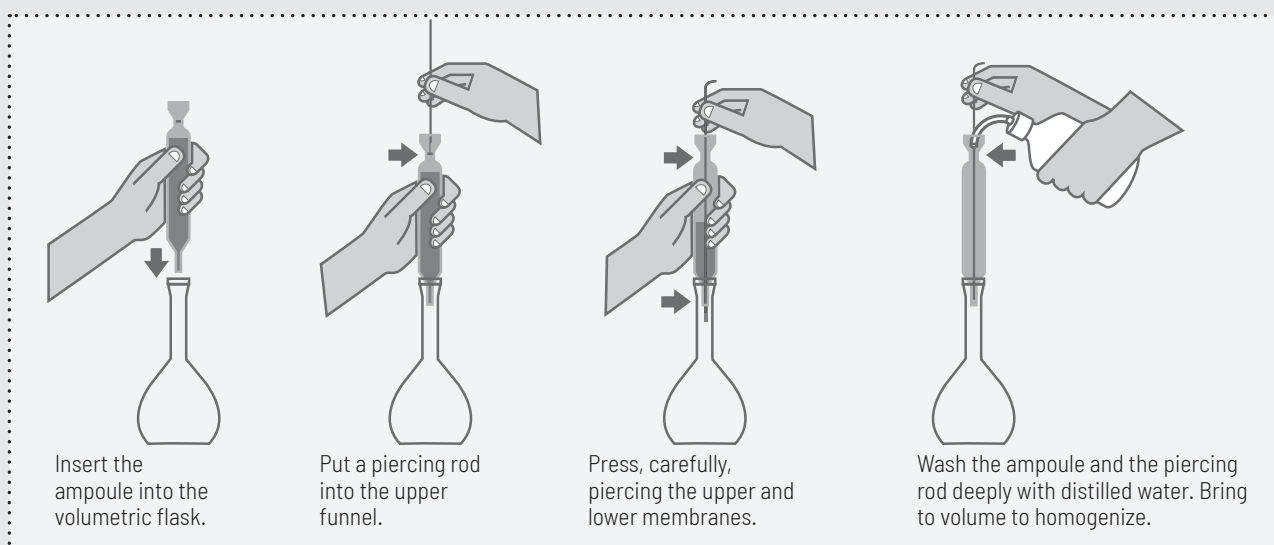
X : included in the Volumetric Solution general chapters and standardized according to pharmacopoeias (according to USP, other methods of standardization, capable of yielding at least the same degree of accuracy, may be used).

TS or R: not included in the Volumetric Solution chapters but used as Test Solution (USP) or Reagent (Ph. Eur.). Where it is directed that a volumetric solution be used as Test Solution (USP) or Reagent (Ph. Eur.) in a qualitative procedure, standardization of the solution is not required.

Concentrated Volumetric Solutions

We offer concentrated solutions for the preparation of volumetric solutions by dilution. By using them you will save storage space, they are also very stable and have a very long shelf life (5 years). Quick and easy to make, just dilute with the desired solvent. You can prepare different concentrations than those specified on the label. If the solution has been diluted under optimal conditions, we guarantee the concentration with $\pm 0.2\%$ accuracy.

Product name	Code	Package
EDTA Disodium Salt 0.1 mol (37.224 g $C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$) to prepare 1 L of 0.1 M solution	303118.1920	1 ampoule
Hydrochloric Acid 0.1 mol (3.646 g HCl) to prepare 1 L of 0.1 N solution	303110.1920	1 ampoule
Hydrochloric Acid 1 mol (36.461 g HCl) to prepare 1 L of 1 N solution	303112.1920	1 ampoule
Iodine 0.05 mol (12.690 g I_2) to prepare 1 L of 0.1 N solution	303119.1920	1 ampoule
Potassium Permanganate 0.02 mol (3.161 g $KMnO_4$) to prepare 1 L of 0.1 N solution	303124.1920	1 ampoule
Silver Nitrate 0.1 mol (16.987 g $AgNO_3$) to prepare 1 L of 0.1 N solution	303117.1920	1 ampoule
Sodium Hydroxide 0.1 mol (4.000 g NaOH) to prepare 1 L of 0.1 N solution	303125.1920	1 ampoule
Sodium Hydroxide 1 mol (40.00 g NaOH) to prepare 1 L of 1 N solution	303126.1920	1 ampoule
Sodium Thiosulfate 0.1 mol (24.818 g $Na_2S_2O_3 \cdot 5H_2O$) to prepare 1 L of 0.1 N solution	303127.1920	1 ampoule
Sulfuric Acid 0.05 mol (4.904 g H_2SO_4) to prepare 1 L of 0.1 N solution	303114.1920	1 ampoule



Indicators for Volumetry

For end-point detection by color change. Our program includes indicators in both powder form and ready-to-use solutions.



Indicators and Indicator solutions for analysis according to pharmacopoeia:

Description	Code	Package
Bromocresol Purple (Reag. USP) for analysis	121546.1606	25 g
Bromophenol Blue (Reag. USP, Ph. Eur.) for analysis, ACS	131165.1604	5 g
	131165.1606	25 g
Bromothymol Blue (Reag. USP) for analysis, ACS	131167.1604	5 g
	131167.1606	25 g
Calconcarboxylic Acid (Reag. Ph. Eur.) for analysis	123575.1606	25 g
Crystal Violet (C.I. 42555) (Reag. Ph. Eur.) for analysis, ACS	131762.1608	100 g
2,6-Dichlorophenol Indophenol Sodium Salt 2-hydrate (Reag. Ph. Eur.) for analysis, ACS	132056.1604	5 g
Dimidium Bromide (Reag. Ph. Eur.) for analysis	122844.1603	1 g
Diphenylamine (Reag. Ph. Eur.) for analysis, ACS	131828.1608	100 g
Eriochrome Black T (C.I. 14645) (Reag. Ph. Eur.) for analysis, ACS	131439.1606	25 g
	131439.1608	100 g
Methyl Orange (C.I. 13025) (Reag. Ph. Eur.) for analysis, ACS	131431.1606	25 g
Methyl Orange solution 0.1% (Reag. Ph. Eur.) for volumetric analysis	281432.1208	100 ml
	281432.1209	250 ml
Methyl Red (C.I. 13020) (Reag. USP, Ph. Eur.) for analysis, ACS	131617.1605	10 g
	131617.1606	25 g
	131617.1608	100 g
Methylene Blue (C.I. 52015) (Reag. Ph. Eur.) for analysis	121170.1606	25 g
	121170.1608	100 g
Murexide (C.I. 56085) (Reag. Ph. Eur.) for analysis, ACS	131436.1604	5 g
Phenolphthalein (Reag. USP, Ph. Eur.) for analysis, ACS	131325.1208	100 g
	131325.1210	500 g
Phenolphthalein solution 0.1 % (Reag. Ph. Eur.) for volumetric analysis	283090.1208	100 ml
Phenolphthalein solution 1% (Reag. USP, Ph. Eur.) for volumetric analysis	281327.1209	250 ml
	281327.1211	1000 ml
Phenol Red (Reag. USP) for analysis, ACS	131615.1604	5 g
	131615.1607	50 g
5-Sulfosalicylic Acid 2-hydrate (Reag. Ph. Eur.) for analysis	122838.1209	250 g
Starch from Potato soluble (Reag. USP, Ph. Eur.) for analysis	121096.1210	500 g
	121096.1211	1000 g
Starch solution 1% (Reag. Ph. Eur.) for volumetric analysis	283146.1208	100 ml
	283146.1209	250 ml
	283146.1211	1000 ml
Thymolphthalein (Reag. Ph. Eur.) for analysis, ACS	131739.1604	5 g

Volumetric Standards

For the standardization of volumetric solutions, we supply Standards for Volumetry, our range of reference materials with a high purity of $100 \pm 0.05\%$ after drying. Available in 100-g glass bottles and some of them in boxes of 10 individually sealed glass tubes containing 1.5 g each of the ready-to-use product. We also provide suitable methods for drying the product.

Each standard comes with its corresponding certificate of analysis indicating its purity and tolerance, the method used to determine this value, the NIST reference standard and the expiry date. In the following table you will find information about the available standards and the suitable method for drying the product if necessary.

Substance	Drying method *	Code	Package
Potassium Dichromate	130 °C	241500.1608	100 g
Potassium Hydrogen Phthalate	105 °C	241481.1521	10 x 1.5 g
		241481.1608	100 g
Potassium Iodate	130 °C	241540.1608	100 g
Sodium Carbonate anhydrous	120 °C	241648.1608	100 g
Sodium Chloride	110 °C	241659.1608	100 g
di-Sodium Oxalate	130 °C	241706.1608	100 g
Sodium Tartrate 2-hydrate	110 °C	241719.1608	100 g
Tris (Trometanol, THAM)	105 °C	241940.1608	100 g

* Dry in an oven at the specified temperature for 2 hours and allow to cool in a desiccator before use.



Waste Water Analysis

During the manufacture of pharmaceuticals and drugs the wastewater generated contains a wide variety of compounds. These wastewaters have a complex composition of organic and inorganic pollutants in high concentrations that can not be discharged into the **environment** without a previous treatment.



Most wastewater is produced during the washing of the equipment at the end of the production process. There are other smaller amounts from purifying the water used (rejects from reverse osmosis and regeneration of ion exchange resins), from the cleaning of installations, from laboratory effluents, etc.

Pharmaceutical industry **wastewaters varies** greatly not only in composition but also in flow (volume), depending on factors such as the raw materials, the processes used in the manufacture of different pharmaceutical products, the production rate, etc. which means that the pollution of the final effluent can be very diverse and variable over time.



In general, may contain:

- Organic matter, although easily biodegradable, toxic at high concentration (alcohol, acetone, etc.).
- Slowly biodegradable organic compounds and substances resistant against biodegradation (aromatic compounds, chlorinated hydrocarbons, etc.).
- Toxic compounds and biological active substances (antibiotics).
- Soaps and detergents with surfactants




There is no general law specifying which parameters should be analyzed, the **methods of analysis** or their **limits**. Each river basin defines discharge limits. Still, there are some parameters that are common to most of them:




- COD (Chemical Oxygen Demand)
- BOD₅ (Biochemical Oxygen Demand)
- TOC (Total Organic Carbon)
- TKN (Total Kjeldahl Nitrogen)
- NH₃-N (Ammoniacal Nitrogen)
- TDS (Total Dissolved Solids)
- pH
- Anions (Nitrates, Nitrites, Phosphates, Sulfates, Chlorides, etc.)
- Metals and alkali metals (Cadmium, Copper, Iron, Manganese, Lead, ...)
- Turbidity
- Color



There are different ways of analyzing each of them. Generally, the most common way is the use of rapid kits that allow a simple, fast and effective reading of the parameter.

Package pictograms

	Glass bottle
	Plastic bottle
	Plastic jerrycan

	Sol-Pack: Plastic container in a carton box (cubitainer), with tap
	Glass or plastic ampoule
	Glass tube with stopper and screw top



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