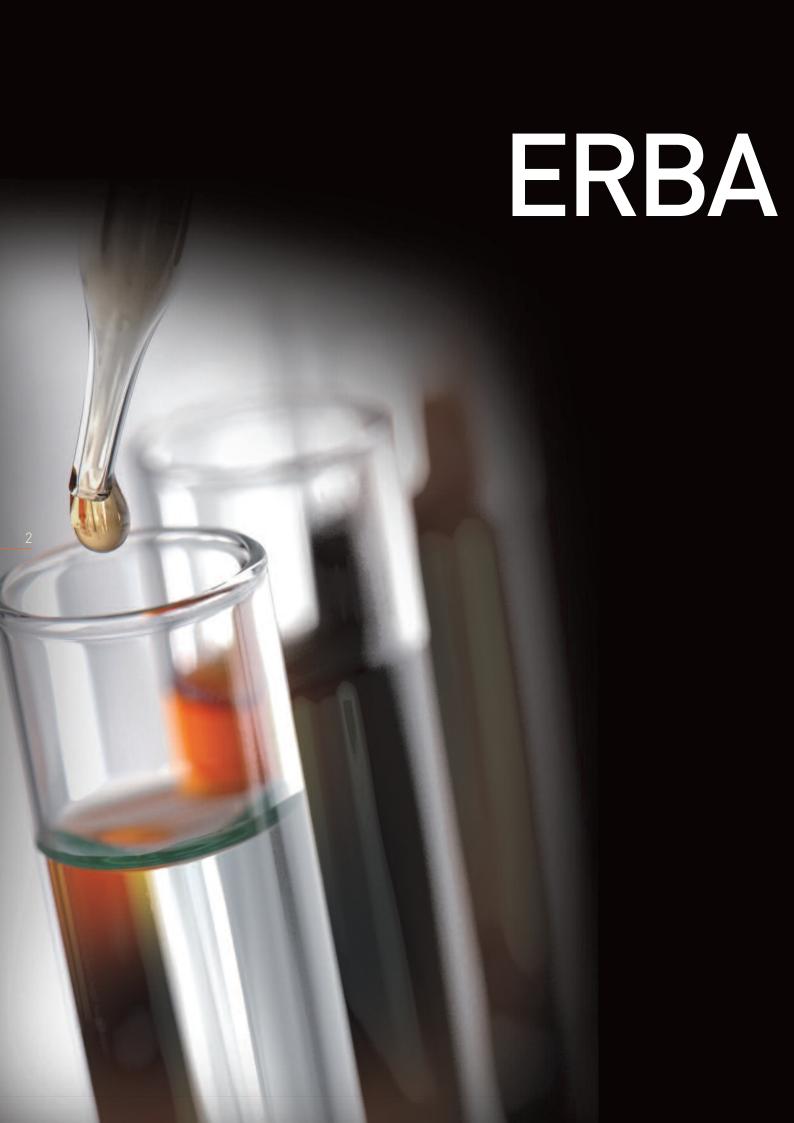


ERBApharm Your requirements are our mission









pharm

ERBApharm is the range of products developed by CARLO ERBA Reagents for the pharmaceutical market:

- Starting Materials, intermediates, reagents for API
- Bulk Pharmaceutical Excipients
- Pharmaceutical Solutions

Our SOP's are focused on the management of master file documents like raw materials, finished goods and packaging specifications, control methods, test reports, batch records (laboratory and production), change control, required by the pharmaceutical market.

Our state of the art facilities challenge IPEC quidelines:

- The IPEC-PQG Good Manufacturing Practices Guideline for Pharmaceutical excipients from 2006
- The IPEC Good Distribution Practices Audit Guideline from 2011

"The International Pharmaceutical Excipients Council (IPEC) first published a GMP Audit Guideline for Distributors of Bulk Pharmaceutical Excipients in 2000. This document was designed as a questionnaire to assist in evaluating the practices and quality systems of distributors who sell, store or repackage pharmaceutical excipients or any combination thereof." (IPEC 2011)

Our 2 premises are declared to the French authorities (ANSM) under the regulation Decree N° 2008-109 for the production of raw materials for pharmaceutical use.



CARLO ERBA Reagents is able to handle both liquids and powders, including hazardous and high flammable materials:

- Solvents
- Acids and bases pure, diluted and titrated
- Organic and inorganic powders
- Mixtures (solvents, acids, basis,..)

ERBApharm range contains more than 500 products. Their specifications comply with the effective requirements of main Pharmacopoeia or - in the absence of those requirements - with strict sales specifications.

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The documentation available for these materials is in line with the needs and traceability requirements associated with the use of these materials :

Name of the producer of the raw material with confidential agreement and batch number associated

Synthesis or production chart flow

BSE/TSE EMEA/410/01

Residual solvents CPMP/ICH/283/95

Residues of metal catalysts or metal compounds EMEA/CHMP/SWP/4446/2000

GMO statement

Limits of genotoxic impurities EMEA/CHMP/QWP/251344/2006

Aflatoxins statementDirective CE/1525/98AllergensDirective 2007/68/CE

On request we can guarantee different level of change control





Packaging

Pack size from:

1l to 25000 liters for liquids 1 g to 1 ton for solids

Different packaging:

Cans
Drums
Buckets with inner plastic bag
Kraft bags
Kraft drums with inner plastic bag
Stainless steel shuttle containers

The documentation available for these packaging is in line with the regulation:

Transport homologation
Certificate of conformity to Pharmacopoeia
Certificate for heavy metals
Food contact certificate for immediate
packaging certificate
Declaration of SVHC / REACH Conformity
Specific container content interaction study
can be performed



Quality Management

The production sites are located in France : Peypin (13) and Val de Reuil (27) and certified :

- NF EN ISO 9001:2008

Our Quality Management System includes:

- Quality manual
- Management of documentation
- Control of record
- Traceability
- Change control
- Periodic review of key indicators
- Continual improvement : CAPAs
- Internal audit
- Training, including GMP training

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The quality and production department are 2 independant divisions.

QA and QC are located on both sites.

QA Quality Assurance:

- Control of processes: each critical step of the life cycle of the product is under control: choice of the raw materials and packaging supplier, manufacturing, cleaning, filling, packaging
- Control of batch production and laboratory control records
- Release of finish goods
- Customer complaints
- Control of non conforming products and deviations
- Recall criteria



QC Quality Control:

The analysis of individual batches is carried out according to methods outlined in Pharmacopeia.

- Release of raw materials
- Retest dating of raw materials
- Qualification and calibration policies for laboratory instruments
- Management of reference substances
- Managing analytical reagents

- Managing of samples collection
- Out Of Specification investigation
- Preparation and maintenance of stability test protocols
- Creation of certificate of analysis on LIMS







Equipment

All the critical equipment are dedicated or, if not, cleaning procedures are validated:

- solvents : tanks, pumps and filtration systems
- solids : clean rooms and laminar flow qualified ISO8 for raw material sampling and production
- mixtures : mixer, pumps and filtration systems

Preventive maintenance plan



Production

With 2 production units, CARLO ERBA Reagents offers its customers quality and service throughout the production flexibility and facilities:

- Distillation columns from 400 liters to 10 000 liters
- Tanks from 10 000 to 32 000 liters
- Filtration units
- Water production (reverse osmosis and Electro-deionization) quality purified according to European Pharmacopoeia. This water is used to make as well pharmaceutical mixtures as finished products
- Mixers up to 7000l, rectifying columns and several packaging lines
- Salts production with clean rooms and laminar flow qualified ISO8 and laminar flow for toxic, grinding and filling thanks to pneumatic equipment

There are dedicated area for:

- Raw material
- Packaging
- Finished products

Warehousing and Storage

3 hubs in the Group:

- Val de Reuil in Normandy for France and export
- Arese near Milano for Italy
- Sabadell near Barcelona for Spain

Product reception recorded/documented according to a written procedure

Storage of products according to FEFO

Materials are stored in compliance with safety requirements in dedicated areas

Batch reservation

Shipment in single batch

Material planning based on in-house developed MRP (SAP) algorithm

Materials Planning Team work very closely with our customers service to ensure optimum buffer stock through:

- Weekly, monthly review and updates
- Materials planned according to forecast & actual usage
- Monitor closely any world situations which could potentially affect supply such as strikes, shortage
- Make-to-order



Traceability

Traceability warranteed by documentation:

- Worksheet for mix
- Production batch record (bill of material, weighing during production, set up of workplace, checking of labels, line clearance)
- Batch number
- Expiry date
- Witness label
- Reconciliation and traceability with raw material
- Analysis of finished product following internal specification or external in case of delegation of analysis

Every product batch is released with a certificate of analysis with:

- name of product, including grade and amount
- batch number
- expiry date

On request:

- Name of the producer of the raw material
- Batch number of this producer
- Date of production

Shipment data documented so that details can easily be traced back

MSDS provided in the local language with the first order of the delivered product

Repacking

Dedicated procedure to guarantee absence of cross contamination for hazardous products

For the equipment not dedicated there is a cleaning procedure validated

Line clearance

Labels reconciliation

One batch record with all the information for each production





Product range

You will find in the next pages an exhaustive list of our products included in the ERBApharm range.

This is, for sure, not the entire list of products we can propose at this level of quality and one of our main strengths is our capacity to propose tailor made solutions to our customers.

We will so welcome any request you may have on specific compounds you would like us to propose as ERBApharm. Your request will be studied by our dedicated Tailor Made department and an offer including pricing and detailed specifications will be submitted in short time.

As usual, CARLO ERBA Reagents remains your partner of choice, dedicated to offer you the best service, at the height of your requirements.



Mixtures and titrated solutions

Product		Monographs	CAS
Acetic acid solution 80%	Manufactured from raw material according to Eur.Ph.		64-19-7
Acetic acid solution 60%	Manufactured from raw material according to Eur.Ph.		64-19-7
Acetic acid solution 30%	Manufactured from raw material according to Eur.Ph.		64-19-7
Acetic acid 1 mol/l (1N)	Manufactured from raw material according to Eur.Ph.		64-19-7
Ammonia solution 28%		Eur.PhFU-NF	1336-21-6
Ethanol 70 % v/v		Eur.Ph.	64-17-5
Ethanol 70 % v/v		Eur.PhBP	64-17-5
Ethanol 70 % v/v - Microbiological tested		Eur.Ph.	64-17-5
Ethanol 50% v/v	Manufactured with raw material according to Eur.Ph.		64-17-5
Ethanol 20 % v/v		Eur.Ph.	64-17-5
Hydrochloric acid solution 35%		Eur.PhNF-FU-French PhBP-JP	7647-01-0
Hydrochloric acid solution 10%		Eur.Ph.	7647-01-0
Hydrochloric acid solution 8%	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid solution 5%	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 6 mol/l (6N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 5 mol/l (5N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 4 mol/l (4N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 3 mol/l (3N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 2 mol/l (2N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 1 mol/l (1N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrochloric acid 0.1 mol/l (0.1N)	Manufactured from raw material according to Eur.Ph.		7647-01-0
Hydrogen peroxide solution 40% w/v - Not stabilized	Manufactured from raw material according to Eur.Ph.	Eur.Ph.	7722-84-1
Hydrogen peroxide solution 30% - Stabilized		Eur.Ph.	7722-84-1
Hydrogen peroxide solution 3% - Stabilized		Eur.PhFU	7722-84-1
Propanol-2 70%	Manufactured from raw material according to Eur.Ph.		67-63-0
Propanol-2 70% - Microbiological tested		Eur.Ph.	67-63-0
Sodium hydroxide solution 32%	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide solution 30%	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 8 mol/l (8N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 6 mol/l (6N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 3 mol/l (3N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 2 mol/l (2N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 1 mol/l (1N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 0.5 mol/l (0.5N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 0.25 mol/l (0.25N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sodium hydroxide 0.1 mol/l (0.1N)	Manufactured from raw material according to Eur.Ph.		12200-64-5
Sorbitol solution 70%		Eur.PhFU-BP	50-70-4

For more details on available packaging and complete specifications, please contact your local representative.

Salts and liquids forms

Product	Monographs	CAS
Acetone	Eur.PhNF-BP	67-64-1
Acetic acid glacial	Eur.PhUSP-FU-NF-DAB-JP	64-19-7
Aluminum chloride hexahydrate	Eur.PhUSP	7784-13-6
Aluminum potassium sulfate dodecahydrate	Eur.PhUSP-FU-French PhBP	7784-24-9
p-Aminobenzoic acid	USP	150-13-0
Ammonium carbonate	NF	10361-29-2
Ammonium chloride	Eur.PhUSP-FU-French PhBP-DAB	12125-02-9
Benzalkonium chloride	NF	63449-41-2
Benzoic acid	Eur.PhUSP-FU-French PhBP	65-85-0
Benzyl alcohol	Eur.PhNF-FU-French PhBP	100-51-6
Benzyl benzoate	Eur.PhUSP-FU-French PhBP	120-51-4
Boric acid	Eur.PhFU-French PhDAB-USP	10043-35-3
Caffeine anhydrous	Eur.PhUSP-FU-French PhBP-DAB	58-08-2
Calcium acetate	BP	62-54-4
Calcium carbonate	Eur.PhUSP	471-34-1
Calcium chloride dihydrate	Eur.PhUSP-FU-French PhBP-DAB	10035-04-8
Calcium chloride hexahydrate	Eur.Ph.	7774-34-7
Calcium gluconate	Eur.PhFU	18016-24-5
Calcium hydroxide	Eur.PhUSP	1305-62-0
Calcium lactate	BP-FU-Eur.PhFrench Ph.	5743-47-5
Calcium pantothenate	Eur.PhFU-French PhDAB-USP	137-08-6
Calcium phosphate dibasic dihydrate	Eur.PhUSP-FU-French Ph.	7757-77-7
Calcium phosphate tribasic	Eur.Ph.	7758-87-4
Calcium stearate - Vegetal origin	USP-NF	1592-23-0
Calcium sulfate dihydrate	NF	10101-41-4
Camphor natural	Eur.PhUSP-BP	464-49-3
Camphor synthetic	Eur.PhFU-French PhBP-DAB-USP	21368-68-3
Castor oil	Eur.PhFU-French PhBP	8001-79-4
Cetyl alcohol	NF-Eur.PhFrench Ph.	36653-82-4
Chlorobutanol	Eur.PhNF-FU-French PhBP	6001-64-5
Chloroform stabilized with ethanol	BP	67-66-3
Cholesterol	Eur.PhNF-FU-BP	57-88-5
Citric acid anhydrous	Eur.PhUSP-FU-BP-DAB-JP	77-92-9
Citric acid monohydrate, powder	Eur.PhUSP-FU-BP-DAB	5949-29-1
Citric acid monohydrate	Eur.PhUSP-FU-BP-DAB	5949-29-1
Copper (II) sulfate pentahydrate	Eur.PhUSP-FU-BP	7758-99-8
Di-n-butylphthalate	Eur.Ph.	84-74-2
Dichloromethane stabilized with amylene	Eur.Ph.NF	75-09-2
Dichloromethane stabilized with ethanol	NF	75-09-2
Dichloromethane stabilized with ethanol	Eur.Ph.	75-09-2
 Diethanolamine	USP-NF	111-42-2
Diethyl ether not stabilized	Eur.PhBP	60-29-7
Diethyl ether stabilized with BHT	Eur.PhBP	60-29-7
Diethyl phthalate	Eur.PhNF-BP	84-66-2
Diisopropyl oxide	Eur.Ph.	108-20-3
Dimethylsulfoxide	Eur.Ph.	67-68-5
Ethanol absolute anhydrous	Eur.PhUSP-BP-JP	64-17-5
Ethanol absolute denaturated with 4% butanol 0.5% isopropanol	French Ph.	64-17-5
Ethanol 96°	Eur.PhUSP	64-17-5
Ethanol 96° - Microbiological tested	Eur.Ph.	64-17-5
Ethanol 96° with denaturated 4% butanol 0.5% isopropanol	French Ph.	64-17-5
Ethyl acetate	Eur.PhNF-DAB	141-78-6
Ethylenediaminetetraacetic acid	NF	60-00-4
Ethylenediaminetetraacetic acid disodium salt	Eur.PhFU	6381-92-6
Ethylenediaminetetraacetic acid disodium salt	Eur.PhUSP	6381-92-6
Formaldehyde 35% w/w	Eur.PhFU-French PhBP	50-00-0
Formic acid 99%	DAB	64-18-6
Fumaric acid	NF	110-17-8
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Salts and liquids forms

Product	Monographs	CAS
D(+) - Glucose anhydrous	Eur.PhUSP-FU-French PhBP-DAB	50-99-7
D(+) - Glucose monohydrate	Eur.PhUSP-French PhBP-DAB	5996-10-1
Glycerol	Eur.PhUSP	56-81-5
Glycerol 30° Be, vegetal origin	Eur.PhUSP-FU-French PhBP-DAB	56-81-5
Glycerol 30° Be, synthetic origin	Eur.PhUSP-FU-French PhBP-DAB	56-81-5
Glycine	Eur.PhUSP-French Ph.	56-40-6
Gum arabic	Eur.PhFU-French PhBP	9000-01-5
lodine	Eur.PhUSP-FU-French PhBP-DAB	7553-56-2
Iron II sulfate	Eur.PhFU-French PhBP-DAB	7782-63-0
Lactic acid	Eur.PhFU-French PhBP-DAB	79-33-4
D(+)-Sucrose	Eur.PhNF-FU-French PhBP-DAB	10039-26-6
D(+)-Sucrose - Microbiological tested	Eur.PhNF-FU-French PhBP-DAB	
Lanolin anhydrous	Eur.PhFU	8006-54-0
Magnesium carbonate basic	BP-FU-Eur.PhFrench Ph.	39409-82-0
Magnesium carbonate basic	USP	39409-82-0
Magnesium chloride hexahydrate	Eur.PhUSP-FU-French PhBP	7791-18-6
Magnesium hydroxide	BP-FU-Eur.PhFrench Ph.	1309-42-8
Magnesium oxide heavy	Eur.Ph.	1309-48-4
Magnesium stearate - Vegetal origin	Eur.PhBP-FU-NF	557-04-0
Magnesium sulfate heptahydrate	Eur.PhFU-BP-DAB-USP	10034-99-8
Maleic acid	Eur.PhBP-USP-NF	110-16-7
D-Mannitol	Eur.PhUSP-FU	69-65-8
L-Menthol	USP	2216-51-5
Methanol	NF-DAB-Eur.Ph.	67-56-1
Methyl 4-hydroxybenzoate	Eur.PhNF-FU-French PhBP-DAB	99-76-3
Methyl salicylate	Eur.PhFU-French PhBP-DAB	119-36-8
Nicotinamide	Eur.PhUSP-FU-French PhBP-DAB	98-92-0
Oil refined of almonds	NF	8007-69-0
Orthophosphoric acid 85%	Eur.PhUSP-FU-French PhBP-DAB	7664-38-2
Paraffin oil	Eur.PhUSP-FU-French PhBP	8012-95-1
Paraffin white soft	BP-NF	8009-03-08
Phenol	Eur.PhUSP-FU-French PhBP-DAB	108-95-2
2-Phenylethanol	USP	60-12-8
Potassium acetate	Eur.PhBP	127-08-2
Potassium hydrogen carbonate	USP	298-14-6
Potassium bromide	Eur.PhFrench PhBP-DAB	7758-02-3
Potassium chloride	Eur.PhUSP-FU-French PhBP-DAB	7447-40-7
tri-Potassium citrate	Eur.PhUSP-French PhBP	6100-05-06
Potassium hydroxide, flakes	Eur.PhBP	1310-58-3
Potassium hydroxide, pellets	Eur.PhFU	1310-58-3
Potassium iodide	Eur.PhUSP-FU-French PhBP-DAB	7681-11-0
Potassium metabisulphite	NF	16731-55-8
Potassium nitrate	Eur.PhBP	7757-79-1
	Eur.PhUSP-FU-French PhBP-DAB	7722-64-7
Potassium permanganate		
Potassium phosphate monobasic	NF.	7778-77-0
Potassium sodium tartrate tetrahydrate	USP	6381-59-5
Propanol-1	Eur.Ph.	71-23-8
Propanol-2	Eur.PhUSP-French PhBP	67-63-0
Propionic acid	USP-NF	79-09-4
Propyl p-hydroxybenzoate	Eur.PhNF-FU-French PhBP-DAB	94-13-3
Propylene glycol	Eur.PhUSP-FU-French PhBP	57-55-6
Salicylic acid	FU	69-72-7
Salicylic acid	Eur.PhUSP-FU	69-72-7
Silicon dioxide	NF	14808-60-7
Silver nitrate	Eur.PhUSP-FU-French PhBP-DAB	7761-88-8
Sodium acetate trihydrate	Eur.PhUSP-FU-French PhBP	6131-90-4
Sodium acetate anhydrous	USP	127-09-3
Sodium alginate	Eur.PhFU	9005-38-3

Salts and liquids forms

Product	Monographs	CAS
Sodium benzoate	Eur.PhNF-FU-French PhBP	
Sodium bicarbonate	Eur.PhUSP-FU-French PhBP-DAB	144-55-8
Sodium bromide	Eur.PhFrench Ph.	7647-15-6
Sodium carbonate anhydrous	Eur.PhNF	497-19-8
Sodium carbonate decahydrate	Eur.PhFU-French PhBP	6132-02-01
Sodium carbonate monohydrate	Eur.PhFU-French Ph.	497-19-8
Sodium chloride	Eur.PhUSP-FU-French PhBP-DAB-JP	7647-14-5
Sodium chloride - Microbiological tested	Eur.Ph.	7647-14-5
Sodium citrate dibasic sesquihydrate	BP	144-33-2
Sodium citrate tribasic anhydrous	USP	68-04-2
Sodium citrate tribasic dihydrate	Eur.PhUSP-FU-BP-DAB	6132-04-03
Sodium glycerophosphate	Eur.Ph.	819-83-0
Sodium hydroxide, pellets	Eur.PhNF-BP	1310-73-2
Sodium hydroxide, pearls	Eur.PhNF	1310-73-2
Sodium iodide	Eur.PhFU-French PhBP	7681-82-5
Sodium metabisulphite	Eur.PhNF-FU-BP	7681-57-4
Sodium nitrite	USP-BP	7632-00-0
Sodium phosphate dibasic anhydrous	Eur.PhUSP	7558-79-4
Sodium phosphate dibasic dihydrate	Eur.PhUSP	10028-24-7
Sodium phosphate dibasic dodecahydrate	Eur.PhFU-French PhBP-DAB-USP	10039-32-4
Sodium phosphate monobasic monohydrate	USP	10049-21-5
Sodium phosphate monobasic dihydrate	Eur.PhUSP	13472-35-0
Sodium salicylate	Eur.PhUSP-FU-French PhBP-DAB	54-21-7
Sodium stearate vegetable	FU-NF	822-16-2
Sodium sulphate anhydrous - Microbiological tested	Eur.PhNF-FU-French PhBP-DAB	7757-82-6
Sodium sulphate anhydrous	Eur.Ph.	7757-82-6
Sodium sulphite anhydrous	Eur.PhBP	7757-83-7
Sodium tetraborate decahydrate	Eur.PhNF-FU-French PhBP	1303-96-4
Sodium thiosulfate pentahydrate	Eur.PhUSP-FU-French PhBP	10102-17-7
Sorbitol	Eur.PhFU	50-70-4
Starch from maize	Eur.PhNF-FU-French PhBP	9005-84-9
Starch from rice	Eur.PhFU-French PhBP	9005-25-8
Stearic acid - Vegetal origin	Eur.PhUSP-NF	57-11-4
D(+) - Sucrose	Eur.PhNF-FU-French PhBP	57-50-1
Sulphuric acid 96%	Eur.PhNF-BP	7664-93-9
Talc	Eur.PhUSP-FU-French PhBP	14807-96-6
Tannic acid	Eur.PhUSP-FU	1401-55-4
L(+) - Tartaric acid	Eur.PhNF-FU-French PhBP-DAB	87-69-4
L(+) - Tartaric acid, crystals	Eur.PhNF-FU-French PhBP-DAB	87-69-4
Thymol	BP-DAB-NF-Eur.PhFU	89-83-8
Titanium dioxide	Eur.PhUSP-FU-BP	13463-67-7
Triethanolamine	Eur.PhFU	102-71-6
Tris (hydroxymethyl)-aminomethane	USP	77-86-1
Vanillin	Eur.PhNF-FU-BP-DAB	121-33-5
Water purified	Eur.PhFU-French PhBP-DAB-USP-JP	7732-18-5
Zinc chloride	USP	7646-85-7
Zinc oxide	Eur.PhUSP-FU-French PhBP	1314-13-2
Zinc stearate vegetal	Eur.PhUSP-FU	557-05-1
Zinc sulfate vegetat Zinc sulfate heptahydrate	Eur.PhUSP-FU-French PhBP	7446-20-0
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