



HUVEPHARMA[®]

ITALIA S.R.L.



v. Aug 2021

1 | Huvepharma Italia



- **Huvepharma ITALIA S.R.L.** is a newly established company, 100% owned by Huvepharma EOOD, a private Bulgarian company owned by the Domuschiev family.
- **Huvepharma ITALIA S.R.L.** is a fast growing, pharmaceutical company organized to develop, manufacture and commercialize products for human and animal health.

HUVEPHARMA stands for:

HUman &

VEterinary

PHARMAceuticals

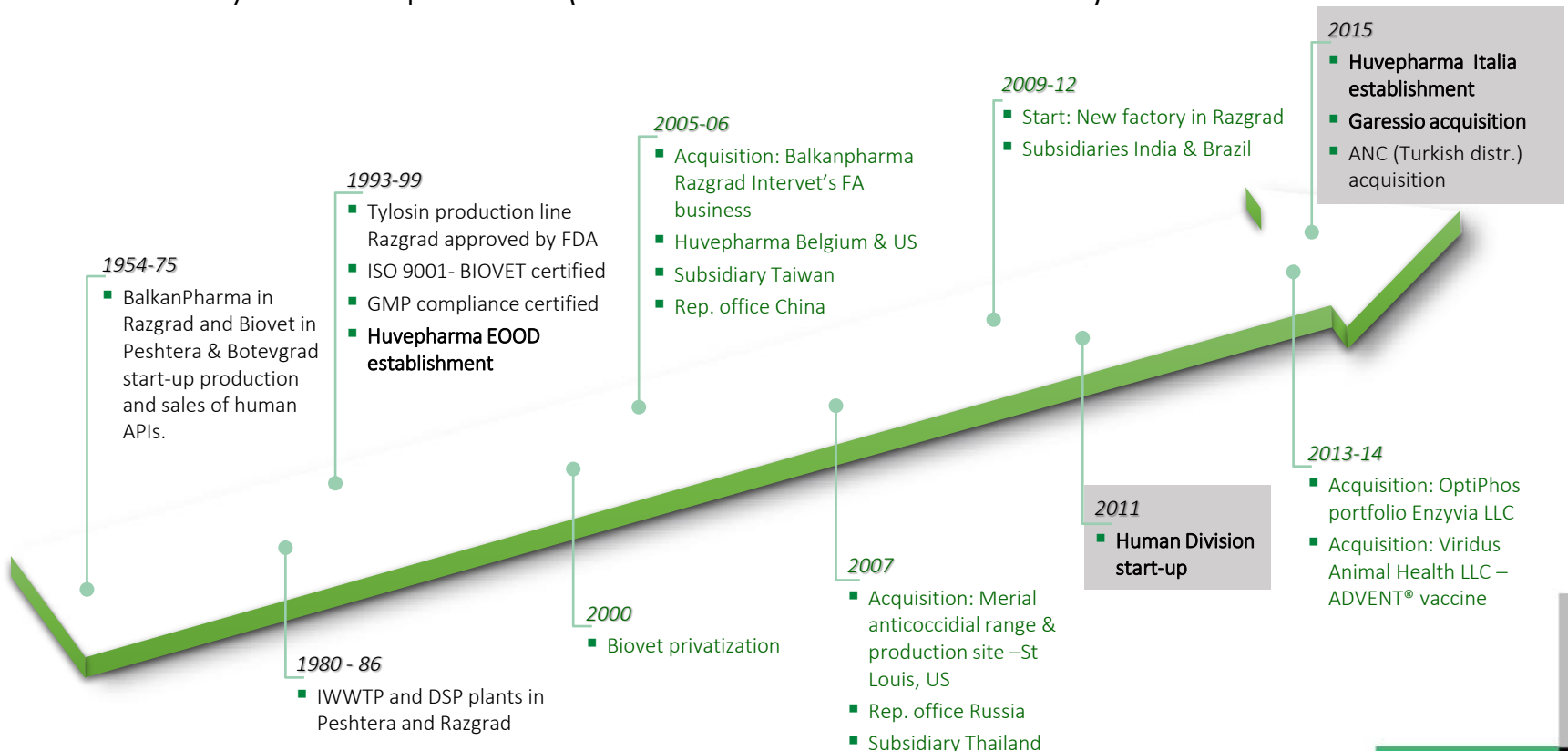
- **Huvepharma ITALIA S.R.L.** was established in 2015 with the acquisition of the Sanofi facility located in Garessio (CN).

- **Huvepharma ITALIA S.R.L.'s** focus is the development, production and commercialization of advanced intermediates and API manufactured by chemical synthesis.

- **Huvepharma ITALIA S.R.L.'s** plan is to:
 - invest in high-potency development and production assets,
 - complete the strategic offer for start-up companies looking for qualified and FDA approved companies,
 - be reliable and qualified partner from Phase 1 through commercial phase.



Huvepharma EOOD is a young European company (founded in 1999), nevertheless possessing consolidated and recognized fermentation knowhow and capabilities owing to the acquisition of companies with over 60 years of experience (f.ex.: BalkanPharma and Biovet).



World Presence



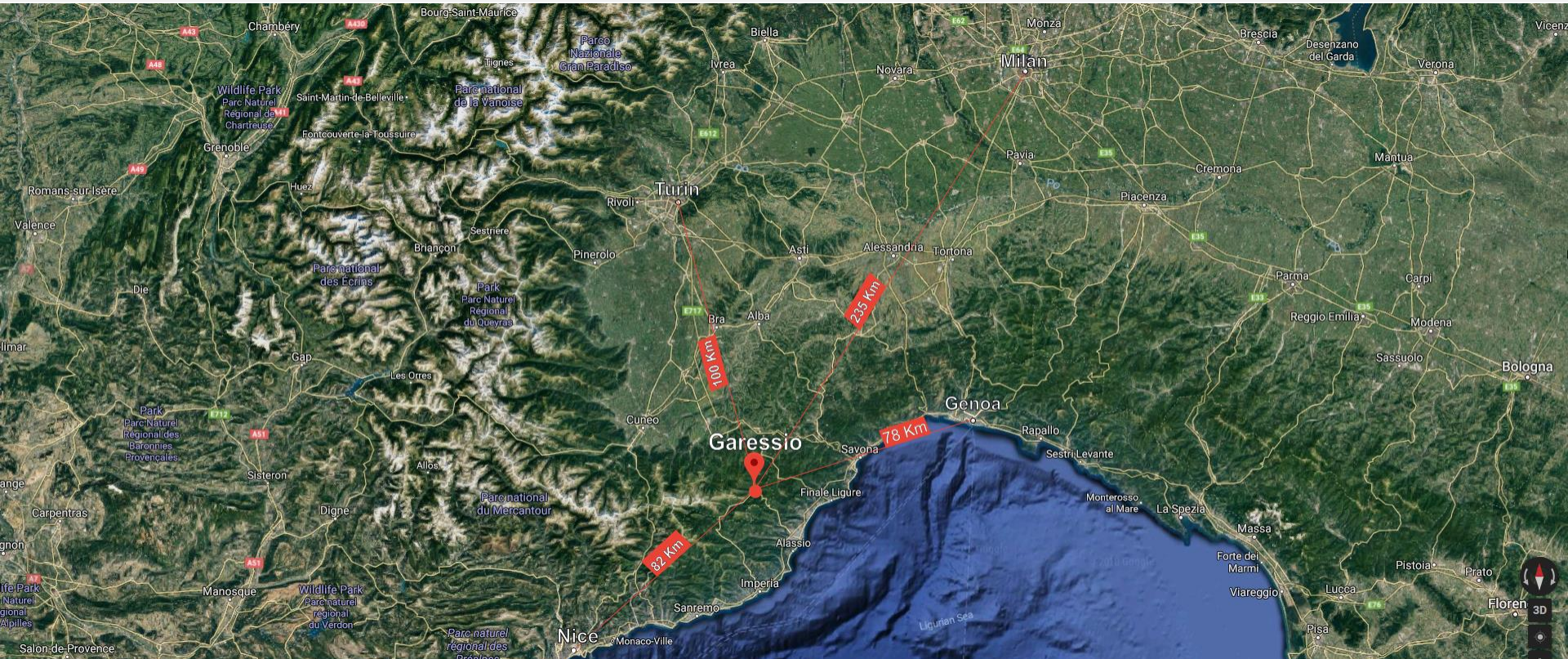
-  Affiliate
-  Production site

2 | Huvepharma Italia Garessio Facilities



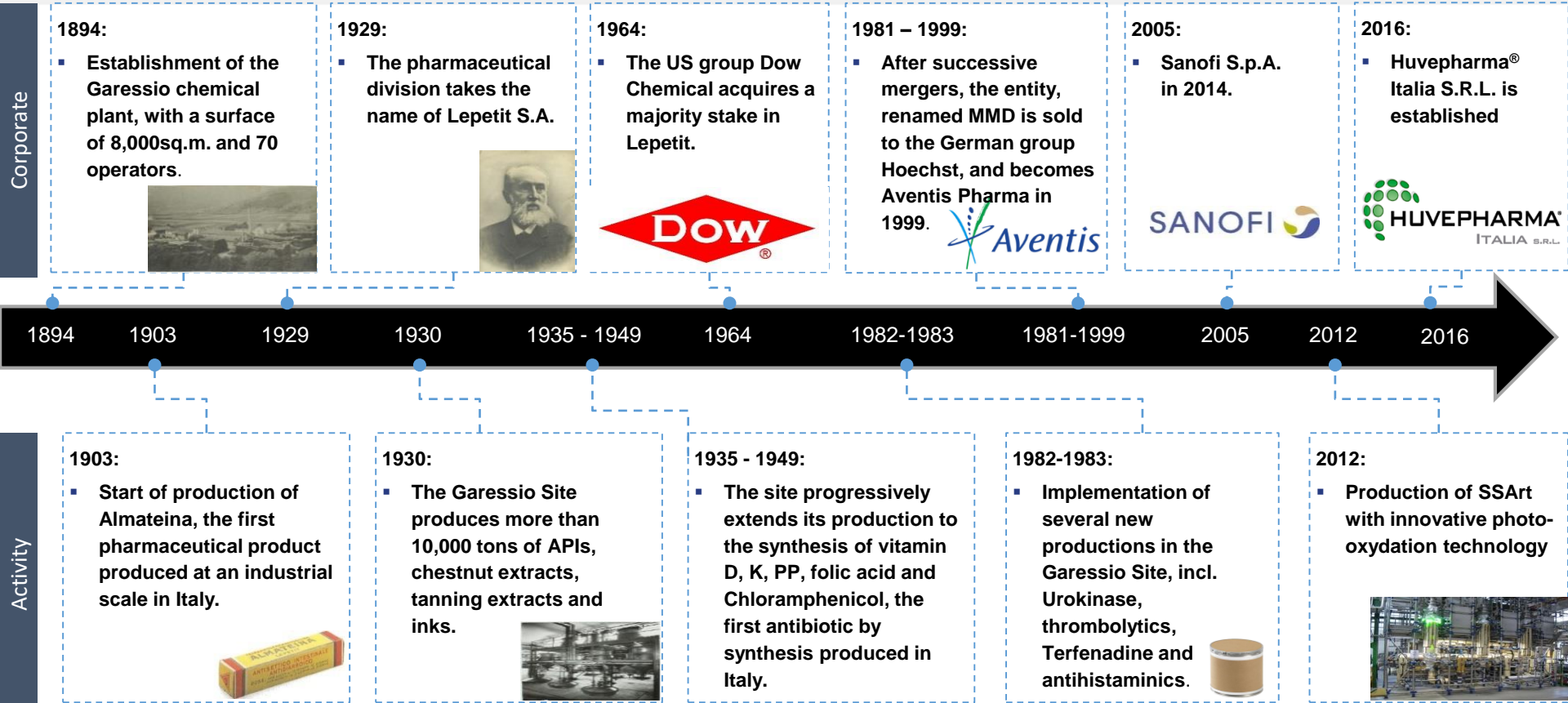


The Garessio facility is specialized in the development, industrialization and production of Active Pharmaceutical Ingredients and API-intermediates via synthetic chemistry



The facility is located in NW Italy,
well connected to multiple international Airports





Long-established player in the pharma-chemical market with a strongly recognized experience in introducing and developing new technologies

3 | Capabilities & Strengths

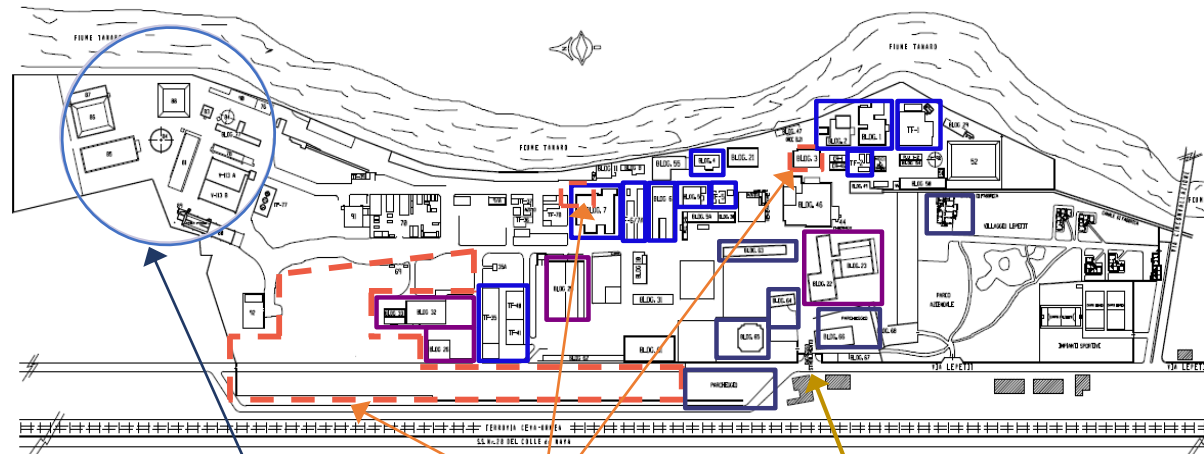


Capabilities & Strengths

An autonomous asset with room for expansion

Production Facilities

5 production bldgs.
8 production lines
3 Solvents recovery units
100 reactors (total vol. 700 cu.m)
97 tanks (3,000 m³) in several tank farms



Waste treatment

Expansion areas
(27,500 m²)

Main entrance

Property:
264,000 m²

Expansion Areas

Available plot of land of 27,500sq.m.
Building 3 currently unused
Expansion area in Building 7 (with a part currently unused)

R&D Facilities

Equipped labs.
1 pilot building
1 very flexible pilot line

Warehouses

8 warehouses

Other Facilities

Administration: site direction, engineering, quality, HR, controlling
Canteen
Parking
Guest house
WWTP
Thermal Oxidizer

- ❑ **Complex chemical reactions in large scale:**
 - ❑ Catalytic hydrogenations (homogeneous, etherogeneous)
 - ❑ various catalysts (Ru, Rh, Pd)
 - ❑ up to 50 bar
 - ❑ up to 10 m³
 - ❑ Catalytic carbonylation with CO gas
 - ❑ Grignard reactions, up to 8 cu m
 - ❑ Friedel Crafts
 - ❑ Gas liquid reactions (by HCl gas)
 - ❑ Peroxide handling (RM, intermediates and finished products)
 - ❑ Acetylation
 - ❑ Photo-oxidation
 - ❑ Bromination
- ❑ **Crystallization controlled by Fiber Optics**
- ❑ **Separation of optical isomers**
- ❑ **Nano particles production**
- ❑ **Production lines 50% computerized**
- ❑ **Cogeneration, thermal-electrical (back pressure turbine)**
- ❑ **Thin layer evaporation**

In addition to the Pilot Plant building with relatively small scale equipment: 19 SS and glass lined reactors (total 59 m³), hastelloy centrifuge and dryer, clean packaging room:

- ❑ Process Development Laboratories: two laboratories dedicated to development activities with HPLC, GC, etc.
- ❑ Process development / optimization
- ❑ Analytical method development
- ❑ Stability program for API and Intermediates
- ❑ Reference standards preparation expertise
- ❑ Process validation

Capabilities & Strengths

Consolidated and qualified Quality organization

Quality Control

- Sampling
- Testing and Release of RMs
- Release tests for INT and API
- In-process control
- Reference Standards management
- Retained samples
- Stability programs

Quality Assurance

- Release INT and API
- Batch record review
- Deviation management
- Validation and Qualification
- Annual Product Review
- SOPs management
- Change control management
- Suppliers management
- GMP training

Regulatory

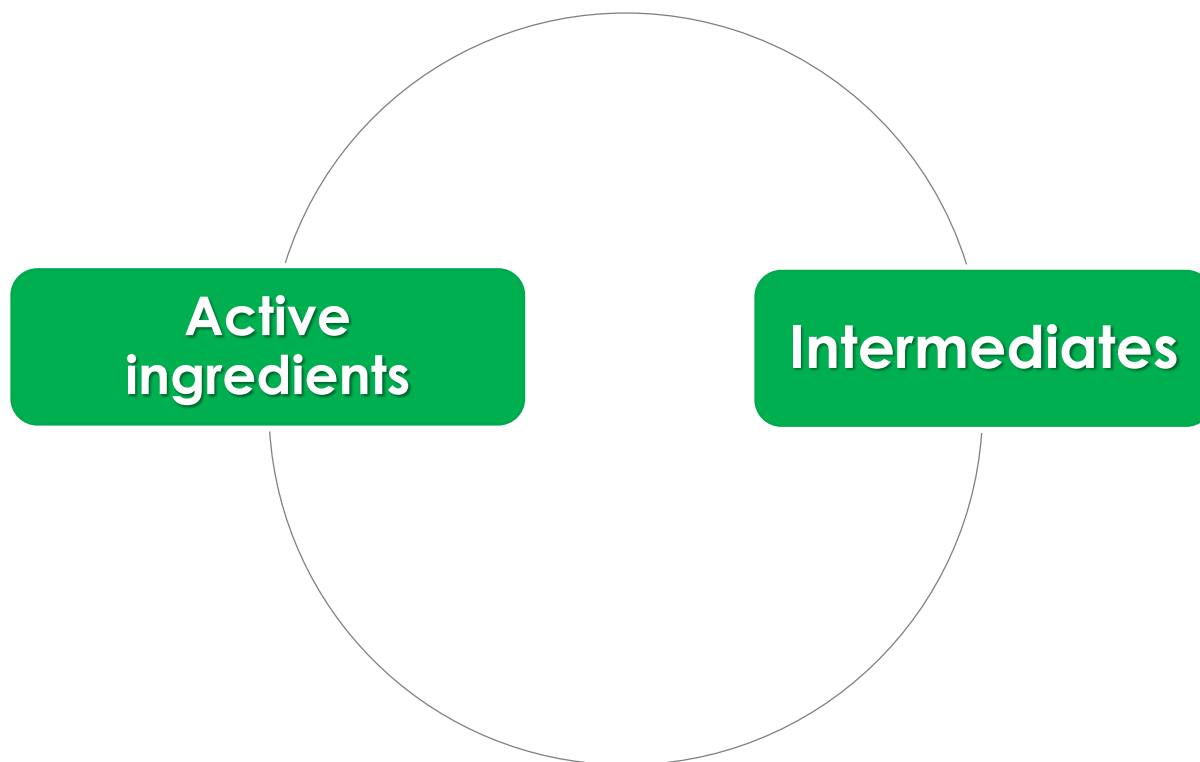
- Regulatory documentation (DMFs, CEPs, Abridged Dossiers)
- SMF management
- Change Control assessment

Huvepharma Italia is approved by the following Regulatory Agencies

- AIFA (Italian Authority) – GMP Certificate
- EDQM – CEP available for some APIs
- US FDA
- PMDA Accredited
- WHO

Huvepharma Italia can offer the following Services:

- R&D and Process Development
- Analytical support including Reference Standards preparation via Preparative HPLC
- Products purification by Preparative HPLC
- Production of validation batches
- Dossier preparation and submission to various Agencies
- Toll Manufacturing



Artesunate

•anti-malaria | CAS n. 88495-63-0 |

FDA, WHO approved

Oxybutynin HCl

•anticholinergic | CAS n. 1508-65-2 |

PMDA accredited

Antiepileptic API

•toll manufacturing |

FDA approved

Artemether

•anti-malaria | CAS n. 71963-77-4 |

WHO approved

ASK2 - Potassium N-acetylaminosuccinate

•nootropic | CAS n. 3397-52-2

Tiapride HCl

•neurological and psychiatric disorders | CAS n. 51012-33-0 |

CEP available

Sulpiride

•antipsychotic | CAS n. 15676-16-1 |

CEP available

Deflazacort

•anti inflammatory | CAS n. 14484-47-0 |



Semisynthetic Artemisinin

CAS n. 63968-64-9

WHO approved

(intermediate for antimalarial APIs : Artesunate, Artemether, Dihydroartemisin)

Cis triol acetone

- 2,2-dimethyl-3 α ,4,9,9 α -tetrahydro-naphto[2,3-d][1,3]dioxol-5-ol
- CAS n. 52187-19-6 (intermediate for Nadolol)

Cortiseven

- 21-hydroxy- Δ^4 -pregnene-3,20-dione-[17 α ,16 α -d]-2'-methyloxazoline-21-acetate
- CAS n. 21269-13-6 (intermediate for Deflazacort)

Thiophene Ester Base

- 3-Amino-4 methylthiophen-2-methyl carboxylate
- CAS n. 85006-31-1 (Intermediate for Articaine)



Food Fragrance

- Toll Manufacturing

Methylphenylcyclohexyl glycolate

MPCG
CAS n. 10399-13-0 (intermediate for oxybutynin HCl)

Diethyl amino butynyl Acetate

- DABA
- CAS n. 52187-19-6 (intermediate for Oxybutynin HCl)

Sanitizing Liquid for Hand Rub

- WHO-recommended Formulation
- PMC "Mani"
- Approved by the Italian Ministry of Health



Anidulafungin

- API (Antifungal)
- 1-[(4R,5R)-4,5-Dihydroxy-N2-[[4''-(pentyloxy)[1',1':4',1''-terphenyl]-4-yl]carbonyl]-ornithine] echinocandin B
- CAS n. 166663-25-8

Dalbavancin

- API (Lipoglycopeptide Antibiotic)
- CAS n. 171500-79-1

Beclometasone dipropionate

- API (Glucocorticoid)
- [2-[(8S,9R,10S,11S,13S,14S,16S,17R)-9-chloro-11-hydroxy-10,13,16-trimethyl-3-oxo-17-propanoyloxy-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl]-2-oxoethyl] propanoate
- CAS n. 5534-09-8

Budesonide

- API (Anti inflammatory)
- 16,17-Butylidenebis(oxy)-11,21-dihydroxypregna-1,4-diene-3,20-dione
- CAS n. 51333-22-3

Mestanolone

- API (Anabolic agent)
- CAS n. 521-11-9



Cilnidipine

- API (Anti hypertension)
- CAS n. 132203-70-4

Pilsicainide

- API (Anti arrhythmic agent)
- CAS n. 88069-67-4

Doxycycline

API (Antibiotic)
CAS n. 564-25-0

1-Amino-4-methyl piperazine

- Intermediate for Rifampicin
- CAS n. 6928-85-4





CERTIFICATO n. **2429**
 CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE
 WE HEREBY CERTIFY THAT THE ORGANIZATION

HUVEPHARMA ITALIA S.r.l.

IT - 12075 GARESSIO (CN) - VIA R. LEPETIT 142

NEI SEGUENTI SITI / IN THE FOLLOWING SITES

IT - 12075 GARESSIO (CN) - VIA R. LEPETIT 142

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE AMBIENTE CHE E' CONFORME ALLA NORMA
 HAS IMPLEMENTED AND MAINTAINS AN ENVIRONMENT MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI EN ISO 14001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES SETTORE / CODE **IAF 13, 12**

Produzione di intermedi e principi attivi farmaceutici per uso umano e veterinario, materie prime per l'industria cosmetica e alimentare attraverso processi di sintesi chimica e di purificazione. Stoccaggio di materie prime sfuse ed a collette. Stoccaggio e spedizione di prodotti finiti sfusi ed a collette.

Production of intermediates and pharmaceutical active ingredients for human and veterinary use, raw materials for the cosmetic and food industry by chemical synthesis and purification process. Stocking of raw materials, loose and packaged. Stocking and shipment of finished products, loose and packaged.

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT 09

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
 THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE: 20/12/1999
 FIRST ISSUE
 DATA DELIBERA: 01/12/2020
 DECISION DATE
 DATA SCADENZA: 30/11/2023
 EXPIRY DATE
 EMISSIONE CORRENTE: 03/02/2021
 ISSUE DATE

Luca Romersì
 CERTIQUALITY S.r.l. - IL PRESIDENTE
 Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



554 n. 001 D
 Ministero degli Affari Esteri e della Cooperazione Internazionale, Roma, 20/1/2014
 Approvazione di D.M. 10/1/2014 e D.M. 10/1/2014



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.
 IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

For information concerning the validity of the certificate, you can visit the site www.certiquality.it

The validity this certificate depends on annual audit and on a complete review every three years of the Management System.



CISQ is the Italian Federation of Organisms of Certification of Management Systems.
 CISQ is the Italian Federation of management system Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

HUVEPHARMA ITALIA S.r.l.

IT - 12075 GARESSIO (CN) - VIA R. LEPETIT 142
 for the following scope

Production of intermediates and pharmaceutical active ingredients for human and veterinary use, raw materials for the cosmetic and food industry by chemical synthesis and purification process. Stocking of raw materials, loose and packaged. Stocking and shipment of finished products, loose and packaged.

has implemented and maintains a
Environmental Management System
 which fulfills the requirements of the following standard
ISO 14001:2015

Issued on: 2020-12-01
 First issued on: 1999-12-20
 Expires on: 2023-11-30

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration number: **IT-10005**



Alex Stoichitoui
 Alex Stoichitoui
 President of IQNET



Mario Romersì
 Ing. Mario Romersì
 President of CISQ

IQNet Partners*:

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 CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
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 IRAM Argentina IQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
 NYCE-SIGE Mexico PCBQ Poland Quality Austria Austria PR Russia SII Israel SIQ Slovenia
 SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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CERTIFICATO n. **28813**
 CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE
 WE HEREBY CERTIFY THAT THE ORGANIZATION

HUVEPHARMA ITALIA S.r.l.

IT - 12075 GARESSIO (CN) - VIA R.LEPETIT 142

NEI SEGUENTI SITI / IN THE FOLLOWING SITES

IT - 12075 GARESSIO (CN) - VIA R. LEPETIT 142

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE SICUREZZA CHE E' CONFORME ALLA NORMA
 HAS IMPLEMENTED AND MAINTAINS A SAFETY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI ISO 45001:2018

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES SETTORE
 COSE IAF 13, 12

Produzione di intermedi e principi attivi farmaceutici per uso umano e veterinario, materie prime per l'industria cosmetica e alimentare attraverso processi di sintesi chimica e di purificazione. Stoccaggio di materie prime sfuse ed a collette. Stoccaggio e spedizione di prodotti finiti sfusi ed a collette.

Production of intermediates and pharmaceutical active ingredients for human and veterinary use, raw materials for the cosmetic and food industry by chemical synthesis and purification process. Stocking of raw materials, loose and packaged. Stocking and shipment of finished products, loose and packaged.

IL PRESIDENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
 THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE 13/12/2007
 FIRST ISSUE
 DATA DELIBERA 01/12/2020
 DECISION DATE
 DATA SCADENZA 01/08/2022
 EXPIRY DATE
 EMISSIONE CORRENTE 03/02/2021
 ISSUE DATE

CERTIQUALITY S.r.l. - IL PRESIDENTE
 Via G. Garibaldi 4 - 20123 MILANO (MI) - ITALY



SEI n. 802 F
 Federazione Nazionale delle Associazioni Italiane delle Imprese di Certificazione
 Federazione di IAF, AF and ISO Mutual Recognition Arrangements



www.cisq.com

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The validity this certificate depends on annual audit and on a complete review every three years of the Management System.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.
 has issued an IQNet recognised certificate that the organization:

HUVEPHARMA ITALIA S.r.l.

IT - 12075 GARESSIO (CN) - VIA R.LEPETIT 142
 for the following scope

Production of intermediates and pharmaceutical active ingredients for human and veterinary use, raw materials for the cosmetic and food industry by chemical synthesis and purification process. Stocking of raw materials, loose and packaged. Stocking and shipment of finished products, loose and packaged.

has implemented and maintains a
Safety Management System
 which fulfils the requirements of the following standard
UNI ISO 45001:2018

Issued on: 2020-12-01
 First issued on: 2007-12-13
 Expires on: 2022-08-01

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration number: IT-133167



Alex Stoichitoiu
 Alex Stoichitoiu
 President of IQNET



Mario Romeri
 Ing. Mario Romeri
 President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
 CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
 FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
 IRAM Argentina IQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
 NYCE-SIGE Mexico 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

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CERTIFICATO n. **12044**
 CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE
 WE HEREBY CERTIFY THAT THE ORGANIZATION

HUVEPHARMA ITALIA S.r.l.

IT - 12075 GARESSIO (CN) - VIA R.LEPETIT 142

NEI SEGUENTI SITI / IN THE FOLLOWING SITES

IT - 12075 GARESSIO (CN) - VIA R. LEPETIT 142

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OHSAS 18001:2007

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES SETTORE CODE **IAF 13, 12**

Produzione di intermedi e principi attivi farmaceutici per uso umano e veterinario, materie prime per l'industria cosmetica e alimentare attraverso processi di sintesi chimica e di purificazione. Stoccaggio di materie prime sfuse ed a collette. Stoccaggio e spedizione di prodotti finiti sfusi ed a collette.

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 THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE FIRST ISSUE	13/12/2007
DATA DELIBERA DECISION DATE	01/08/2019
DATA SCADENZA EXPIRY DATE	30/09/2021
EMISSIONE CORRENTE ISSUE DATE	03/02/2021

CERTIQUALITY S.r.l. - IL PRESIDENTE
 Via G. Galvani 4 - 20123 MILANO (MI) - ITALY



SCR n. 182 F
 Registro degli Accordi di Mutualizzazione C.A. 191 - I.C.A.
 Impresa di R.L. 01/01/2013 - 01/01/2013 Mutualizzazione Imprese



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HUVEPHARMA ITALIA S.r.l.

IT - 12075 GARESSIO (CN) - VIA R.LEPETIT 142
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has implemented and maintains a
Safety Management System
 which fulfills the requirements of the following standard
OH SAS 18001:2007

Issued on: 2019-08-01
 First issued on: 2007-12-13
 Expires on: 2021-09-30

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration number: **IT-62306**



Alex Stoichitoiu
 Alex Stoichitoiu
 President of IQNET



Mario Romeri
 Ing. Mario Romeri
 President of CISQ

IQNet Partners*:
 AENOR, Spain AFNOR, Certification France APCER, Portugal CCC Cyprus CISQ Italy
 CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
 FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Serfifoint Oy Finland INTECO Costa Rica
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Seveso certification UNI 10617



CERTIFICATO n. **23818**
CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

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IT - 12075 GARESSIO (CN) - VIA R.LEPETIT 142

NEI SEGUENTI SITI / IN THE FOLLOWING SITES

IT - 12075 GARESSIO (CN) - VIA R. LEPETIT 142

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE SICUREZZA CHE E' CONFORME ALLA NORMA
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UNI 10617

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES SETTORE
CODE **IAF 13, 12**

Produzione di intermedi e principi attivi farmaceutici per uso umano e veterinario, materie prime per l'industria cosmetica e alimentare attraverso processi di sintesi chimica e di purificazione. Stoccaggio di materie prime sfuse ed a collettame. Stoccaggio e spedizione di prodotti finiti sfusi ed a collettame.

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PRIMA EMISSIONE **03/08/2016**
FIRST ISSUE
DATA DELIBERA **24/08/2021**
DECISION DATE
DATA SCADENZA **30/08/2024**
EXPIRY DATE
EMISSIONE CORRENTE **24/08/2021**
ISSUE DATE

CERTIQUALITY S.r.l. - IL PRESIDENTE
Via G. Galvani 4 - 20122 MILANO (MI) - ITALY



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CISQ
IONet is the international organization
www.ionet-certification.com

IONet, the association of the world's best class
certification bodies, is the largest provider of management
system certifications in the world.
Isted is composed of more than 20 bodies and serves
over 400,000 customers of over 100 plus.

For information concerning the validity
of this certificate, you can visit the web
www.ionet-certification.com

The validity of this certificate depends
on annual surveillance as a consequence
rather than from expiry of the
Management System.



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione del sistema di gestione aziendale.
CISQ is the Italian Federation of management
system certification bodies.



ecovadis

HUVEPHARMA ITALIA SRL

has been awarded a
Silver medal

as a recognition of their EcoVadis CSR (Corporate Social Responsibility) Rating

- SEPTEMBER 2019 -



You are receiving this score/medal based on the disclosed information and news resources available to EcoVadis at the time of assessment. Should any information or circumstances change materially during the period of the scorecard/medal validity, EcoVadis reserves the right to place the business' scorecard/medal on hold and, if considered appropriate, to re-assess and possibly issue a revised scorecard/medal.

Valid until: September 2020

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DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
279357-2018-FSMS-ITA-RvA

Initial date:
5 December 2018

Valid:
5 December 2018 - 5 December 2021

This is to certify that the management system of

HUVEPHARMA ITALIA SRL

Via R Lepetit, 142 - 12075 Garessio (CN) - Italy

has been assessed and determined to comply with the requirements of
FOOD SAFETY SYSTEM CERTIFICATION 22000

Certification scheme for food safety management systems consisting of the following elements: ISO 22000:2005, FSSC 22000 V4.1 - ISO TS 22002-1:2009 (Food) and additional FSSC 22000 requirements.

This certificate is applicable for the scope of:

Isolation, purification and packaging of vanillin flavour from raw vanillin in ethylacetate. Category K.

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 applicable technical specification for sector PRPs. Validity of this certificate can be verified in the FSSC 22000 database of certified organizations available on www.fssc22000.com.

Date of Certification Decision:
5 December 2018
Place and date:
Barendrecht, 5 December 2018



For the issuing office:
DNV GL - Business Assurance
Zwolsseweg 1, 2994 LB, Barendrecht,
Netherlands


Eric Koek
Management Representative



6 | Conclusion



Our Competitive Advantage

Huvepharma Italia is a recognized partner offering:

Excellent regulatory reputation

- Sites that operate under high quality standards (FDA & AIFA approvals; OHSAS 18001 & ISO 14001 certifications)

Flexible & fast response

- Consolidated experience in collecting all data & process information from the start for easy regulatory submission.

Chemistry & fermentation cost competitive expertise

- Strong experience in implementing new productions & new technologies
- In addition to Garessio facility expertise in chemical synthesis, Huvepharma Italia takes advantage of the fermentation expertise & cost effectiveness of the Bulgarian manufacturing plants.

Confidentiality

- A key policy of the Huvepharma Group





**THANK YOU
FOR YOUR ATTENTION**

