GENTEC pharmaceutical group

A private Spanish company, established in 1985, with headquarters located in Barcelona.

Our main business areas are :

Manufacture of API's and HPAPI's
Pharmaceutical Trading
Trading of Raw Materials for the food Industry

How we do that:

According to the highest standard of quality, in compliance with national and international pharmacopeia standards and the customer requirements.

Production, R&D and testing activities are carried out following the current GMP and ICH guidelines.

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Pharmaceutical Facilities, group companies & brands

Duke Chem
gentec pharmaceutical group

PHARMANOID
gentec pharmaceutical group

TESEO
FARMACÉUTICA

Based in Barcelona (Spain), GENTEC pharmaceutical group formed by a dedicated and experienced team in the areas of: Pharmaceutical, Regulatory, Licensing, Business Development, Marketing, and Sales.

We offer our current worldwide partners the possibility to conduct Pharmaceutical Development Activities from the initial selection of alternatives to the final registration which includes licensing and the supply of the final product.

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Duke Chem

Duke Chem is a company focused on:

Developing, manufacturing and marketing Active Pharmaceutical Ingredients (API's), as well as Advanced Intermediates or Fine Chemicals addressed to the Nutraceutical and Food markets.

It is located close to Barcelona city. Easy access to airport.

We also offer Custom and Contract Manufacturing services including process development from laboratory to industrial scale.

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Duke Chem

EGMP API Facility - Product List & Pipeline

PRODUCT		CAS	THERAPEUTIC USE	STATUS
Azithromycin Bitterless	API	83905-01-05	Antibiotic	EDMF
Bepotastine	API	190786-44-8	Antihistaminic	Lab. Samples
Brinzolamide	API	138890-62-7	Antiglaucoma	EDMF, JDMF
L - Carnosine	API	305-84-0	Nutraceutical	Development
Diacerein	API	13739-02-1	Antiarthritic	EDMF
Dorzolamide	API	130693-82-2	Antiglaucoma	EDMF
Etofenamate	API	30544-47-9	Anti-inflammatory	EDMF, CEP
Febuxostat	API	144060-53-7	Antihyperuricemia	EDMF
Lifitegrast	API	1025967-78-5	Dry Eye Agent (DED)	Development
Nitazoxanide	API	55981-09-4	Antihelmintic	EDMF
Silodosin	API	160970-54-7	Prostatic Hyperplasia	Development

Pharmanoid

Pharmanoid is the High Potent Active Pharmaceutical Ingredients (HPAPI's) division of GENTEC.

Focused on: developing and manufacturing high potent active pharmaceuticals ingredients, specialized on prostaglandins and similar

It is located in Avinyonet del Penedès, close to Barcelona city. Easy access to airport.






Our facilities and quality system follow c-GMP and the suggested practice on handling this kind of compounds with high containment.

Our approach is comprehensive and includes all the activities from R&D and analysis to production including chemical synthesis, Purification, large scale chromatography, cleaning and waste management.

Contention level from R&D until QC

Full regulatory support is provided for the complete life cycle of the product.

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Pharmanoid

EGMP HPAPI Facility - Product List Pipeline

PRODUCT		CAS	THERAPEUTIC USE	STATUS
Bimatoprost	HPAPI	155206-00-1	Antiglaucoma	Commercial
Carboprost	HPAPI	58551-69-2	Oxytocic	Lab. Samples
Fingolimod	HPAPI	162359-55-9	Multiple Sclerosis	Pipeline
Latanoprost	HPAPI	130209-82-4	Antiglaucoma	Commercial
Lubiprostone	HPAPI	136790-76-6	IBS Agent (CIC)	Development
Ripasudil	HPAPI	887375-67-9	Antiglaucoma	Pipeline
Tafluprost	HPAPI	209860-87-7	Antiglaucoma	Development
Travoprost	HPAPI	157283-68-6	Antiglaucoma	Commercial

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Pharmaceutical Trading

- **During our growth we have acquired a powerful network of alliances in order to provide personalized solutions to our customers**

- **We cooperate and help the necessities of the generic markets**
- **Our company has joint partners through our offices in order to increase the possibilities of "benchmarking".**
- **Sales offices are located in Argentina, Brazil, China ,India and Mexico.**

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TESEO

Teseo is an investigation and advisory company focused on technical research and development for the pharmaceutical industry. We can collaborate with our clients in the following areas:

Galenic Development: Formulation, Excipient Compatibility, Quantitative formulae, Design of manufacturing method, Establishment of process controls, Transfer of technology to the customer

Analytical Development: Study and validation of analytical methods for controlling the active substance and the impurities of the raw materials and the finished product

Stability studies according to ICH

Registration dossier documentation and monitoring of the evaluation process

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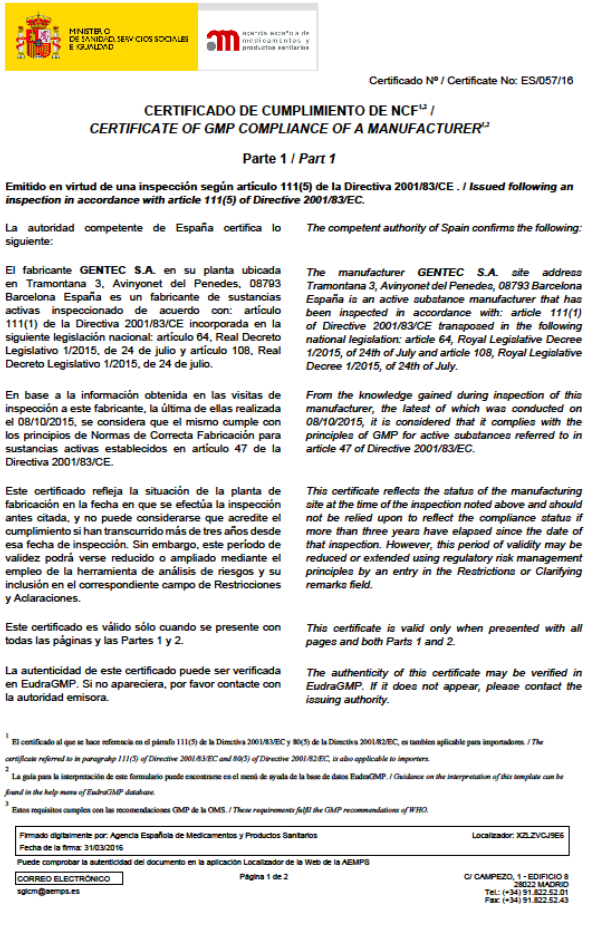
EGMP / ISO 14001 Certificates



MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

Certificado Nº / Certificate No: ES/057/16

CERTIFICADO DE CUMPLIMIENTO DE NCF[1,2] /
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1,2]

Parte 1 / *Part 1*

Emitido en virtud de una inspección según artículo 111(5) de la Directiva 2001/83/CE . / *Issued following an inspection in accordance with article 111(5) of Directive 2001/83/EC.*

La autoridad competente de España certifica lo siguiente:

The competent authority of Spain confirms the following:

El fabricante **GENTEC S.A.** en su planta ubicada en Tramontana 3, Avinyonet del Penedes, 08793 Barcelona España es un fabricante de sustancias activas inspeccionado de acuerdo con: artículo 111(1) de la Directiva 2001/83/CE incorporada en la siguiente legislación nacional: artículo 64, Real Decreto Legislativo 1/2015, de 24 de julio y artículo 108, Real Decreto Legislativo 1/2015, de 24 de julio.

*The manufacturer **GENTEC S.A.** site address Tramontana 3, Avinyonet del Penedes, 08793 Barcelona España is an active substance manufacturer that has been inspected in accordance with: article 111(1) of Directive 2001/83/CE transposed in the following national legislation: article 64, Royal Legislative Decree 1/2015, of 24th of July and article 108, Royal Legislative Decree 1/2015, of 24th of July.*

En base a la información obtenida en las visitas de inspección a este fabricante, la última de ellas realizada el 08/10/2015, se considera que el mismo cumple con los principios de Normas de Correcta Fabricación para sustancias activas establecidos en artículo 47 de la Directiva 2001/83/CE.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/10/2015, it is considered that it complies with the principles of GMP for active substances referred to in article 47 of Directive 2001/83/EC.

Este certificado refleja la situación de la planta de fabricación en la fecha en que se efectúa la inspección antes citada, y no puede considerarse que acredite el cumplimiento si han transcurrido más de tres años desde esa fecha de inspección. Sin embargo, este período de validez podrá verse reducido o ampliado mediante el empleo de la herramienta de análisis de riesgos y su inclusión en el correspondiente campo de Restricciones y Aclaraciones.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

Este certificado es válido sólo cuando se presente con todas las páginas y las Partes 1 y 2.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

La autenticidad de este certificado puede ser verificada en EudraGMP. Si no apareciera, por favor contacte con la autoridad emisora.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

[1] El certificado al que se hace referencia en el párrafo 111(5) de la Directiva 2001/83/EC y 80(5) de la Directiva 2001/82/EC, es también aplicable para importadores. / *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, is also applicable to importers.*

[2] La guía para la interpretación de este formulario puede encontrarse en el menú de ayuda de la base de datos EudraGMP. / *Guidance on the interpretation of this template can be found in the help menu of EudraGMP database.*

[3] Estos requisitos cumplen con las recomendaciones GMP de la OMS. / *These requirements fulfil the GMP recommendations of WHO.*

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 31/03/2016
Localizador: XZLZVCJ9E6

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
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Página 1 de 2

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Tel.: (+34) 91.822.52.01
Fax: (+34) 91.822.52.43

Generalitat de Catalunya
Departament de Salut
Direcció General d'Ordenació i Regulació Sanitàries

1 / 4

Certificat número / Certificado número / Certificate number: **NCF-II/1504/001/CAT**

Certificat de compliment de les normes de correcta fabricació de medicaments (NCF) d'un fabricant
Part 1

Emès com a conseqüència d'una inspecció duta a terme d'acord amb l'article 111(5) de la Directiva 2001/83/EC.

L'autoritat competent de la Generalitat de Catalunya Espanya certifica que:

L'empresa, en la planta que s'indica a continuació:

Certificado de cumplimiento de las normas de correcta fabricación de medicamentos (NCF) de un fabricante
Parte 1

Emitido en virtud de una inspección según el artículo 111(5) de la Directiva 2001/83/CE.

La autoridad competente de la Generalitat de Catalunya - España certifica que:

La empresa, en la planta que se indica a continuación:

Certificate of Good Manufacturing Practices (GMP) compliance of a manufacturer
Part 1

Issued following an inspection in accordance with Article 111(5) of Directive 2001/83/EC.

The competent authority of the Government of Catalonia – Spain certifies that:

The manufacturer, in its site address indicated below:

DUKE CHEM SA
Avda. Ma de Déu de Montserrat, 93-99. Pol. Ind. Sant Pere Molanta
08799 OLÈRDOLA (BARCELONA)

Es un fabricant de principis actius farmacèutics que ha estat inspeccionat d'acord amb l'article 111(1) de la Directiva 2001/83/EC, incorporada a la legislació nacional següent: article 63 de la Llei 29/2006 i Reial decret 824/2010.

Es un fabricante de sustancias activas inspeccionado de acuerdo con el Art. 111(1) de la Directiva 2001/83/CE, incorporada en la siguiente legislación nacional: artículo 63 de la Ley 29/2006 y Real decreto 824/2010.

Is an active substance manufacturer that has been inspected in accordance with article. 111(1) of Directive 2001/83/EC, transposed in the following national legislation: article 63 of Law 29/2006 and Royal decree 824/2010.

A partir de la informació obtinguda en les visites d'inspecció a aquesta empresa, l'última de les quals es va realitzar a:

desembre de 2014 (9, 10 i 12)

En base a la información obtenida en las visitas de inspección a esta empresa, la última de ellas realizada en:

diciembre de 2014 (9, 10 y 12)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on:

December 2014 (9, 10 and 12)

Es considera que compleix els requisits establerts a les Normes de Correcta Fabricació (NCF) per a principis actius farmacèutics a les quals es fa referència a l'article 47 de la Directiva 2001/83/CE.

Aquest certificat reflecteix la situació de la planta de fabricació en la data en què es va fer la inspecció citada abans, i no pot considerar-se que acredita el compliment si han transcorregut més de 3 anys des de la data de dita inspecció. Passat aquest temps, ha de consultar-se la validesa del certificat amb l'autoritat emissora.

Se considera que cumple con los requisitos establecidos en las Normas de Correcta Fabricación para sustancias activas a las que se hace referencia en el artículo 47 de la Directiva 2001/83/CE.

Este certificado refleja la situación de la planta de fabricación en la fecha en que se efectúa la inspección antes citada, y no puede considerarse que acredite el cumplimiento si han transcurrido más de 3 años desde la fecha de dicha inspección. Pasado ese período, deberá consultarse con la autoridad emisora sobre la validez del certificado.

It is considered that it complies with the Good Manufacturing Practice requirements for active substances laid down in Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than 3 years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

L'autenticitat d'aquest certificat pot ser verificada consultant l'autoritat emissora.

La autenticidad de este certificado puede ser verificada con la autoridad emisora.

The authenticity of this certificate may be verified with the issuing authority.

Nom i signatura de la persona autoritzada del Departament de Salut de la Generalitat de Catalunya - Espanya

Nombre y firma de la persona autorizada del Departamento de Salud de la Generalitat de Catalunya - España

Name and signature of the authorised person of the Ministry of Health of Government of Catalonia - Spain

Roser Vilella i Navarro
Directora general d'Ordenació i Regulació Sanitàries

Barcelona, 27/02/2015

Departament de Salut
Direcció General d'Ordenació i Regulació Sanitàries
Travessera de les Corts, 131-159 (pavelló Ave Maria)
08028 Barcelona

Telf. 93 556 61 62
Fax. 93 227 29 90

Certificate

Standard: **ISO 14001:2004**

Certificate Registr. No.: 3.00.09160

TÜV Rheinland Ibérica Inspection, Certification & Testing S.A. certifies:

Certificate Owner:

Duke Chem

DUKE CHEM
Av. Mare de Déu de Montserrat, 93-99
Pol. Ind. Sant Pere Molanta
E - 08799 Olèrdola (Barcelona)

Scope: Manufacture and marketing of active pharmaceutical ingredients.

An audit was performed, Report No.09160. Proof has been furnished that the requirements according to ISO 14001:2004 are fulfilled.

The due date for all future audits is 22-12 (dd-mm).

Validity: The certificate is valid from 2010-03-12 until 2013-03-11.
First certification 2010-03-12.

2010-03-18 TÜV Rheinland Ibérica Inspection, Certification & Testing S.A.
Garrotxa, 10-12 – E-08820 El Prat de Llobregat

www.tuv.com

IAF ENAC CERTIFICACIÓN Nº 04/C - NA 616

TÜVRheinland®
Precisely Right.

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

TÜVRheinland® CERT ISO 14001

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ISO 9001:2008 Certificates

Certificado del
Sistema de Gestión de la Calidad

AENOR
ER
Empresa Registrada
ISO 9001

ER-0487/2007

AENOR, Asociación Española de Normalización y Certificación, certifica que la organización

GENTEC, S.A.

dispone de un sistema de gestión de la calidad conforme con la Norma ISO 9001:2008

para las actividades: La comercialización de principios activos farmaceuticos y materias primas alimentarias.

que se realizan en: CL TARRAGONA, 161 PLANTA 18. 08014 - BARCELONA

Fecha de primera emisión: 2007-04-13
Fecha de última emisión: 2016-04-13
Fecha de expiración: 2018-09-14

Avelino BRITO MARQUINA
Director General de AENOR

AENOR Asociación Española de Normalización y Certificación | Génova, 6. 28004 Madrid. España Tel. 902 102 201 – www.aenor.es

IAF ENAC CERTIFICACIÓN IQNet

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and
AENOR
hereby certify that the organization

GENTEC, S.A.

CL TARRAGONA, 161 PLANTA 18.
08014 - BARCELONA

for the following field of activities

The commercialization of pharmaceutical active principles and raw materials for the food sector.

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

First issued on: 2007-04-13 Last issued: 2016-04-13 Validity date: 2018-09-14

Registration Number: **ES-0487/2007**

IQNet AENOR

Michael Drechsel
President of IQNet

Avelino BRITO
Chief Executive Officer

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* AIB-Vincotte International *Belgium* ANCE *Mexico* APCER *Portugal* CCC *Cyprus* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* IMNC *Mexico* Inspecta Certification *Finland* IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

gentec pharmaceutical group

Our commitments

- **Top priority for Quality Certifications**
- **Continuous feedback and support in any quality aspect and regulatory affairs of our products**
- **Continuous upgrading of manufacturing facilities as may be needed**
- **Company growth by launching new products on the market and optimization of the current manufacturing processes**
- **Keep and maintain GMP certification and approval of the Spanish authorities (AEMPS), foreign authorities and customers**
- **To keep an Environmental Management System (EMS) according to ISO 14001: 2004**

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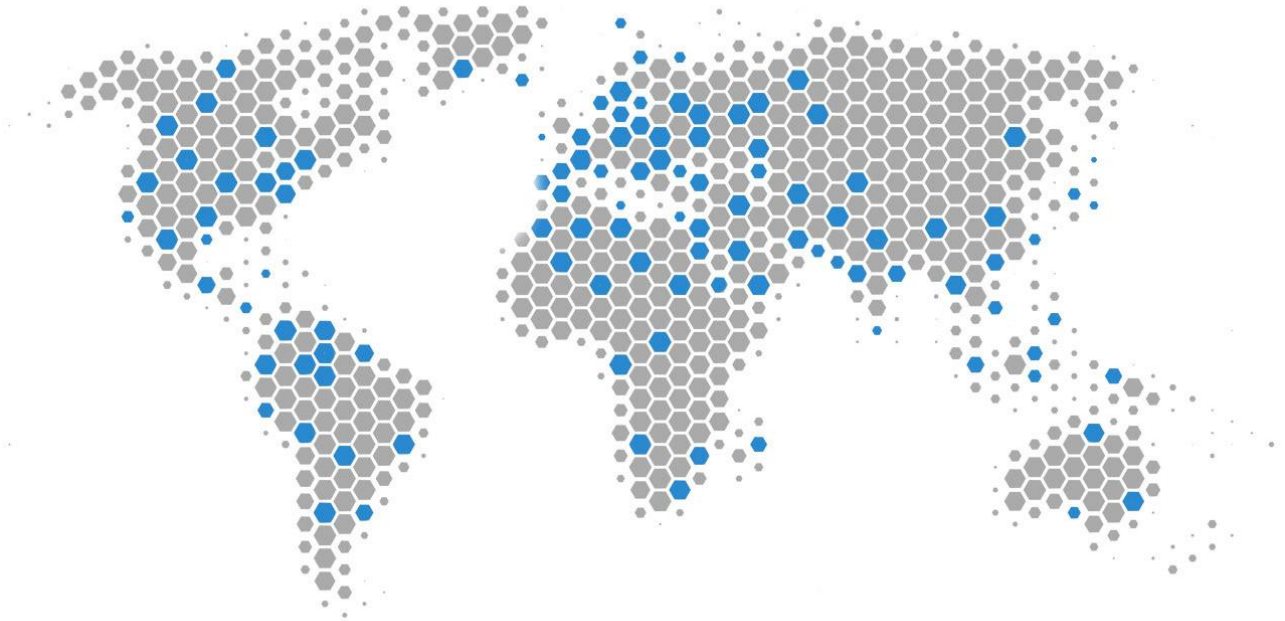
GENTEC pharmaceutical group Worldwide

We are present in more than 60 countries



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Thank you

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pharmaceutical
group

Duke Chem
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PHARMANOID
gentec pharmaceutical group

genthealth
gentec pharmaceutical group

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