

# Pharma solutions

DEDICATED TO QUALITY



# High quality standards

Our purpose is to improve the quality and sustainability of life. To help create a society, in which, people can make a conscious choice for safe and healthy products. We also strive to protect the planet by offering environmentally friendly solutions made from renewable resources. Corbion is the worldwide market leader in production of lactic acid and derivatives - important ingredients in a range of active pharmaceutical ingredients and excipients. For almost 100 years, Corbion has been using white biotechnology for the creation of our products. We are one of the most experienced companies producing ingredients and chemicals through fermentation of carbohydrates. Our production technology is being constantly improved by innovative teams, driven by efficiency, quality and sustainability.

► Please note our logo has been changed, but our pharma registrations stay under the existing legal entity names (PURAC Biochem bv and PURAC bioquímica SA). Our logo change will have no impact on our pharma registrations.



## Quality and Regulatory

We observe an increasing quality and regulatory demand across the value chain in the pharmaceutical industry with growing emphasis on risk management, transparency and control. For our most important APIs (active pharmaceutical ingredients), Corbion holds the necessary pharmaceutical registrations (CEP, US-DMF, CA-DMF). Through continuous investment in Quality and Regulatory activities, we embed practices into our culture to improve business performance. cGMP (Good Manufacturing Practice) compliance to ICH (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Q7 'Good Manufacturing Practice Guidance for APIs standards align Corbion with the concepts established by the ISO (International Organisation for Standardization). In addition, registration with European Union (EU) Regulation on REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) since 1 June 2007, and we successfully registered all substances that required registration before 1 Dec 2010 and before 31 May 2013 under Regulation (EC) No.1907/2006 (REACH). As well as the registration for the Biocidal Products Regulation (EU BPR 528/2012), effective from September 2013. This ensures Corbion is compliant within the particularly stringent European market.

## Quality and Regulatory Services

We understand that customers expect suppliers to provide high quality products manufactured under a consistent quality regime that follows the latest regulatory standards. That is why we also make it a top priority for us. Corbion has a



## Corbion factory in The Netherlands

dedicated team of Quality and Regulatory experts that is ready to assist our customers. We offer support in preparing essential documentation. Please feel free to contact us for more information.

## Parenteral and Dialysis

Major factors driving global market growth include the growing adult population, rising numbers of diabetic patients, increasing incidence of obesity, growing impact of hypertension and escalating expenditure on healthcare worldwide. It is anticipated that these factors will accelerate market growth strongly in the near future.

Corbion produces pharmaceutical grades of Natural L-Lactic acid/(S)-Lactic acid and its derivatives, such as sodium (S)-lactate, which is sold as PURASAL S/PF®, for parenteral applications. sodium (S)-lactate functions as electrolyte or as an alkalinizing agent in these kind of applications. Calcium Gluconate is used in human injectable applications to prevent acute hypocalcaemia, and in veterinary applications, to prevent milk fever in cattle, for example.



## Mineral Solutions

Increasing consumer-awareness of preventive healthcare is driving sales of over-the-counter mineral products. There is a growing focus on boosting health and wellness to prevent disease. The trend reflects key health concerns, such as calcium deficiency (which can lead to osteoporosis), inflammatory disorders, menopause, heart health, and anti-aging.



# We offer you

- ▶ High quality standards
- ▶ Reliable supply chain
- ▶ Backward integrated process
- ▶ High service support
- ▶ 100 years experience
- ▶ Biobased products

To stay competitive in this growing market segment, it is imperative for companies to have the technical and marketing expertise to take minerals from product design to final delivery.

Corbion has a wide range of natural minerals that are suitable sources of additional nutrients in all types of supplement. Our products are used for mineral and electrolyte delivery. Corbion's mineral lactates and gluconates are characterized by good solubility, high bioavailability and neutral flavor. Our range incorporates directly-compressible product grades that are easy-to-process (non-hygroscopic, free-flowing powders).



Corbion factory in Spain

## Global vs. Local

In order to offer valuable and competitive products that comply with local standards, Corbion offers locally-based solutions as well. For more information, please contact us and we will be happy to explain all options.

## Connect with Corbion

Corbion is proud of its ability to develop the best solutions in partnership with its customers. We offer solutions that meet the needs of our customers within the shortest possible lead time. Our target is to give you a hassle-free experience!

Contact us to share your experiences and challenges.

Product name	Pharmacopoeia	Specification
<b>PURAC® PF</b>	USP, JP, EP	L-lactic acid/(S)-lactic acid pharma grade
<b>PURASAL® S/PF 50%</b>	USP, EP, JP	sodium (S)-lactate pharma grade 50%
<b>PURASAL® S/PF 60%</b>	USP, EP, JP	sodium (S)-lactate pharma grade 60%
<b>PURACAL® PP/USP</b>	USP, EP	calcium lactate pharma grade
<b>PURACAL® DC</b>	USP, EP	calcium lactate for direct compressible use
<b>PURACAL® XPRESS</b>		calcium lactate gluconate pharma grade
<b>GLUCONAL® CAM-P-IN-EP</b>	EP	calcium gluconate monohydrate pharma grade for injectable applications
<b>GLUCONAL® CAM-P-IN</b>	USP	calcium gluconate monohydrate pharma grade for injectable applications
<b>GLUCONAL® CAM-P-OR</b>	USP, EP	calcium gluconate monohydrate pharma grade for oral applications
<b>GLUCONAL® CADS</b>	USP	calcium D-saccharate
<b>GLUCONAL® FE-Pharma</b>	USP, EP	ferrous gluconate pharma grade
<b>GLUCONAL® MG</b>	USP	magnesium gluconate
<b>GLUCONAL® K</b>	USP	potassium gluconate
<b>GLUCONAL® ZN</b>	USP	zinc gluconate
<b>PURAMEX® MG</b>	EP	magnesium lactate
<b>PURAMEX® ZN</b>		zinc lactate

# Let us know how we can help you

● Corbion Headquarters ● Corbion Production Location ● Corbion Sales Office ● Corbion Innovation Center



[corbion.com/contact](http://corbion.com/contact)

## Corbion in Pharma

For the pharmaceutical industry, Corbion offers Lactic Acid, Lactic Acid derivatives and gluconic acid based mineral salts. Corbion's pharma products are produced under cGMP guidelines and comply with the highest quality standards demanded by the pharmaceutical industry.

## About Corbion

Corbion: biobased solutions, designed by science, powered by nature, and delivered through dedication. Corbion is the global market leader in lactic acid, lactic acid derivatives and lactides, and a leading company in emulsifiers, functional enzyme blends, minerals and vitamins. The company delivers high performance biobased products made from renewable resources and applied in global markets such as bakery, meat, pharmaceuticals and medical devices, home and personal care, packaging, automotive, coatings and adhesives. Its products have a differentiating functionality in all kinds of consumer products worldwide. Corbion is listed on Euronext Amsterdam.

Interested in solutions for pharmaceutical industry? [Go to corbion.com/pharma](http://Go to corbion.com/pharma)



[pharma@corbion.com](mailto:pharma@corbion.com)



© Copyright 2017 Corbion. All rights reserved. No part of this publication may be copied, downloaded, reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photocopied, recorded or otherwise, without permission of the publisher. No representation or warranty is made as to the truth or accuracy of any data, information or opinions contained herein or as to their suitability for any purpose, condition or application. None of the data, information or opinions herein may be relied upon for any purpose or reason. Corbion disclaims any liability, damages, losses or other consequences suffered or incurred in connection with the use of the data, information or opinions contained herein. In addition, nothing contained herein shall be construed as a recommendation to use any products in conflict with existing patents covering any material or its use.

