



ALWAYS AHEAD











# KIRSCH PHARMA WORLDWIDE







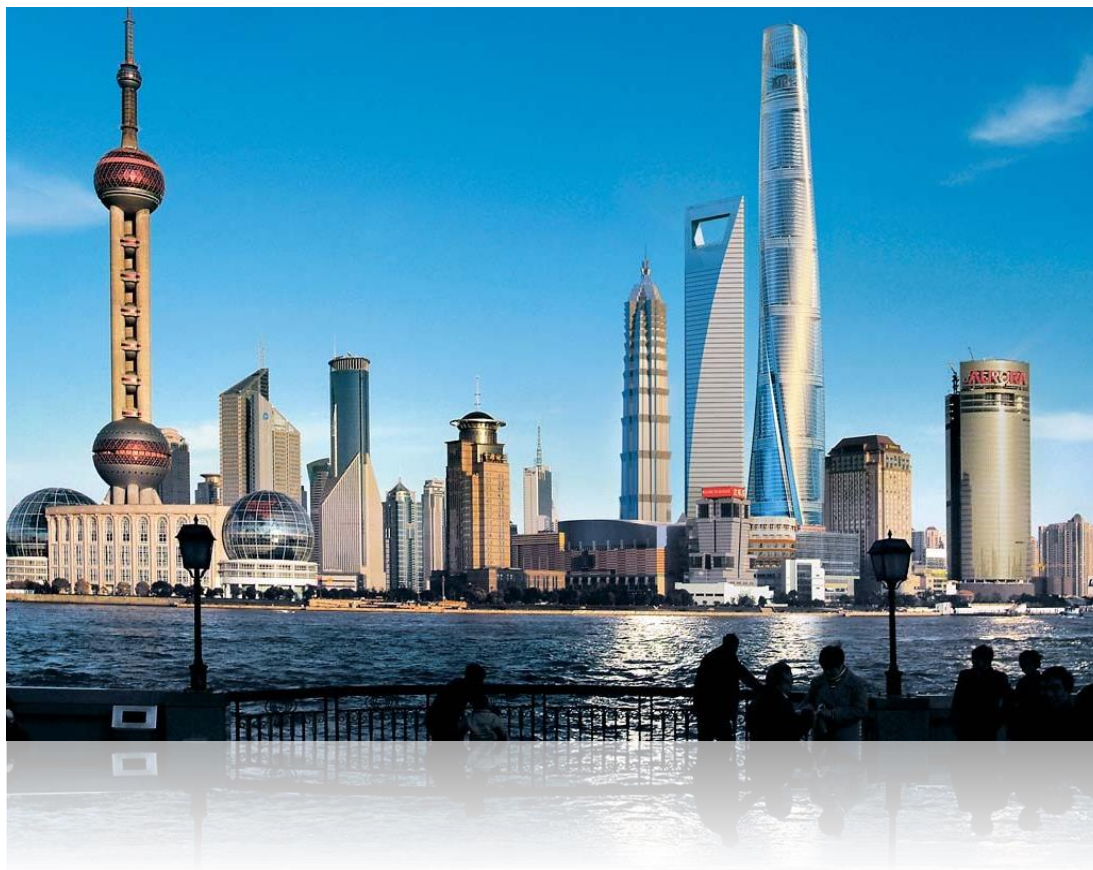




















# INTERNATIONAL WAREHOUSING









## FOOD AND PHARMA











# PRODUCTION









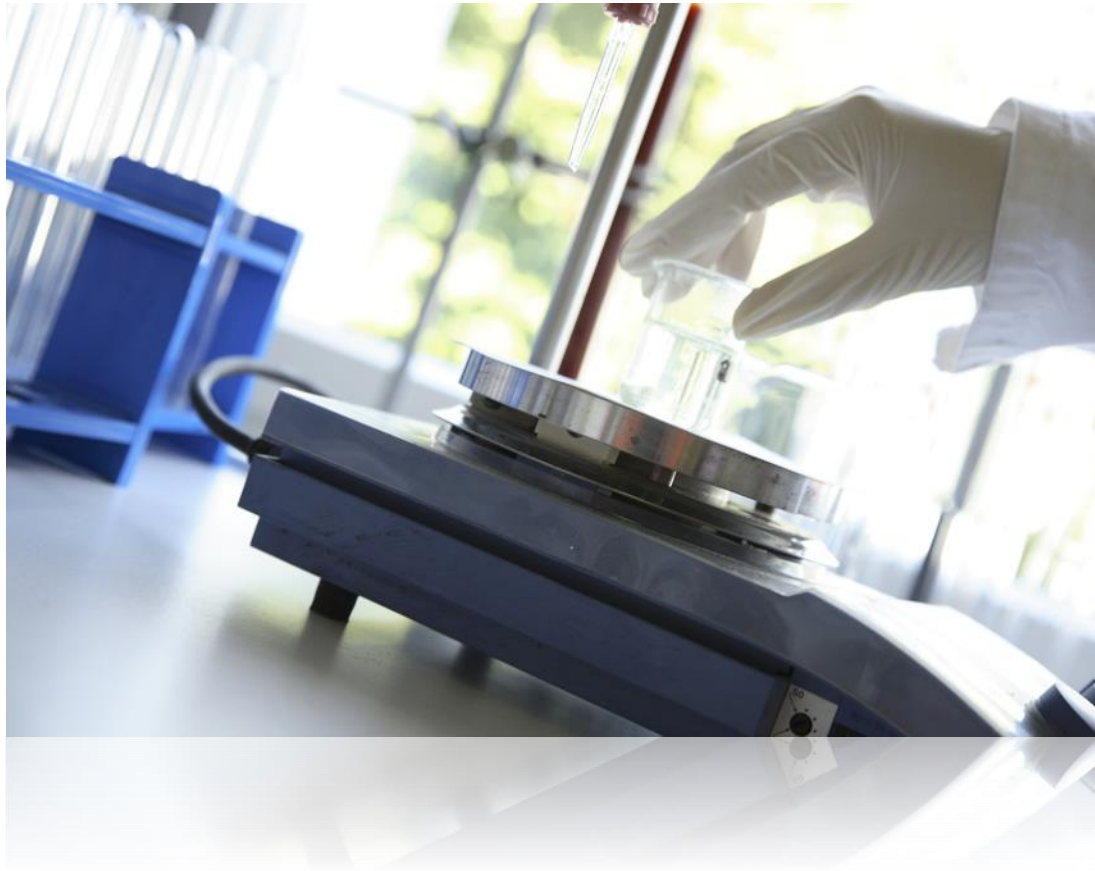




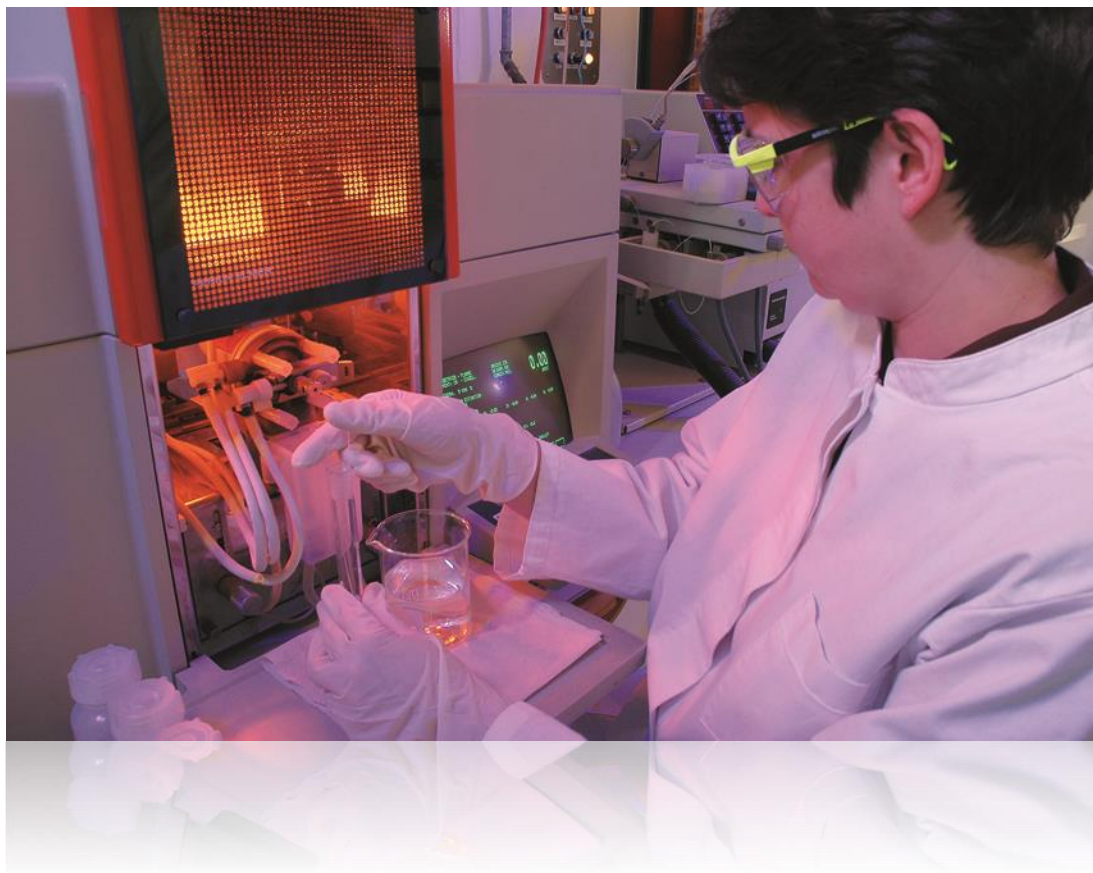


## QUALITY ASSURANCE SYSTEM



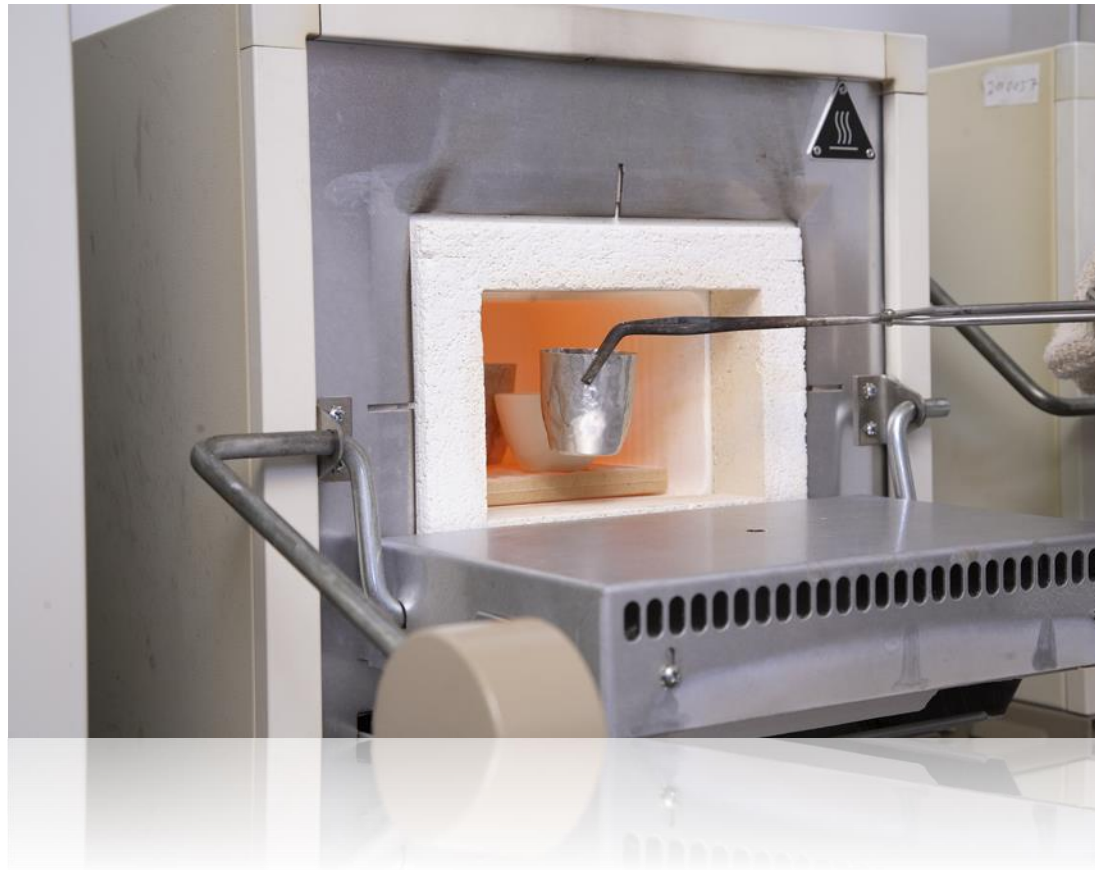








## QUALITY MANAGEMENT











WELCOME!





## CONTENT

**KIRSCH  
PHARMA  
WORLDWIDE**



**BUSINESS AREAS**



**BUSINESS MODEL**



**WORLDWIDE  
SOURCING**



**PRODUCTION**



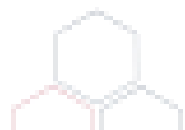
**GMP**



**PRODUCTS**

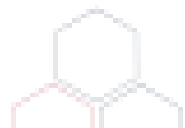


**QUALITY  
MANAGEMENT  
SYSTEM**



## | KIRSCH PHARMA WORLDWIDE

- | Founded 1980
- | Privately owned by Heinz-Jürgen Kirsch
- | International subsidiaries and warehousing
- | Worldwide sourcing
- | Sales to 85 countries
- | Member of ipec EUROPE
  - The **I**nternational **P**harmaceutical **E**xciipients **C**ouncil **E**UROPE

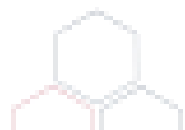




## KIRSCH PHARMA WORLDWIDE

»I will always devote our full energy to  
the prompt fulfilment of your needs at  
the highest quality level.«

Heinz-Jürgen Kuhl

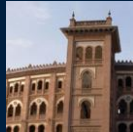


## INTERNATIONAL SUBSIDIARIES AND WAREHOUSING

### GERMANY (HEADQUARTER)



### SPAIN



### SOUTH AFRICA



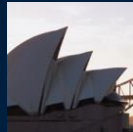
### CHINA



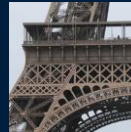
### SINGAPORE



### AUSTRALIA



### FRANCE

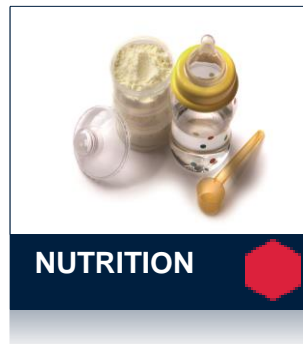


### ITALY



## | BUSINESS AREAS

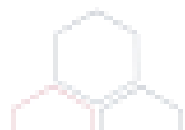
### | Raw materials and semifinished products



## I NUTRITION

Raw materials for:

- I Infant formula
- I Dietetic salts
- I Nutritional supplements
- I Nutraceuticals
- I Fermentation, Purification and Stabilisation of enzymes

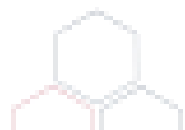
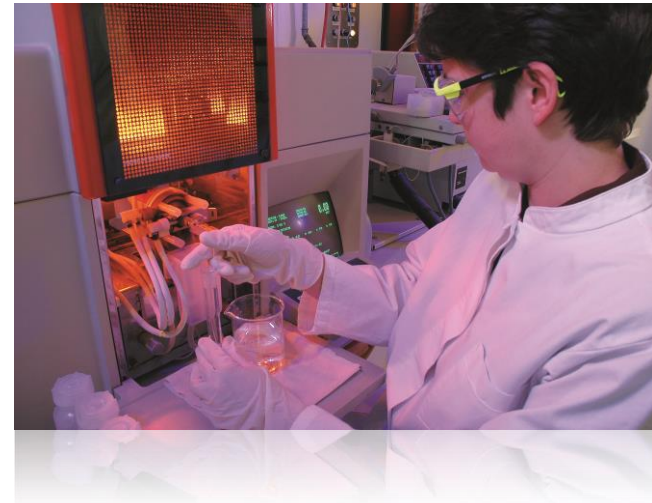




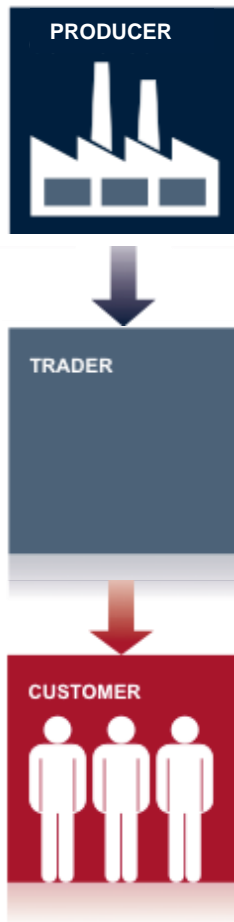
## PHARMA

Raw materials for:

- | Dialysis and Infusion Solutions
- | Tablets and Powders
- | Ointments
- | Oral Rehydration Salts
- | Cell Cultivation and Fermentation
- | Peptide Purification



## TRADING COMPANY



## BUSINESS MODEL KIRSCH PHARMA

Added Value:

- Analytics of products
- Co-Producer management
- Full documentation
- Physical modification
- Special packaging
- Warehousing
- Consolidated Purchasing Concept
- Competent customer support



## GLOBAL CO-PRODUCER NETWORK

### Worldwide presence

- Global sourcing with emphasis on Europe, East Asia and USA

### Global consolidated purchasing

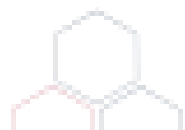
- Coordination within subsidiary network

### Strategic purchasing alliances

### Quality agreements incl. change control

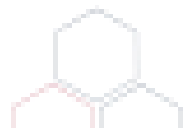
### Supplier qualification

- Experienced certified audit team



## PRODUCTION

- Physical modification  
(Blending, Breaking, Milling, Sieving, Compacting, Granulation, Micronisation)
- Special customized packaging





## I GMP

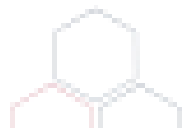
**Kirsch Pharma's production facilities comply with current and anticipated future national and international GMP standards for both APIs and excipients along with standards for nutritional quality. Additionally the whole Kirsch Pharma group follows corporate GMP systems and standards.**

We have implemented pharmaceutical standards in accordance with:

ICHQ7 / EU GMP part 2

EXIPEC GMP

AMG / AMWHV

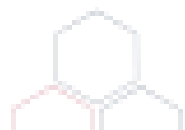


## PRODUCT GROUPS

- Salts in premium quality
- Organic compounds in premium quality
- Blends
- APIs

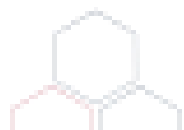
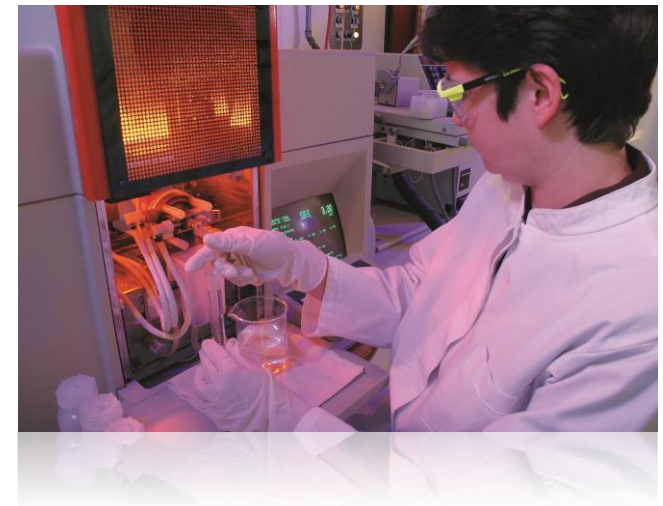
Further available in our subsidiaries

- Hormones
- Oils
- Herbal extracts



## SALTS IN PREMIUM QUALITY

- |                |                |
|----------------|----------------|
| Potassium      | Acetates       |
| Sodium         | Bromides       |
| Calcium        | Carbonates     |
| Magnesium      | Chlorides      |
| Iron           | Citrates       |
| Zinc           | Formiates      |
| Copper         | Hydroxides     |
| Manganese etc. | Nitrates       |
|                | Oxides         |
|                | Phosphates     |
|                | Sulphates etc. |



## ORGANIC COMPOUNDS OF PREMIUM QUALITY

- Urea
- Dextrose
- Sugar alcohols
- Amino acids and Cholines
- Vitamins
- Acetic acid
- Lactic acid etc.



## QUALITY MANAGEMENT SYSTEM

Integrated quality  
management system

Certification

Supplier / co-producer  
qualification

GMP-compliant quality assurance

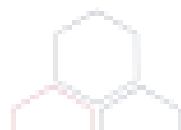
GMP-compliant quality control

GMP certified by local  
authorities

QA-supervised production

Process control by SAP R3

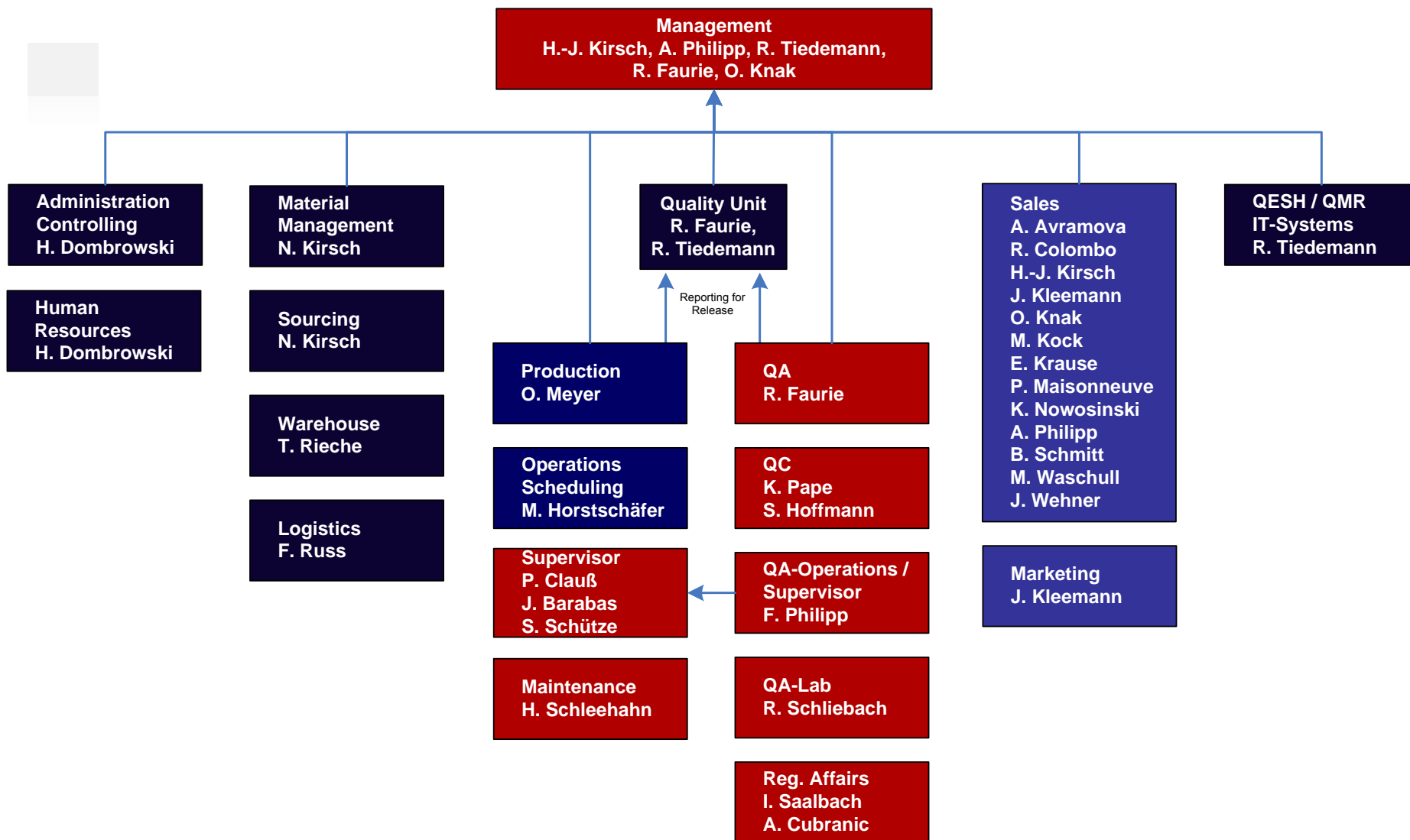
Successfully qualified by leading  
pharmaceutical companies







LOOKING AHEAD  
TOGETHER WITH  
KIRSCH PHARMA



## ISO 9001



**CERTIFICATE**

This is to certify that

**Kirsch Pharma GmbH**  
Erzbecksche 2  
38229 Salzgitter  
Germany

with the organizational units/sites as listed in the annex  
has implemented and maintains a **Quality Management System**.

Scope:  
Production and Treatment of Salts and Saline Mixtures, Distribution of Salts, Excipients, Active Substances and Essential Oils for the Pharmaceutical, Food and Cosmetic Industry

Through an audit, documented in a report, it was verified that the management system fulfils the requirements of the following standard:

**ISO 9001 : 2015**

Certificate registration no. 003275 GM15  
Valid from 2017-01-20  
Valid until 2020-01-07  
Date of certification 2017-01-20

**DAKKS**  
Deutsche  
Akreditierungsstelle  
D-384 10714 01-00

**DQS GmbH**  
Frank Gräßler  
Managing Director

Accredited Body: DQS GmbH, August-Schorz-Strasse 21, 60433 Frankfurt am Main, Germany

1 / 2

## FSSC 22000



**CERTIFICATE**

This is to certify that the food safety management system of the company

**Kirsch Pharma GmbH**  
Erzbecksche 2  
38229 Salzgitter  
Germany

has been assessed and complies with the requirements of

**FSSC 22000**  
Certification scheme for food safety systems including  
ISO 22000:2005, ISO/TS 22002-1:2009 and additional FSSC 22000 requirements

This certificate is applicable for:  
Manufacturing of food ingredient additives and of dietary food supplements like salts, vitamins, sugars, amino acids, urea and mixtures

Category: K

This certificate is provided on the base of the FSSC 22000 certification scheme, version 3.2, published February 26<sup>th</sup> 2015. The certification system consists of a minimum annual audit of the food safety management systems and a minimum annual verification of the PRP elements and additional requirements as included in the scheme and ISO/TS 22002-1.

Date of initial certification 2016-09-15  
Certification decision 2016-09-15  
Date of audit 2016-08-11  
(Re)issuing date 2016-09-15  
This certificate is valid until 2019-09-14  
Registration no. 003275 FSSC2013  
Frankfurt am Main 2016-09-15

**DAKKS**  
Deutsche  
Akreditierungsstelle  
D-384 10714 01-00

**FSSC 22000**

**DQS CFS GmbH**  
German Association for Sustainability  
Dr. Sieb Stadel  
Managing Director

Accredited Body: DQS CFS GmbH, August-Schorz-Strasse 21, 60433 Frankfurt am Main, Germany

## GMP+



**PROCESS-CERTIFICATE**

GMP+ International-Reg.-No.: 30523

**Kirsch Pharma GmbH**  
Erzbecksche 2  
38229 Salzgitter  
Germany

GMP+ International-Reg.-No.: GMP007591

The scope of this process certificate relates to:  
Distribution, Production and Processing of Feed for Productive Livestock

DQS CFS GmbH declares that it has justifiable confidence that the process(es)  
**Production of feed materials  
Trade in feeds**

at the company location  
Kirsch Pharma GmbH  
complies with the applicable requirements and conditions of the standard(s)  
**GMP+ B1 Production, Trade and Services**  
of the GMP+ FSA scheme (based on the GMP+ C6) of GMP+ International.

Certificate registration no. 003275 HQC  
Valid from 2016-06-24  
Valid until 2019-06-23  
Date of certification 2016-06-13

**DAKKS**  
Deutsche  
Akreditierungsstelle  
D-384 10714 01-00

**GMP+**

**DQS CFS GmbH**  
German Association for Sustainability  
Dr. Sieb Stadel  
Managing Director

Accredited Body: DQS CFS GmbH, August-Schorz-Strasse 21, 60433 Frankfurt am Main, Germany



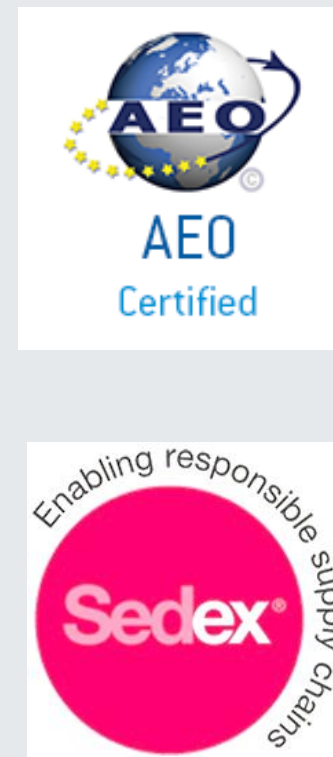
## HALAL



## KOSHER



## Further certifications:



## GMP



Staatliches Gewerbeaufsichtsamt Braunschweig  
Ludwig-Winter-Str. 2, 38120 Braunschweig



**Staatliches Gewerbeaufsichtsamt  
Braunschweig**  
Behörde für Arbeits-, Umwelt- und  
Verbraucherschutz

Zertifikat-Nr./Certificate no:  
DE\_NI\_01\_GMP\_2014\_0012  
Aktenzeichen/Reference Number:  
41401.02.03

**BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES  
HERSTELLERS MIT GMP****Teil 1**

Ausgestellt nach einer Inspektion gemäß

• Art. 111 (5) der Richtlinie 2001/83/EG

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller  
**Kirsch Pharma GmbH**

Anschrift der Betriebsstätte  
**Kirsch Pharma GmbH  
Erzwische 2  
38229 Salzgitter  
Deutschland**

• Ist Wirkstoffhersteller und wurde inspiziert gemäß

• Art. 111 (1) der Richtlinie 2001/83/EG  
umgesetzt in deutsches Recht durch:  
§ 64 Abs. 1 Arzneimittelgesetz

Aufgrund der aus der letzten Inspektion vom  
15. Januar 2014 gewonnenen Erkenntnisse wird für die  
oben genannte Betriebsstätte des Herstellers die  
Übereinstimmung mit den Anforderungen der Guten  
Herstellungspraxis festgestellt, die sich aus

• den GMP-Grundsätzen für Wirkstoffe gemäß  
• Artikel 47 der Richtlinie 2001/83/EG

ergeben.

Dieses Zertifikat bestätigt den Status der Betriebsstätte  
zum Zeitpunkt der oben genannten Inspektion. Es

**CERTIFICATE OF GMP COMPLIANCE OF A  
MANUFACTURER****Part 1**

Issued following an inspection in accordance with

• Art. 111 (5) of Directive 2001/83/EC

The competent authority of GERMANY confirms the  
following:

The manufacturer  
**Kirsch Pharma GmbH**

Site address  
**Kirsch Pharma GmbH  
Erzwische 2  
38229 Salzgitter  
Germany**

• Is an active substance manufacturer that has been  
inspected in accordance with

• Art. 111 (1) of Directive 2001/83/EC  
transposed in the following national legislation:  
Sect 64 para 1 Arzneimittelgesetz (German Drug Law)

From the knowledge gained during the inspection of  
this manufacturer, the latest of which was conducted on  
15 January 2014, it is considered that it complies with  
the Good Manufacturing Practice requirements referred  
to in

• the principles of GMP for active substances referred  
to in  
• Article 47 of Directive 2001/83/EC

This certificate reflects the status of the manufacturing  
site at the time of the inspection noted above and

sollte nicht zur Bestätigung der Übereinstimmung  
herangezogen werden, wenn seit der genannten  
Inspektion mehr als drei Jahre vergangen sind. Nach  
Ablauf dieser Zeit sollte mit der zuständigen Behörde  
Kontakt aufgenommen werden. Das Zertifikat ist nur  
bei Vorlage sämtlicher Seiten inklusive der Teile 1 und  
2 gültig. Die Echtheit dieses Zertifikates kann ggf.  
durch die ausstellende Behörde bestätigt werden.

should not be relied upon to reflect the compliance  
status if more than three years have elapsed since the  
date of that inspection, after which time the issuing  
authority should be consulted. This certificate is valid  
only when presented with all pages and both parts 1  
and 2. The authenticity of this certificate may be  
verified with the issuing authority.

## • Wirkstoffe

Wirkstoffherstellung: Namen der Substanzen, die  
Gegenstand der Inspektion waren:

Calciumcarbonat  
Calciumcarbonat leicht  
Calciumchlorid-Dihydrat  
Kaliumchlorid  
Magnesiumchlorid-Hexahydrat  
Magnesiumhydroxid  
Magnesiumoxid schwer  
Magnesiumsulfat-Hepthahydrat  
Natriumhydrogencarbonat  
Natriumcarbonat leicht  
Natriumchlorid  
Harnstoff

Einschränkungen oder Klarstellende Anmerkungen  
betreffend den Umfang des Zertifikates:

Anmerkungen: Der Umfang des Zertifikates umfasst  
ausschließlich das Umfüllen einschließlich Abfüllen, das  
Brechen, das Sieben, das Abpacken, das Kennzeichnen  
und die Freigabe der Wirkstoffe.

13. Juni 2014  
Im Auftrag

Name und Unterschrift des Bearbeiters der zuständigen  
Behörde

Andreas Meißner  
Staatliches Gewerbeaufsichtsamt Braunschweig  
Inspektorat Braunschweig  
Ludwig-Winter-Str. 2  
38120 Braunschweig  
Deutschland

Tel.: +49(0)531 35476151  
Fax: +49(0)531 35476333

DE\_NI\_01\_GMP\_2014\_0012 13.06.2014

Unterschrift: Andreas Meißner

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**Teil 2****Part 2**

## • Substances

Manufacture of active substance. Names of substances  
subject to inspection:

Calcium Carbonate  
Calcium Carbonate light  
Calcium Chloride Dihydrate  
Potassium Chloride  
Magnesium Chloride Hexahydrate  
Magnesium Hydroxide  
Magnesium Oxide heavy  
Magnesium Sulfate Heptahydrate  
Sodium Hydrogen Carbonate  
Sodium Carbonate light  
Sodium Chloride  
Urea

Any restrictions or clarifying remarks related to the scope  
of this certificate:

Comments: The scope of this certificate solely covers  
filling as well as decanting, breaking, sieving, packaging,  
labelling and release of active pharmaceutical  
ingredients.

13 June 2014  
On behalf



Name and signature of the authorised person of the  
Competent Authority

Andreas Meißner  
Staatliches Gewerbeaufsichtsamt Braunschweig  
Inspektorat Braunschweig  
Ludwig-Winter-Str. 2  
38120 Braunschweig  
Deutschland

Tel.: +49(0)531 35476151  
Fax: +49(0)531 35476333

Unterschrift: Andreas Meißner

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