Excipients & Raw Materials for Pharmaceutical Industry

pcc

More than Chemistry

Trust matters

QUALITY PRODUCTS

- formulated specifically for variety of pharmaceutical applications
- in-process control
- validated analytical procedures
- significantly reduced time to market

MANUFACTURING EXCELLENCE

- seamless production capability
- technological support
- customized solutions
- selection of applicable container systems
- suitable samples of applicable size

REGULATORY

- regulatory compliance as per customer needs
- complete product documentation
- risk management and hazard identification support
- process characteristics upon request
- effective complaint resolving procedure

SUPPLY RELIABILITY

- the highest standards of transportation safety
- solid supply chain management
- just-in-time delivery

PCC ROKITA

RAW MATERIALS FOR API SYNTHESIS

Phosphorus derivatives

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
Phosphorus Trichloride PF	Non-applicable	7719-12-2	Semi-product for API production	Liquid	Non-applicable
Phosphorus Oxychloride PF	Non-applicable	10025-87-3	Semi-product for API production	Liquid	Non-applicable

Main applications of Phosphorus Trichloride:

- a Phosphorus introducing agent in the formation of phosphites and phosphonates like hydroxyphosphonates and amino-phosphonates (enzyme inhibitors),
- chlorination reagent: in substitution reactions of hydroxyl groups with a chlorine atom or an activator in coupling reactions, converting carboxylic or sulphonic/sulphinic acids into more reactive derivatives – chlorides, conjugated to nucleophiles (examples for the above are converting alcohols to esters or amines to amides),
- a substrate for the synthesis of catalysts, where it acts as a building block for ligands.

Main applications of Phosphorus Oxychloride:

- as Phosphorus introducing agent in the formation of phosphates (phosphorylation),
- chlorination reagent, used in substitution reactions of hydroxyl groups with a chlorine atom,
- activator in coupling reactions, converting carboxylic or sulphonic/sulphinic acids into more reactive derivatives – chlorides, conjugated to various nucleophiles (examples for the above are alcohols to form esters or amines to form amides),
- substrate for the synthesis of catalysts, where it acts as a building block for ligands,
- reagent in cyclisation processes, e.g. isoquinoline synthesis using the Bischler-Napieralski procedure: the use of POCl3 allows intramolecular aromatic electrophilic substitution of isoquinoline derivatives, as in the synthesis of drotaverine,
- synthesis of nucleosides analogues like fludarabine phosphate,
- manufacturing of B-group vitamins for pharmaceutical and nutraceutical purposes.

Important notice:
Dangerous goods – transport and storage in original packaging protected from moisture.
Products are dual-use items according to the REGULATION (EU) 2021/821 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 May 2021.

Chlorine derivatives

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
Monochlorobenzene PF	Non-applicable	108-90-7	Semi-product for API production	Liquid	Non-applicable
Orthodichlorobenzene PF	Non-applicable	95-50-1	Semi-product for API production	Liquid	Non-applicable

Monochlorobenzene and Orthodichlorobenzene:

Monochlorobenzene (MCB) and Orthodichlorobenzene (ODCB) are used, among others, in:

- acetaminophen synthesis,
- production of vitamin B6 (pyridoxine),
- production of zoledronic acid,
- production of Chlorphenoxamine.

PCC ROKITA

FUNCTIONAL ADDITIVES

Caustic soda – Sodium Hydroxide Flakes PF

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
Sodium hydroxide flakes PF	Sodium hydroxide	1310-73-2	Intermediates in pharma production, pH control	Solid (Flakes)	conforms

Caustic soda is mainly applicable:

- in the production of salicylic acid and sulfonamides,
- in the production of sodium ascorbate - an alternative to vitamin C as the sodium salt of ascorbic acid,
- in the production of iodoform used as a raw material (sodium carrier) in various kinds of syntheses in the pharmaceutical industry (including in the production of polopyrine, salicylic acid, sulfanilamides),
- as an auxiliary in the production of ointments and medicated creams for external use. Aqueous solution of sodium hydroxide is used to neutralize the carboxylic groups and thus to the cross-linking of gelling agents, e.g. polyacrylic acids in therapeutic gels. This increases the pharmaceutical availability of active ingredients in hydrogel preparations.

PCC EXOL

EXCIPIENTS FOR PHARMACEUTICAL FORMULATIONS

Macrogols – Polyethylene Glycols

Product name	Monograph name	CAS	Chemical description	Molecular mass [g/mol]	Appearance	Compliance with Eur.Ph monograph
POLIkol 300PF	Macrogol 300	25322-68-3	Polyethylene glycol	300	Liquid	conforms
POLIkol 400PF	Macrogol 400	25322-68-3	Polyethylene glycol	400	Liquid	conforms
POLIkol 600PF	Macrogol 600	25322-68-3	Polyethylene glycol	600	Liquid	conforms
POLIkol 1500PF	Macrogol 1500	25322-68-3	Polyethylene glycol	1500	Solid in form of wax or flakes	conforms
POLIkol 3350PF	Macrogol 3350	25322-68-3	Polyethylene glycol	3350	Solid in form of wax or flakes	conforms
POLIkol 6000PF	Macrogol 6000	25322-68-3	Polyethylene glycol	6000	Solid in form of wax or flakes	conforms

Main advantages for using Macrogols in final dosage forms are:

- solubilisation,
- improvement in bioavailability of active ingredients,
- rheology modifiers,
- good thickeners,
- lubricating and binding properties,
- formulation of stable ointments basis ,
- high stability.

ROKAnols TPF – Macrogols Cetostearyl Ethers

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
ROKAnol® T6PF	Macrogol 6 Cethostearyl Ether	68439-49-6	Polyoxyethylene (6) Cetostearyl Ether	Solid in a form of wax	conforms
ROKAnol® T12PF	Macrogol 12 Cethostearyl Ether	68439-49-6	Polyoxyethylene (12) Cetostearyl Ether	Solid in a form of wax	conforms
ROKAnol® T20PF	Macrogol 20 Cethostearyl Ether	68439-49-6	Polyoxyethylene (20) Cetostearyl Ether	Solid in form of wax or flakes	conforms
ROKAnol® T25PF	Macrogol 25 Cethostearyl Ether	68439-49-6	Polyoxyethylene (25) Cetostearyl Ether	Solid in form of wax or flakes	conforms

ROKAnols OPF – Macrogol Oleyl Ethers

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
ROKAnol® O10PF	Macrogol 10 Oleyl Ether	9004-98-2	Polyoxyethylene (10) Oleyl Ether	Solid in a form of wax	conforms
ROKAnol® O20PF	Macrogol 20 Oleyl Ether	9004-98-2	Polyoxyethylene (20) Oleyl Ether	Solid in a form of wax	conforms

Common applications for ROKAnol OPF & ROKAnol TPF:

- antiseptic ointments,
- oils,
- ointments,
- spray dressings,
- creams.

ROKAcet R36PF – Macrogol Glycerol Ricinoleate

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
ROKAcet R36PF	Macrogol Glycerol Ricinoleate	61791-12-6	Catstor Oil Ethoxylated	Clear, yellow viscous liquid or semi-solid	conforms

- Rokacet R36PF is recomended to use as a solubiliser for preparing stable emulsion for oral, topical, parental application,
- very good emulsifier for active substances like: Miconazole, Hexetidine, Clotrimazole,
- emulsifier widely used in formulations containing ingredients like vitamins: A, D, E, K.

Rokacet HR40PF – Macrogolglycerol Hydroxystearate

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
ROKAcet HR40PF	Macrogolglycerol Hydroxystearate	61788-85-0	Castor Oil, Hydrogenated, Ethoxylated	White to yellowish paste	conforms

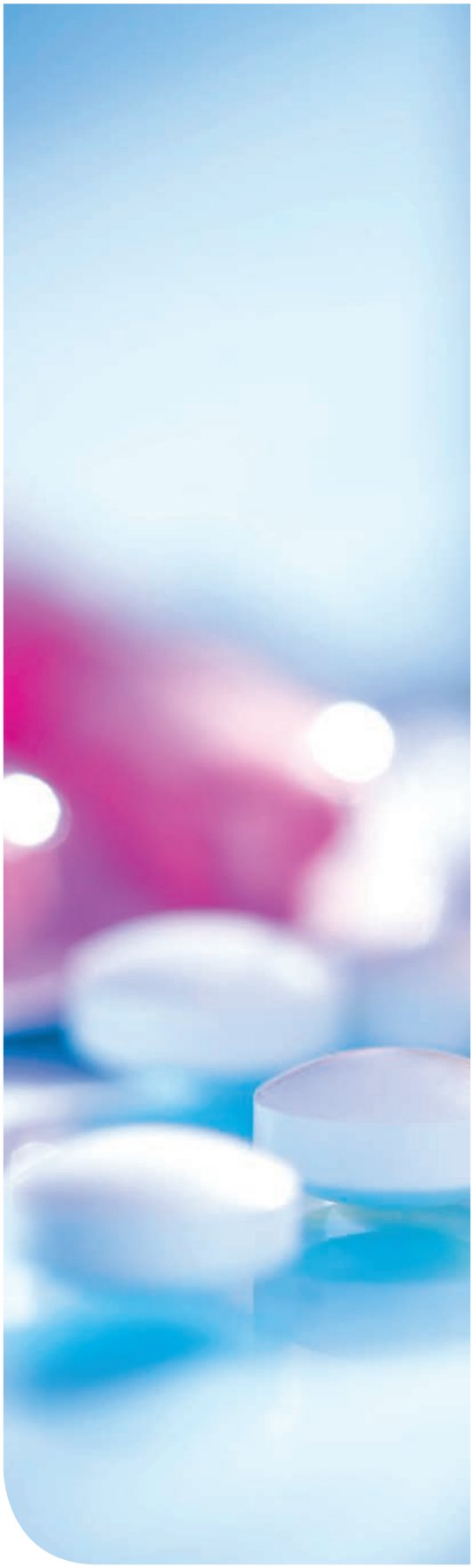
ROKAfenol N9PF – Nonoxynol-9

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
ROKAfenol N9PF	Nonoxynol-9	127087-87-0	Nonylphenol, Ethoxylated	Clear or opalescent oily liquid	conforms

ROKwinol 20PF – Sorbitan Monolaureate Ethoxylated

Product name	Monograph name	CAS	Chemical description	Appearance	Compliance with Eur.Ph monograph
ROKwinol 20PF	Polysorbate 20	9005-64-5	Sorbitan Monolaureate, Ethoxylated	Clear liquid	conforms

The product is a nonionic emulsifier and O/W type co-emulsifier, applied to emulsification of oils, waxes and solvents of cosmetic and pharmaceutical formulations.



PCC Group
Sienkiewicza 4
56-120 Brzeg Dolny, Poland
products@pcc.eu

Please visit our capital group business platform:
www.products.pcc.eu

PCC
More than Chemistry