EXCIPIENTS & RAW MATERIALS
FOR THE PHARMACEUTICAL INDUSTRY

from R&D to final production scale

DASITGROUP | CARLO ERBA REAGENTS

WE ARE YOUR PARTNER

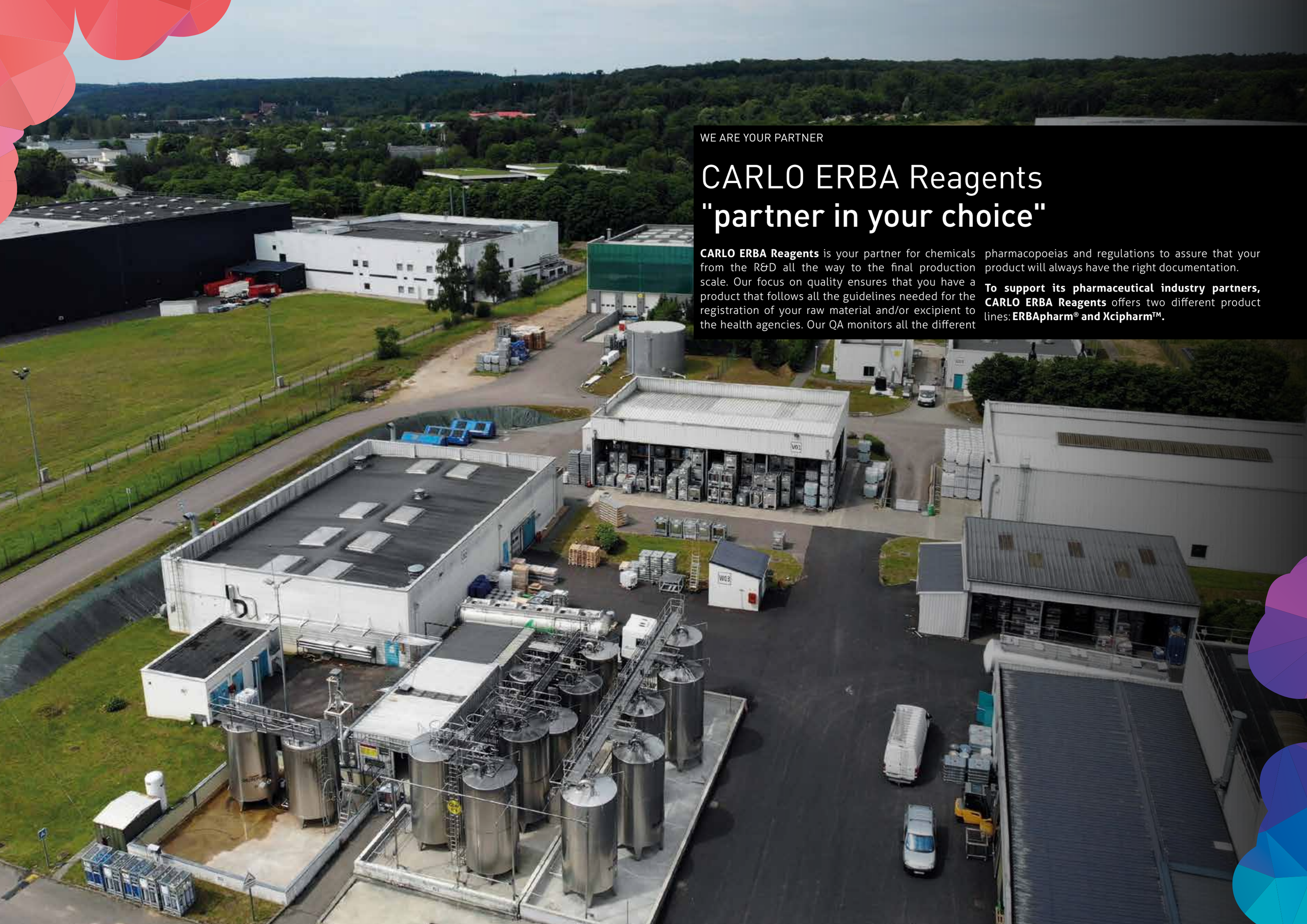
INTRODUCTION

The introduction of a new drug on the market is a very time intensive process taking on average 12 years, going through different milestones requiring different levels of specifications throughout the process.

One of the most challenging steps is the approval by the pharmaceutical authorities of the final drug. This process includes different steps with one involving demonstrating that the drug can be manufactured properly.

To accomplish this task, the manufacturer needs to have suppliers with a high transparency of their supply chain and a strong QA system in place to provide all of the appropriate documentation.

CARLO ERBA Reagents is your partner for all of these steps with all the documentation needed for the registration process.



WE ARE YOUR PARTNER

CARLO ERBA Reagents
"partner in your choice"

CARLO ERBA Reagents is your partner for chemicals from the R&D all the way to the final production scale. Our focus on quality ensures that you have a product that follows all the guidelines needed for the registration of your raw material and/or excipient to the health agencies. Our QA monitors all the different pharmacopoeias and regulations to assure that your product will always have the right documentation.

To support its pharmaceutical industry partners, CARLO ERBA Reagents offers two different product lines: **ERBApharm® and Xcipharm™.**

WE ARE YOUR PARTNER

ERBApharm®

With more than 500 products that can be used as **starting materials, intermediates or reagents** the **ERBApharm®** product line covers a wide range of reagents, salts and solvents.

Their specifications comply with the requirements of main pharmacopoeia or, in the absence of those requirements, with strict sales specifications.

We have an extensive portfolio of products for starting materials, intermediates and reagents for API and pharmaceutical solutions with:

- Solvents
- Acids, Bases and solutions at different concentration
- Water and Alcohols
- Oils
- Starches and Sugars
- Inorganic & Organic substances
- Mixtures

Following **the latest version of the ISO 9001 Quality System**, we are providing the documentation and quality required for your end products.

ERBApharm® Traceability is warranted by specific procedures:

- 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
- Traceability of raw material
- Traceability of finished product: analysis following specification in critical parameters for each batch
- Batch release
- Line clearance which assures that the area is cleaned and ready before starting the next batch

ERBApharm®

DOCUMENTATION PROVIDED

- Certificate of analysis with: Name of product, including grade; Batch number; Expiry/Retest date; Specifications & Results;
- Certificate BSE/TSE: On Request (if available from the producer)
- Certificate Residual solvents: On Request (if available from the producer)
- GMO Certificate: On Request (if available from the producer)
- Change control: On Request

A Confidential Non-Disclosure Agreement is available on request.

WE ARE YOUR PARTNER

Xcipharm™

Xcipharm™ is the new product line dedicated to **excipients.**

To be employed like an excipient, the product must be an inactive substance that serves as a vehicle to medium for drug and active substance.

The **CARLO ERBA Reagents Xcipharm™** product line includes more than 100 products valid as excipients:

- Solvents
- Acids, Bases and solutions at different molarity
- Water and Alcohols
- Oils
- Starches, Sugars and substitutes
- Inorganic & Organic substances
- Mixtures

Their specifications comply with the requirements of main pharmacopoeia or, in the absence of those requirements, with strict sales specifications.

Following the **IPEC Quality System GMP and GDP** ensures that your products have all the necessary documentation for the registration of your excipients to the health authorities and furthermore, they are declared to the French Ministry of Health (ANSM).

The QA team updates the declaration to the ANSM annualy and audits the suppliers of raw materials to be used as excipients.

Xcipharm™ Traceability is warranted by specific procedures:

- Worksheet for mix
- Production batch record (bill of material, weighing during production, set up of workplace, checking of labels, line clearance)
- Traceability of raw material
- Traceability of primary packaging in finished products
- Full analysis for each batch
- Reconciliation of labels which manages the complete inspection of labeling process
- Stability studies of each batch

ansm

DIRECTION DE L'INSPECTION
Pôle inspection des matières premières

Attestation d'inspection / *Attestation of inspection*
Article L. 5313-1 du code français de la santé publique
Article L.5313-1 of the French public health code

Nom de l'établissement inspecté / *Name of the inspected site*	CARLO ERBA REAGENTS
Adresse de l'établissement inspecté / *Address of the inspected site*	Chantrasse du Vexin Parc des Affaires 27106 VAL DE REUIL FRANCE
Dates de l'inspection / *Dates of inspection*	13 et 14 janvier 2020 *13th and 14th January 2020*
Champ de l'inspection / *Scope of the inspection*	☐ Distribution de substances actives *Distribution of active substances* ☒ Fabrication d'excipients *Manufacturing of excipients* ☒ Distribution d'excipients *Distribution of excipients*
Référentiels / *Guidelines*	Guidelines des bonnes pratiques de fabrication et de distribution d'excipients à usage pharmaceutique IPEC - PQG 2017 des excipients à usage pharmaceutique *The Joint IPEC - PQG 2017 Good Manufacturing and Distribution Practices Guide for pharmaceutical excipients*
Clarifications / restrictions / *Clarifications / restrictions*	Opérations de fabrication limitées au reconditionnement d'excipients *Manufacturing operations restricted to excipient repackaging*

L'inspection n'a pas conduit à la remise en cause d'autorisation(s) de mise sur le marché de médicament(s) utilisant la (les) matière(s) première(s) à usage pharmaceutique concernée(s) ni à prendre de mesure de police sanitaire à l'encontre de l'établissement inspecté.
The inspection carried out has not returned invalidation of approved marketing authorisation(s) for drug(s) using the pharmaceutical ingredient(s) concerned, or to institute sanction against the inspected site.

Linda GALLAIS
Cheffe du pôle inspection des matières premières
Direction de l'inspection

Nom et signature de la personne responsable de l'autorité compétente française (ANSM)
Name and signature of the authorised person of the competent authority of France (ANSM)

Date : 20 avril 2020

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Xcipharm™

DOCUMENTATION PROVIDED

- Certificate of analysis with: Name of product, including grade and amount; Batch number; Expiry/Retest date; Specifications & Results; Production site (raw material producer); Manufacturing date (raw material producer); Packaging date;
- Certificate BSE/TSE
- Certificate Residual solvents
- GMO Certificate
- ICHQ3D
- Supply chain and risk assessment

A Confidential Non-Disclosure Agreement is required.

SERVICE GUARANTEED

- Change control
- French Ministry of Health registration

WE PAY ATTENTION TO EVERY STEP

PACKAGING

Pack size:

From 100 ml to 25.000 liters for liquids

From 1 g to 1 ton for solids

Different packaging:

- Vials
- Bottles
- Cans
- Buckets with inner plastic bag
- Drums
- Kraft drums with inner plastic bag
- Stainless steel shuttle containers
- Special packaging under customer requirements (to be evaluated case by case)

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

- Transport homologation
- Certificate of conformity to Pharmacopoeia
- Declaration of SVHC/REACH Conformity

According to your required pharma grade:

- Food contact certificate for immediate packaging certificate
- Certificate for heavy metals
- Specific container-content interaction study can be performed

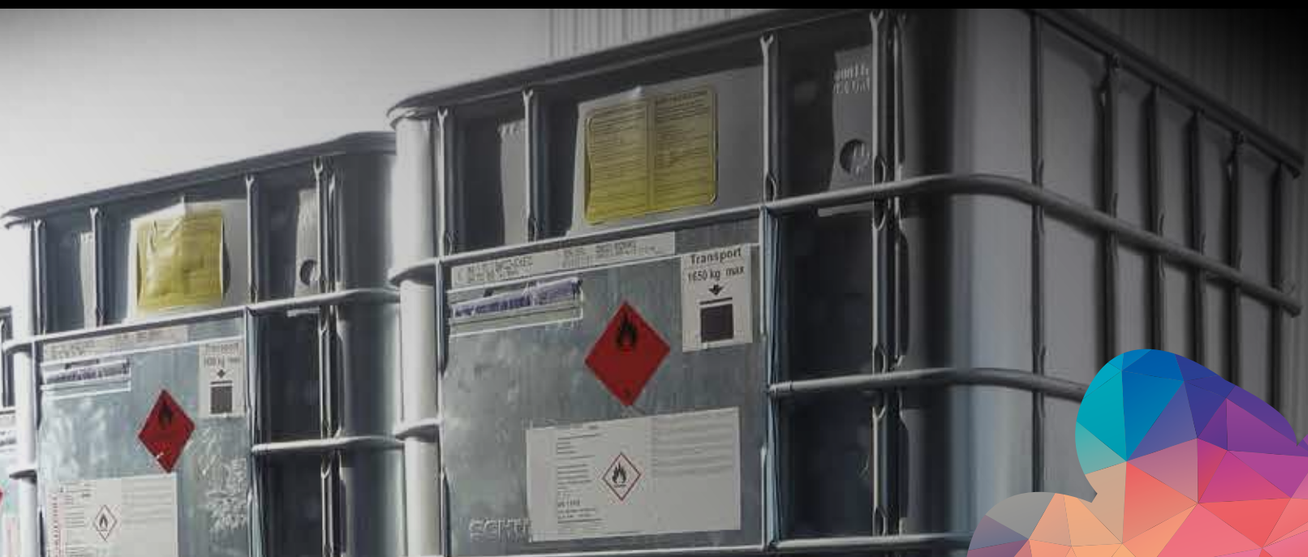
SAFETY IN STORAGE

WAREHOUSING AND STORAGE

CARLO ERBA Reagents accomplishes

- Product reception recorded/documented according to a written procedure
- Storage of products according to FEFO (First Expired, First Out)
- 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.



WE MEET ALL YOUR NEEDS

TAILOR MADE

CARLO ERBA Reagents is at your service to meet your requirements and constraints.

We can manufacture tailored solutions with the ERBApharm® and Xcipharm™ grades for:

PRODUCT

- Specific purity
- Safety stocks

PRODUCTION

- Custom mixtures and dilutions
- Grinding of solids

QUALITY

- Change Control
- Specific QC tests
- Sampling and third party analyses
- ANSM (French Ministry of Health) declaration for Excipients

PACKAGING

- Custom packaging
- Shuttle service
- Deliveries in large volumes

The proximity and experience of our Quality, Production and Logistic teams enables **CARLO ERBA Reagents** to work with you to find the most suitable solution and make us "***partner in your choice***".

OUR OFFER

PRODUCT RANGE

You will find in the next pages a list of products included in the **ERBApharm®** and **Xcipharm™** product lines.

This is not an exhaustive list of products, it is constantly evolving: **CARLO ERBA Reagents**' main strength is the capacity to propose tailor made solutions with the highest quality you need.

CARLO ERBA Reagents will welcome any request you may have on specific compounds you would like us to propose as **ERBApharm®** or **Xcipharm™**. Your request will be studied by **CARLO ERBA Reagents**' dedicated Tailor Made department and an offer including pricing and detailed specifications will be submitted.

CARLO ERBA Reagents remains partner in your choice, dedicated to offer you the best service, at the level of your requirements.

Mixtures and titrated solutions

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

Salts and liquids forms

Product	Monographs	CAS	ERBApharm®	Xcipharm™
Acetone		67-64-1	X	X
Acetic acid glacial		64-19-7	X	X
Aluminum chloride hexahydrate		7784-13-6	X	
Aluminum potassium sulfate dodecahydrate		7784-24-9	X	
p-Aminobenzoic acid	USP	150-13-0	X	
Ammonium carbonate	NF	10361-29-2	X	
Ammonium chloride	Eur.Ph.-USP-FU-French Ph.-BP-DAB	12125-02-9	X	
Benzalkonium chloride		63449-41-2	X	
Benzoic acid		65-85-0	X	X
Benzyl alcohol		100-51-6	X	X
Benzyl benzoate		120-51-4	X	
Boric acid		10043-35-3	X	
Caffeine anhydrous		58-08-2	X	
Calcium acetate		62-54-4	X	
Calcium carbonate		471-34-1	X	

Salts and liquids forms

Product	Monographs	CAS	ERBApharm®	Xcipharm™
Calcium chloride dihydrate	Eur.Ph.-USP-FU-French Ph.-BP-DAB	10035-04-8	X	X
Calcium chloride hexahydrate	Eur.Ph.	7774-34-7	X	
Calcium gluconate	Eur.Ph.-FU	18016-24-5	X	
Calcium hydroxide	Eur.Ph.-USP	1305-62-0	X	
Calcium lactate	BP-FU-Eur.Ph.-French Ph.	5743-47-5	X	
Calcium pantothenate	Eur.Ph.-FU-French Ph.-DAB-USP	137-08-6	X	
Calcium phosphate dibasic dihydrate	Eur.Ph.-USP-FU-French Ph.	7757-77-7	X	
Calcium phosphate tribasic	Eur.Ph.	7758-87-4	X	
Calcium stearate - Vegetal origin	USP-NF	1592-23-0	X	
Calcium sulfate dihydrate	NF	10101-41-4	X	
Camphor natural	Eur.Ph.-USP-BP	464-49-3	X	
Camphor synthetic	Eur.Ph.-FU-French Ph.-BP-DAB-USP	21368-68-3	X	
Castor oil	Eur.Ph.-FU-French Ph.-BP	8001-79-4	X	X
Cetyl alcohol	NF-Eur.Ph.-French Ph.	36653-82-4	X	
Chlorobutanol	Eur.Ph.-NF-FU-French Ph.-BP	6001-64-5	X	
Chloroform stabilized with ethanol	BP	67-66-3	X	
Cholesterol	Eur.Ph.-NF-FU-BP	57-88-5	X	
Citric acid anhydrous	Eur.Ph.-USP-FU-BP-DAB-JP	77-92-9	X	X
Citric acid monohydrate, powder	Eur.Ph.-USP-FU-BP-DAB	5949-29-1	X	X
Citric acid monohydrate	Eur.Ph.-USP-FU-BP-DAB	5949-29-1	X	X
Copper (II) sulfate pentahydrate	Eur.Ph.-USP-FU-BP	7758-99-8	X	
Di-n-butylphthalate	Eur.Ph.	84-74-2	X	
Dichloromethane stabilized with amylene	Eur.Ph.NF	75-09-2	X	
Dichloromethane stabilized with ethanol	NF	75-09-2	X	
Dichloromethane stabilized with ethanol	Eur.Ph.	75-09-2	X	
Diethanolamine	USP-NF	111-42-2	X	
Diethyl ether not stabilized	Eur.Ph.-BP	60-29-7	X	
Diethyl ether stabilized with BHT	Eur.Ph.-BP	60-29-7	X	X
Diethyl phthalate	Eur.Ph.-NF-BP	84-66-2	X	X
Diisopropyl oxide	Eur.Ph.	108-20-3	X	
Dimethylsulfoxide	Eur.Ph.	67-68-5	X	X
Ethanol absolute anhydrous	Eur.Ph.-USP-BP-JP	64-17-5	X	X
Ethanol absolute denaturated with 4% butanol 0.5% isopropanol	French Ph.	64-17-5	X	
Ethanol 96°	Eur.Ph.-USP	64-17-5	X	X
Ethanol 96° - Microbiological tested	Eur.Ph.	64-17-5	X	
Ethanol 96° with denaturated 4% butanol 0.5% isopropanol	French Ph.	64-17-5	X	
Ethyl acetate	Eur.Ph.-NF-DAB	141-78-6	X	X
Ethylenediaminetetraacetic acid	NF	60-00-4	X	X
Ethylenediaminetetraacetic acid disodium salt	Eur.Ph.-FU	6381-92-6	X	X
Ethylenediaminetetraacetic acid disodium salt	Eur.Ph.-USP	6381-92-6	X	X
Formaldehyde 35% w/w	Eur.Ph.-FU-French Ph.-BP	50-00-0	X	
Formic acid 99%	DAB	64-18-6	X	
Fumaric acid	NF	110-17-8	X	
D(+) - Glucose anhydrous	Eur.Ph.-USP-FU-French Ph.-BP-DAB	50-99-7	X	X
D(+) - Glucose monohydrate	Eur.Ph.-USP-French Ph.-BP-DAB	5996-10-1	X	
Glycerol	Eur.Ph.-USP	56-81-5	X	
Glycerol 30° Be, vegetal origin	Eur.Ph.-USP-FU-French Ph.-BP-DAB	56-81-5	X	X
Glycerol 30° Be, synthetic origin	Eur.Ph.-USP-FU-French Ph.-BP-DAB	56-81-5	X	

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

Salts and liquids forms

Product	Monographs	CAS	ERBApharm®	Xcipharm™
Sodium acetate trihydrate	Eur.Ph.-USP-FU-French Ph.-BP	6131-90-4		X
Sodium acetate anhydrous	USP	127-09-3	X	
Sodium alginate	Eur.Ph.-FU	9005-38-3		X
Sodium benzoate	Eur.Ph.-NF-FU-French Ph.-BP	532-32-1	X	
Sodium bicarbonate	Eur.Ph.-USP-FU-French Ph.-BP-DAB	144-55-8		X
Sodium bromide	Eur.Ph.-French Ph.	7647-15-6	X	
Sodium carbonate anhydrous	Eur.Ph.-NF	497-19-8		X
Sodium carbonate decahydrate	Eur.Ph.-FU-French Ph.-BP	6132-02-01	X	
Sodium carbonate monohydrate	Eur.Ph.-FU-French Ph.	497-19-8	X	X
Sodium chloride	Eur.Ph.-USP-FU-French Ph.-BP-DAB-JP	7647-14-5	X	X
Sodium citrate dibasic sesquihydrate	BP	144-33-2	X	X
Sodium citrate tribasic anhydrous	USP	68-04-2	X	
Sodium citrate tribasic dihydrate	Eur.Ph.-USP-FU-BP-DAB	6132-04-03	X	X
Sodium glycerophosphate	Eur.Ph.	819-83-0	X	
Sodium hydroxide, pellets	Eur.Ph.-NF-BP	1310-73-2	X	X
Sodium hydroxide, pearls	Eur.Ph.-NF	1310-73-2	X	
Sodium iodide	Eur.Ph.-FU-French Ph.-BP	7681-82-5	X	
Sodium metabisulphite	Eur.Ph.-NF-FU-BP	7681-57-4	X	X
Sodium nitrite	USP-BP	7632-00-0	X	
Sodium phosphate dibasic anhydrous	Eur.Ph.-USP	7558-79-4	X	X
Sodium phosphate dibasic dihydrate	Eur.Ph.-USP	10028-24-7	X	X
Sodium phosphate dibasic dodecahydrate	Eur.Ph.-FU-French Ph.-BP-DAB-USP	10039-32-4	X	X
Sodium phosphate monobasic monohydrate	USP	10049-21-5	X	X
Sodium phosphate monobasic dihydrate	Eur.Ph.-USP	13472-35-0	X	X
Sodium salicylate	Eur.Ph.-USP-FU-French Ph.-BP-DAB	54-21-7	X	
Sodium stearate vegetable	FU-NF	822-16-2	X	
Sodium sulphate anhydrous - Microbiological tested	Eur.Ph.-NF-FU-French Ph.-BP-DAB	7757-82-6	X	X
Sodium sulphate anhydrous	Eur.Ph.	7757-82-6	X	X
Sodium sulphite anhydrous	Eur.Ph.-BP	7757-83-7	X	X
Sodium tetraborate decahydrate	Eur.Ph.-NF-FU-French Ph.-BP	1303-96-4	X	
Sodium thiosulfate pentahydrate	Eur.Ph.-USP-FU-French Ph.-BP	10102-17-7	X	X
Sorbitol	Eur.Ph.-FU	50-70-4	X	
Starch from maize	Eur.Ph.-NF-FU-French Ph.-BP	9005-84-9	X	
Starch from rice	Eur.Ph.-FU-French Ph.-BP	9005-25-8	X	
Stearic acid - Vegetal origin	Eur.Ph.-USP-NF	57-11-4	X	X
D(+) - Sucrose	Eur.Ph.-NF-FU-French Ph.-BP	57-50-1	X	X
Sulfuric acid 96%	Eur.Ph.-NF-BP	7664-93-9	X	X
Talc	Eur.Ph.-USP-FU-French Ph.-BP	14807-96-6	X	
Tannic acid	Eur.Ph.-USP-FU	1401-55-4	X	X
L(+) - Tartaric acid	Eur.Ph.-NF-FU-French Ph.-BP-DAB	87-69-4	X	X
L(+) - Tartaric acid, crystals	Eur.Ph.-NF-FU-French Ph.-BP-DAB	87-69-4	X	
Thymol	BP-DAB-NF-Eur.Ph.-FU	89-83-8	X	
Titanium dioxide	Eur.Ph.-USP-FU-BP	13463-67-7	X	X
Triethanolamine	Eur.Ph.-FU	102-71-6	X	X
Tris (hydroxymethyl)-aminomethane	USP	77-86-1	X	
Vanillin	Eur.Ph.-NF-FU-BP-DAB	121-33-5	X	

Product	Monographs	CAS	ERBApharm®	Xcipharm™
Vaseline	BP-NF		X	
Water purified	Eur.Ph.-FU-French Ph.-BP-DAB-USP-JP	7732-18-5	X	
Zinc chloride	USP	7646-85-7	X	
Zinc oxide	Eur.Ph.-USP-FU-French Ph.-BP	1314-13-2	X	
Zinc stearate vegetal	Eur.Ph.-USP-FU	557-05-1	X	
Zinc sulfate heptahydrate	Eur.Ph.-USP-FU-French Ph.-BP	7446-20-0	X	

Summary of the documentation and operations done for each grade

	ERBApharm®	Xcipharm™
Quality System	*ISO 9001*	*IPEC guidelines*
Validated cleaning procedure or dedicated equipment	✔	✔
Traceability of raw material / finish good	✔	✔
Traceability of primary packaging / finish good	*N/A*	✔
Labels Management	*Line clearance*	*Reconciliation*
Analysis	*Analytical reduction plan (critical parameters for each batch, full analysis once a year)*	*Full analysis for each batch*
Certificate of analysis	*As current*	*Addition to current: name and address of the raw material producer, production date, packaging date in CARLO ERBA Reagents premises.*
Batch release by AQ service	✔	✔
Samples library	✔ *(raw material for 1 year)*	✔ *(raw material for 1 year)* ✔ *(finish good, shelf life+1 year)*
Change control notification	*On Request/QA*	*Systematic*
Shelf or retest date	✔	✔
Stability study	*N/A*	✔
BSE/TSE certificate	*On Request (if available from the producer)*	*Systematic*
Residual Solvents Certificate	*On Request (if available from the producer)*	*Systematic*
GMO Certificate	*On Request (if available from the producer)*	*Systematic*
Specification summary/ Non-Disclosure Agreement	*On Request*	*Systematic*
ICHQ3D	*N/A*	*Systematic*
Supply chain and risk assessment	*N/A*	✔
French MOH registration	*N/A*	✔

On request, CARLO ERBA Reagents can guarantee different levels of change control.

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