FARCHEMIA

Experts taking care.

CORDENPHARMA

FARCHEMIA is an established manufacturer of bulk APIs and intermediates thereof now belonging to the CORDENPHARMA network

Farchemia business

FARCHEMIA's core business is the manufacturing of pharmaceutical and veterinary intermediates and bulk products by chemical synthesis.

FARCHEMIA supplies APIs both to Generic Companies and Pharma Brand Companies

Farchemia business

2013 turnover : about 50 million of euro

Export: over 90%
Farchemia exports into 60 countries

60% of the turnover is generated by sales of Pharmaceutical Active Ingredients in the generic market

40% of the turnover is generated by contract manufacturing and exclusive production of APIs and advanced intermediates for a number of the leading worldwide Pharmaceutical Companies.

As a bulk pharmaceutical manufacturer FARCHEMIA is an associate of:

Aschimfarma
FEDERCHIMICA

Farchemia history

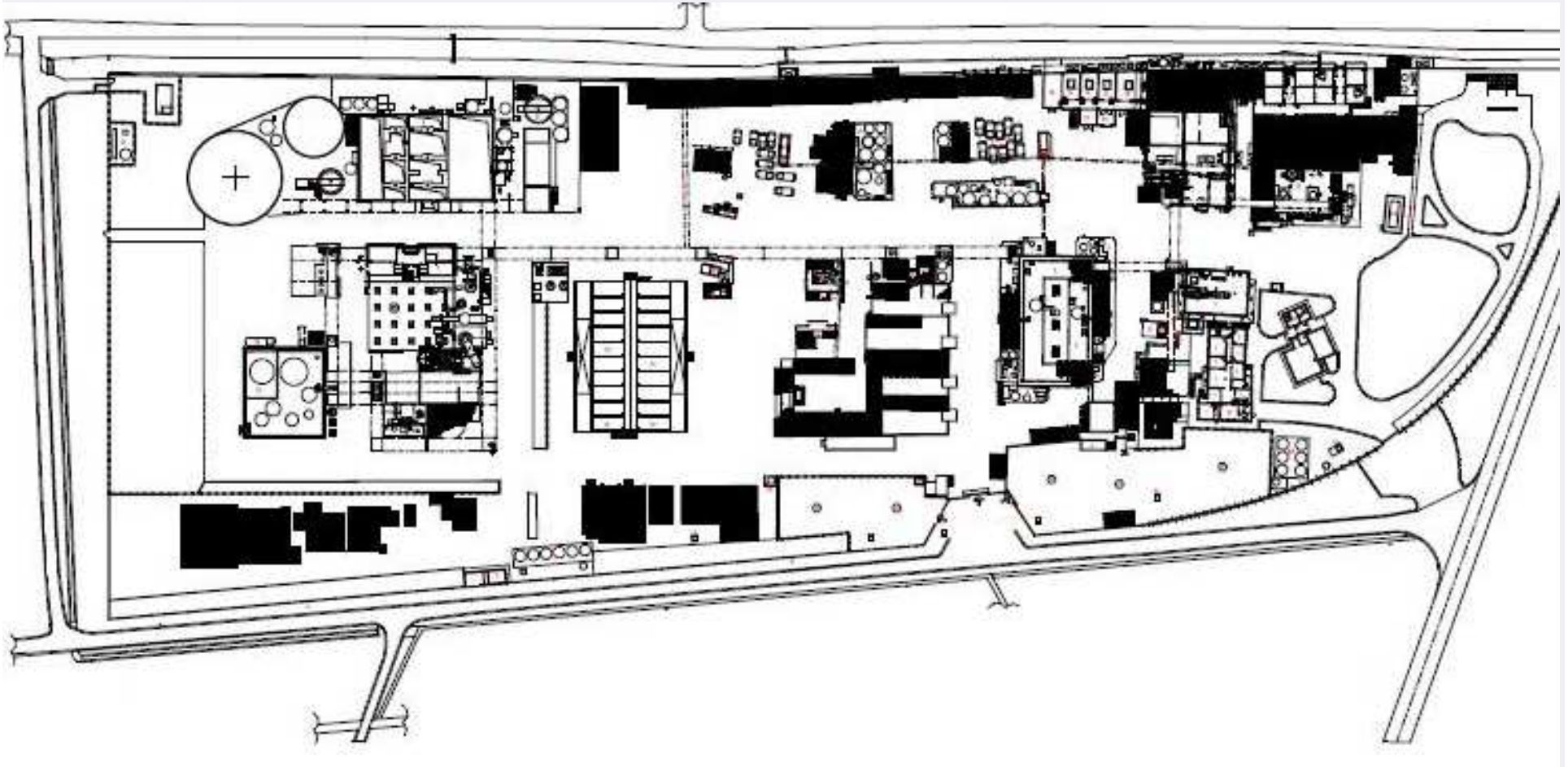
The company was established in 1962 by a private entrepreneure.

In January 1989 was sold to the Belgian multinational chemical company TESSENDERLO.

In December 2012 Farchemia was acquired by the German chemical company ICIG and became a member of the Corden Pharma network.

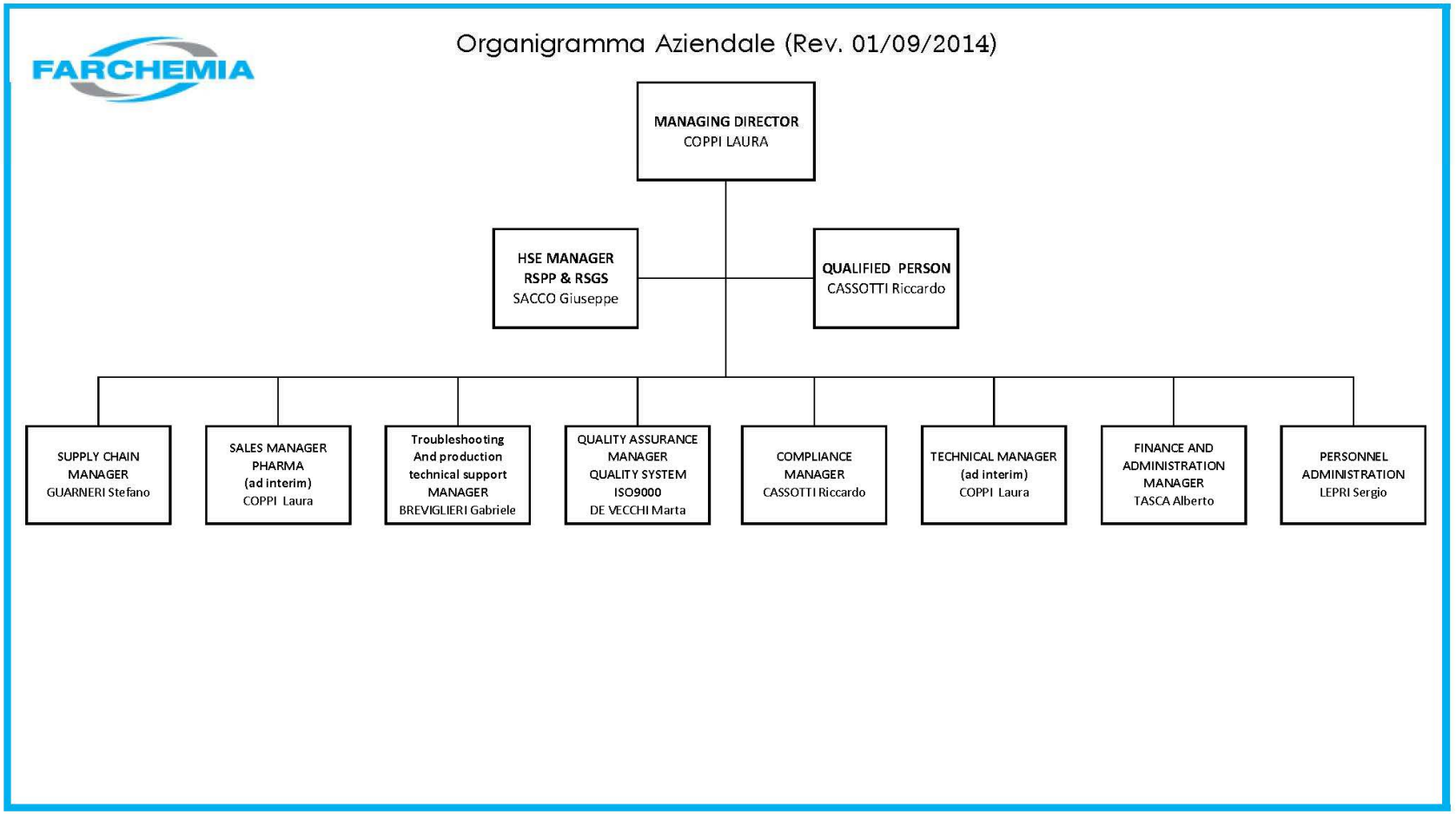
Farchemia Site MAP

Plant location GPS Co-ordinates: 45° 33' 04'' N
09° 35'59'' E



Total Surface 50000 sqm

FARCHEMIA Organizational chart and employees



FARCHEMIA Organizational chart and employees

Total	150
QC	12
QA & Regulatory Affairs	6
Production	68
Maintenance & Engineering	10
R&D	2
Sales	6
Purchasing/Logistics	7
Warehouse	6
HSE Dept	3
Ecology Dept	17
Administration	5
General services / Prodn.	7
HR	1

Inside Farchemia

- R&D
- Engineering & Maintenance
- Warehouses
- Production
  - Plant A
  - Plant B
  - Drying & Packaging Plant
- Quality Assurance
- Regulatory Affairs
- Quality Control
- Safety & Environment
- Utilities

R&D

The R&D Laboratory does not engage in basic research and is responsible for:

- Technical support to production and QC
- Troubleshooting

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INVESTMENTS AND MAINTENANCE 2010-2013

YEAR	2010	2011	2012	2013
CAPEX	2029 K€	3020 K€	3372 K€	3304 K€
MAINTENANCE	3014 K€	3330 K€	2960 K€	3176 K€
TOTAL	5043 K€	6350 K€	6332 K€	6480 K€

Engineering and Maintenance

Engineering and maintenance department is responsible for:

- Plant installations
- Preventative and reactive maintenance
- Development of maintenance projects
- Project & Design Engineering
- Plant & Equipment Calibration
- Plant Qualification

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RAW MATERIAL WAREHOUSES

Via Ticino, 5
20098 S. Giuliano Milanese (MI) - Italy

- Short term storage: ready stocks of raw materials , awaiting analysis or immediate use in production, are held on-site in Farchemia.

- Long term storage: the rest of the stocks of raw materials are held in a third-party warehouse. Stocks may be held under the following statuses: *approved*, *rejected* or *awaiting sampling*.

API WAREHOUSE

neologistica

Largo U. Boccioni 1
21040 Origgio (VA) Italy

A second third-party warehouse GMP approved by the Italian Authorities (AIFA) is used for the storage of APIs. Holding statuses may be *approved*, *rejected* and *quarantine*.

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Typical chemical reaction

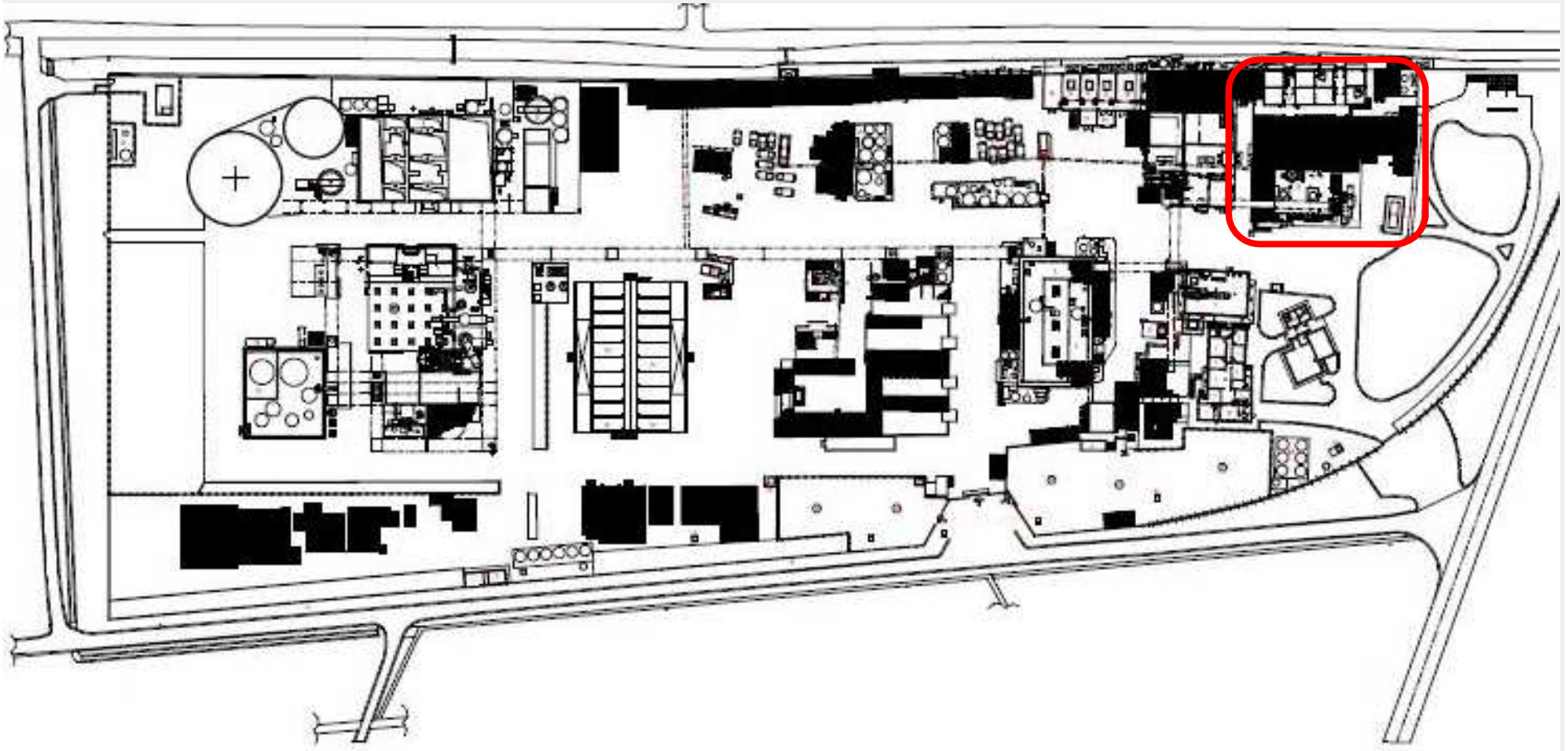
Expertise in working with:

- Aromatic Amines
- Ammonia
- Hydrazine Hydrate
- Ethylene Oxide
- Thionyl Chloride
- Phosphorus Oxychloride
- Dimethyl Sulphate
- Propylene oxide

Reaction conditions range from –20° C up to +290° C.
Pressure up to 15 bar and vacuum as low as 1 mbar
ALL THE REACTORS ARE BLANKETED WITH NITROGEN

Farchemia Site MAP

Production Plant A



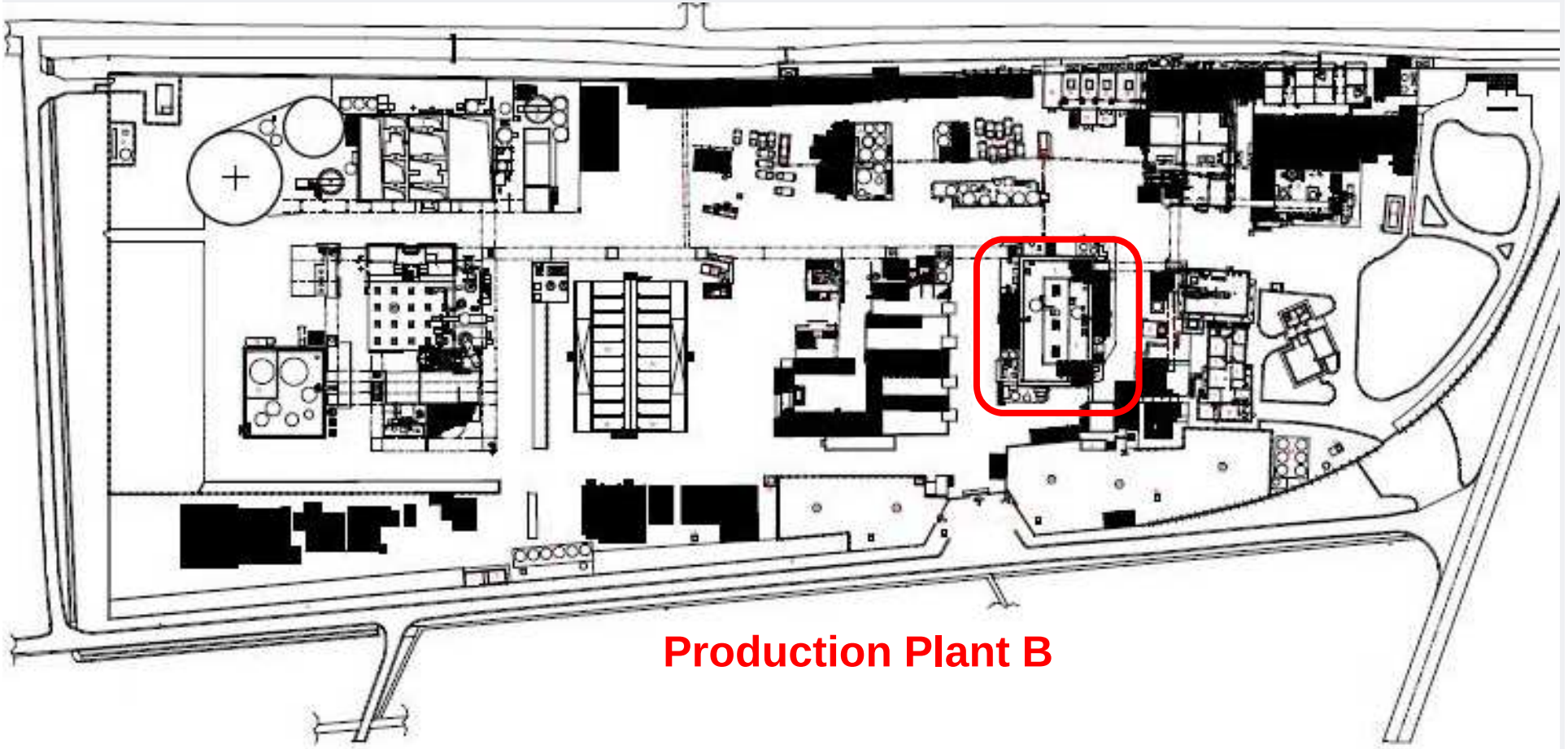
Production Plant A

Built in 1965, the plant occupies an area of 500 sqm.
It was expanded in 1992 and again in 1997. The total surface area today is 800 sqm.

Production Plant A

- Electrical power installed: 200 kW
- Supplied with industrial, potable and purified water
- Sewage and drainage system with connecting interceptors and discharge into the main drain
- 27 reaction vessels with a capacity ranging from 1,500 to 28,000 lt constructed in AISI 316 or glass-lined
- 9 centrifuges in AISI 316 or HALAR – AISI
- ID11 – B1/A dryer with closed loop direct loading system

Farchemia Site MAP



Production Plant B

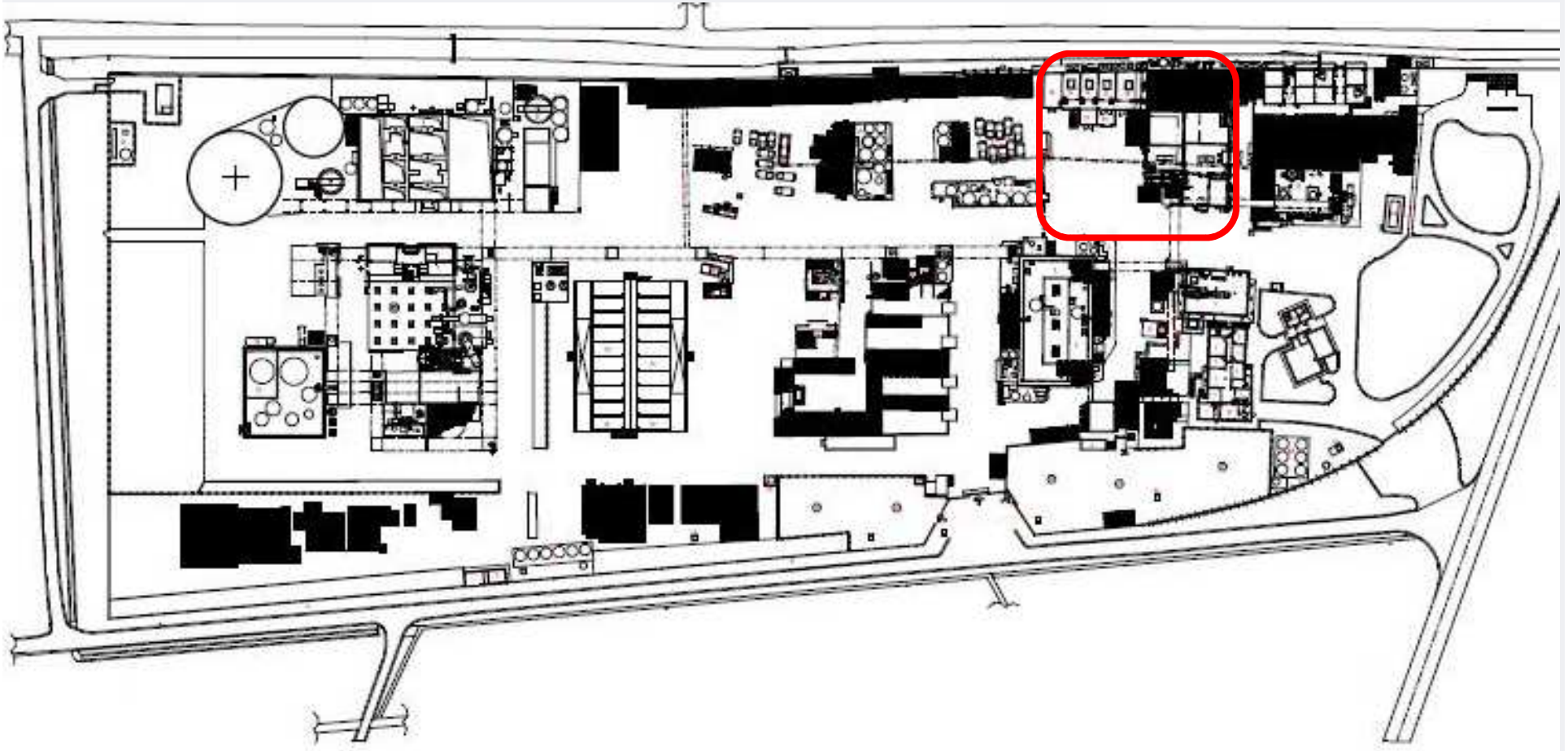
This is a three storey building (600 m2 each floor) built in 1972. The building is made of bricks with tiled side walls.

Production Plant B

- Installed electrical power: 300 kW
- Supplied with industrial, potable and purified water
- Sewage and drainage system with connecting interceptors which discharge into the main drain
- 39 reaction vessels from 1,000 to 20,000 lt capacity in AISI 316 or glass-lined.
- 10 centrifuges in Aisi, Halar-AISI or hastelloy
- 3 filter dryers and a closed loop ID11-B1/B dryer loading system

Farchemia Site MAP

Drying & packaging plant



Drying & packaging plant

The plant is divided into various rooms with one main corridor. The total area: 950 sqm

Drying & packaging plant

B5 Drying Department

A dedicated area for the drying-packaging and/or micronization of Metronidazole, revamped in 2011

Drying & packaging plant

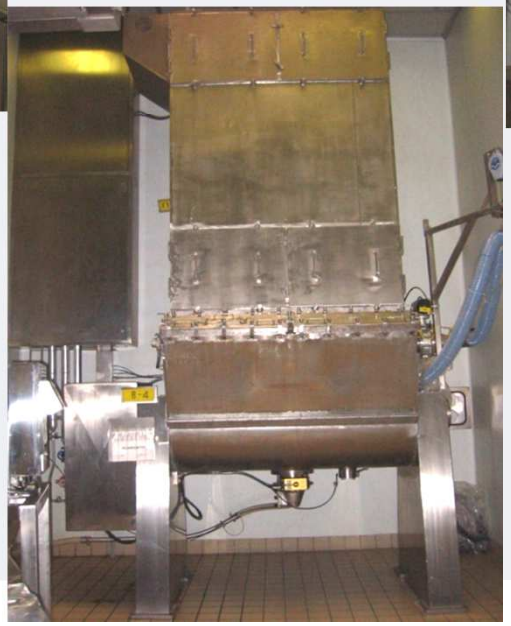
- Industrial water, potable water, purified water, steam and vacuum available in all areas
- Sewage system with clay traps connected to the main drain
- Access to the main corridor through safety doors (separate access for workers and visitors)
- Installed electrical power: 100 kW
- 9 dryers, 2 micronizers, 1 grinder.
- The air conditioning system creates a positive pressure (+) in the rooms and (++) in the main corridor to avoid cross contamination
- HEPA filters installed

Drying & packaging plant

The following are typical drying machines used in the manufacturing of APIs

Vacuum Dryer

Fluid Bed Dryer



Vacuum rotating Dryer (CRIOX)

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Quality Assurance

The Quality Assurance Dept. is responsible for:

- Applying of cGMP and ISO 9001:2008 accreditation
- Reviewing production and analytical documentation for batch releases purpose . The batch release is performed by QA Manager and Qualified Person (QP)
- Supporting government agency inspectors and customer auditors
- Technical agreements management

Quality Assurance

- Qualification and approval of raw materials
- Audit to critical raw materials suppliers
- Coordination of the internal inspection team
- Coordination of validation activities
- Master Batch Records - issuing and updating
- GMP Training
- Customer and suppliers complaints
- Quality documentation management
- Change, Deviation, OOS and CAPA management
- Risk assessment

Quality Assurance

- Since 1979 the company has been regularly inspected by the US *Food & Drug Administration*

- Farchemia continues to work in full cooperation with the FDA and with all our customers also dealing with the FDA.

Inspections

FDA USA	AIFA Italy / Ministry of Health	PMDA Japan
November 2013	March 2014 (veterinary APIs)	June 2008
November 2010	March 2013	
July 2006	March 2011 (veterinary APIs)	
February 2003	January 2010	
June 2000	July 2007	
February 1995	January 2006	
October 1990	February 2003	
July 1986	December 1992	
January 1985	April 1989	
February 1984	October 1983	
June 1981	December 1975	
October 1979		

Compliance

Italian Ministry of Health (AIFA) Authorization n° aMP 157/2013

GMP Certificate AIFA IT aMP/157/2013

Italian Ministry of Health (Veterinary Products) Authorization n° NBF/22/2014/V

FDA Establishment Inspection Report (EIR) on Jan. 29th 2014

Certicate UNI EN ISO 9001:2008 n° 693

Certificate OH SAS 18001:2007 IT-77883

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Regulatory Affairs

The Regulatory Affairs is responsible for:

- Issuing and updating DMFs
- Managing the manufacturing the authorization procedures with AIFA (Italian Health Agency)
- Supplying technical documentation to our customers
- Maintaining relations with Health Authorities worldwide
- Supporting Customers in registration procedures

Products list and DMF filing

Product	Quality	DMF
BALSALAZIDE	Inhouse	CTD
BENSERAZIDE HYDROCHLORIDE	Inhouse	CTD
BENZOYL METRONIDAZOLE	USP, Ph. Eur.	CTD (CoS)
BENZOYL PEROXIDE	USP, Ph. Eur.	CTD
BETHANECHOL CHLORIDE	USP	CTD
CIMETIDINE (FORM A, A+B)	USP, Ph. Eur.	CTD
CIMETIDINE HCl	USP, Ph. Eur.	CTD
CLODRONIC ACID DISODIUM	Ph. Eur.	CTD
CLOTRIMAZOLE	USP, Ph. Eur.	CTD
DICLOFENAC FREE ACID	Inhouse	CTD
DISULFIRAM	USP, Ph. Eur.	CTD
DOXYLAMINNE SUCCINATE	USP, Ph. Eur.	CTD

Products list and DMF filing

Product	Quality	DMF
IMIPRAMINE HCl	USP, Ph. Eur.	CTD
IMIPRAMINE PAMOATE	Inhouse	CTD
LANTHANUM CARBONATE	Inhouse	CTD
MESALAMINE	USP, Ph. Eur.	USA, EU (Cos)
MESALAMINE HD	USP, Ph. Eur.	CTD
METAXALONE	Inhouse	CTD
METRONIDAZOLE	USP, Ph. Eur.	CTD (Cos)
MICONAZOLE NITRATE	USP, Ph. Eur.	CTD
NAPROXEN	USP, Ph. Eur.	CTD (CoS)
NAPROXEN AMINOBUTANOL	Inhouse	CTD
OLSALAZINE SODIUM	Ph. Eur.	CTD

Products list and DMF filing

Product	Quality	DMF
OPIPRAMOL 2 HCl	Inhouse	CTD
OXAPROZIN	USP	CTD
RITALINIC ACID	Inhouse	CTD
SECNIDAZOLE	Inhouse	CTD
SERINHYDRAZIDE HYDROCHLORIDE	Inhouse	CTD
SULFASALAZINE	USP, Ph. Eur.	USA, EU (CoS)
TIZANIDINE HCl	USP	CTD
TRIMEBUTINE BASE	Inhouse	CTD
TRIMEBUTINE MALEATE	EP	CTD

Certificate of Suitability

FARCHEMIA has obtained a “Certificate of Suitability” (CEP) under EDQM regulatory regulation,for the following products:

Metronidazole
Metronidazole benzoate
Naproxen
Sulfasalazine
Mesalamine
Mesalamine HD

2011-2013 MONTHLY DETAIL OF TABLE 2 COMPOUND (DOXYLAMINE PRECURSOR)

Cod.201176 BETADIMETILAMMINO ETILCORURO HCL cas. 4584-46-7

Year 2011		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
IN														0
OUT			1600	3200										4800
INVENT	4800	4800	3200	0	0	0	0	0	0	0	0	0	0	

Year 2012		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
IN							8800							8800
OUT							3200	3200						6400
INVENT	0	0	0	0	0	0	5600	2400	2400	2400	2400	2400	2400	

Year 2013		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
IN						8000		500				5600	5600	19700
OUT						3200	2400	5300					4000	14900
INVENT	2400	2400	2400	2400	2400	7200	4800	0	0	0	0	5600	7200	

2013 MONTHLY DETAIL OF DOC/PSF COMPUNDS

Cod.	Prodotto	gen-13	feb-13	mar-13	apr-13	mag-13	giu-13	lug-13	ago-13	set-13	ott-13	nov-13	dic-13	Tot. 2013
10006	CIMETIDINE FKRF 50 FBA	-	-	-	10.020	8.966	-	-	-	-	-	-	-	18.986
10093	SULFASALAZINE FKRF 25 FCA	-	-	-	-	-	-	11.000	2.000	9.600	-	-	-	22.600
10819	CLODRONIC ACID DISODIUM FKRF 25 FCA	-	-	-	-	-	1.669	-	-	-	-	-	-	1.669
600005	CIMETIDINE II GETTI PURIFICATA	-	-	-	900	1.930	-	-	-	-	-	-	-	2.830
600186	CIMETIDINE XXXTA F.C.	-	-	-	880	610	-	-	-	-	-	-	-	1.490
600187	CIMETIDINE GREZZA F.C.	-	-	-	1.375	825	-	-	-	-	-	-	-	2.200
		-	-	-	13.175	12.331	1.669	11.000	2.000	9.600	-	-	-	49.775

2013 MONTHLY DETAIL OF DOC COMPUNDS

Cod.	Prodotto	gen-13	feb-13	mar-13	apr-13	mag-13	giu-13	lug-13	ago-13	set-13	ott-13	nov-13	dic-13	Tot. 2013
10001	METRONIDAZOLE BENZOATE	5.604	-	-	-	-	-	-	-	-	-	-	3.183	8.787
10006	CIMETIDINE	-	-	-	10.020	8.966	-	-	-	-	-	-	-	18.986
10010	RITALINIC ACID	2.764	-	-	-	2.394	2.310	-	-	-	-	2.288	1.875	11.631
10024	DOXYLAMINE SUCCINATE	-	-	-	-	-	4.147	7.121	1.035	-	-	-	-	12.303
10044	OPIPRAMOL DIHYDROCHLORIDE	-	3.726	1.884	-	-	-	4.511	2.039	3.751	-	-	-	15.911
10051	METRONIDAZOLE	31.835	20.553	-	19.862	25.509	23.697	2.210	-	25.966	23.530	33.479	13.443	220.084
10053	METRONIDAZOLE MICRONIZED	-	9.440	-	9.080	8.780	6.760	-	-	-	8.800	-	9.140	52.000
10064	SECNIDAZOLE	-	-	10.281	883	-	-	9.364	1.347	-	-	-	-	21.875
10068	CARBADOX	-	-	-	-	-	-	-	-	20.014	12.747	-	-	32.761
10079	MICONAZOLE NITRATE	-	-	2.476	-	-	-	-	-	-	-	-	-	2.476
10093	SULFASALAZINE	-	-	-	-	-	-	11.000	2.000	9.600	-	-	-	22.600
10095	CLOTRIMAZOLE	-	-	9.472	2.541	-	-	-	-	-	-	-	-	12.013
10126	DL-SERINHYDRAZID HYDROCHLORID	4.987	-	4.543	3.191	-	-	-	-	-	-	-	-	12.721
10129	ACIDO FORMICO DISTILLATO F.C.	103.920	80.940	83.880	109.300	108.900	136.040	214.020	-	237.720	103.520	84.360	83.040	1.345.640
10134	METRONIDAZOLE BENZOATE MICRO	10.049	1.630	-	-	-	-	-	-	-	-	7.194	7.213	26.086
10136	METRONIDAZOLE MICRONIZED	-	-	-	-	-	2.000	-	-	4.225	-	-	-	6.225
10140	MESALAMINE	3.851	3.733	833	3.436	4.734	-	-	-	3.477	4.866	3.978	2.689	31.597
10143	TRIMEBUTINE MALEATE	-	-	4.751	7.070	-	-	3.947	-	-	-	-	-	15.768
10144	TRIMEBUTINE BASE	-	-	-	414	1.166	-	-	-	-	-	-	-	1.580
10584	BENZOYL PEROXIDE HYDROUS	-	316	371	372	666	521	574	76	660	799	37	-	4.391
10625	DISULFIRAM	-	458	3.838	-	-	1.320	6.063	-	-	-	-	-	11.679
10696	DISULFIRAM POWDERED	-	-	3.830	-	-	-	7.354	-	-	-	-	-	11.184
10819	CLODRONIC ACID DISODIUM	-	-	-	-	-	1.669	-	-	-	-	-	-	1.669
11358	OLSALAZINE SODIUM	-	232	-	-	-	-	-	-	-	-	-	-	232
11466	NAPROXEN ACID	8.849	-	-	-	-	12.387	-	-	-	-	-	-	21.236
11485	MESALAMINE HIGH DENSITY	-	-	-	1.135	1.860	3.194	-	270	779	-	-	-	7.238
12361	RACTOPAMINE HYDROCHLORIDE	-	-	-	-	-	-	-	-	-	835	-	-	835
12492	BENSERAZIDE HCL CRUDE	-	3.190	5.303	5.129	5.130	962	-	-	-	-	-	-	19.714
600000	BENZOIL METRONIDAZOLE GREZZO	19.900	-	-	-	-	-	-	-	-	-	11.047	8.747	39.694
600004	C 7 GREZZA	-	-	-	12.895	7.700	-	-	-	-	-	-	-	20.595
600005	CIMETIDINE II GETTI PURIFICATA	-	-	-	900	1.930	-	-	-	-	-	-	-	2.830
600013	PYRIDINE METHANOL DISTILLATO	-	-	-	-	3.266	3.308	2.314	-	-	-	-	3.326	12.214
600014	DOXILAMINA BASE GREZZA	-	-	-	-	3.378	2.580	5.265	-	-	-	-	4.325	15.548
600017	RITANITRILE CRISTALLIZZATO SECCO	-	5.208	2.256	-	-	-	-	-	8.159	10.932	465	-	27.020
600021	RITAMIDE CRISTALLIZZATA SECCA	-	-	4.856	4.169	-	-	-	-	-	12.617	5.784	-	27.426
600040	SALE POTASSICO	8.260	1.785	6.490	17.465	7.390	12.845	9.160	-	-	15.675	9.400	3.730	92.200
600075	AMINO ALCOOL	-	-	5.440	-	-	-	2.040	-	-	-	2.040	-	9.520
600083	BENZOFURAZAN -1- OXIDE	-	-	-	-	-	-	-	-	-	2.135	-	-	2.135
600085	CHINOSSALINA	-	-	-	-	-	-	-	-	29.220	3.130	-	-	32.350
600086	ACETILIDRAINE (CARBAZATO)	-	-	-	-	-	-	-	-	32.400	-	-	-	32.400
600092	DL-SERINE METHYLESTERE	8.898	840	-	-	-	-	-	-	-	-	-	-	9.738
600093	DL-SERINE GREZZA	2.855	8.265	-	-	-	-	-	-	-	-	-	-	11.120
600281	BENSERAZIDE HCL CRUDE	-	4.180	5.720	5.720	5.720	660	-	-	-	-	-	-	22.000
600286	CARBADOX T.Q.	-	-	-	-	-	-	-	-	27.300	14.500	-	-	41.800
600411	DISULFIRAM GREZZO	-	800	3.300	-	-	1.370	4.935	-	-	-	-	-	10.405
601517	ESTERE DICLOROFOSFONICO	-	-	-	-	-	1.250	-	-	-	-	-	-	1.250
601800	POTASSIO IDROSSIDO SOLUZIONE 27%	16.800	-	-	-	16.800	11.200	-	-	-	-	19.600	8.400	72.800
600023	AC-RACEMATO UMIDO	-	-	-	8.694	2.629	-	-	-	-	5.657	10.212	6.201	33.393
600025	C-RACEMATO UMIDO	-	-	-	4.655	4.025	-	-	-	-	-	9.482	6.357	24.519
		228.572	145.296	159.524	226.931	220.943	228.220	289.878	6.767	403.272	219.743	199.366	161.669	2.490.179

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Quality Control

The Quality Control is responsible for:

- Analytical control of raw materials, intermediates and packaging materials
- Analysis and approval of finished products
- Reference standard management and storage
- Stability protocols and studies
- Validation of analytical methods

Quality Control

The QC Laboratory is equipped with advanced instrumentation for analytical testing of APIs

Quality Control

Examples of QC equipments:

- **13** HPLCs (Diode Array Detector, Refractive Index, conductometer, Fluorescence) and **4** GCs
- FTIR, polarimeter, UV spectrophotometer, KF and 3 potentiometric titrators, 2 pHmeters , 3 balances
- 2 Stability chambers
- TGA apparatus
- ICP Optical
- Particle size analyzers (Malvern, Alpine, Sifting)
- Turbidimeter, colorimeter, 2 melting point apparatus, potentiometric stripping analyzer for heavy metals
- Thermo gravimetric balance

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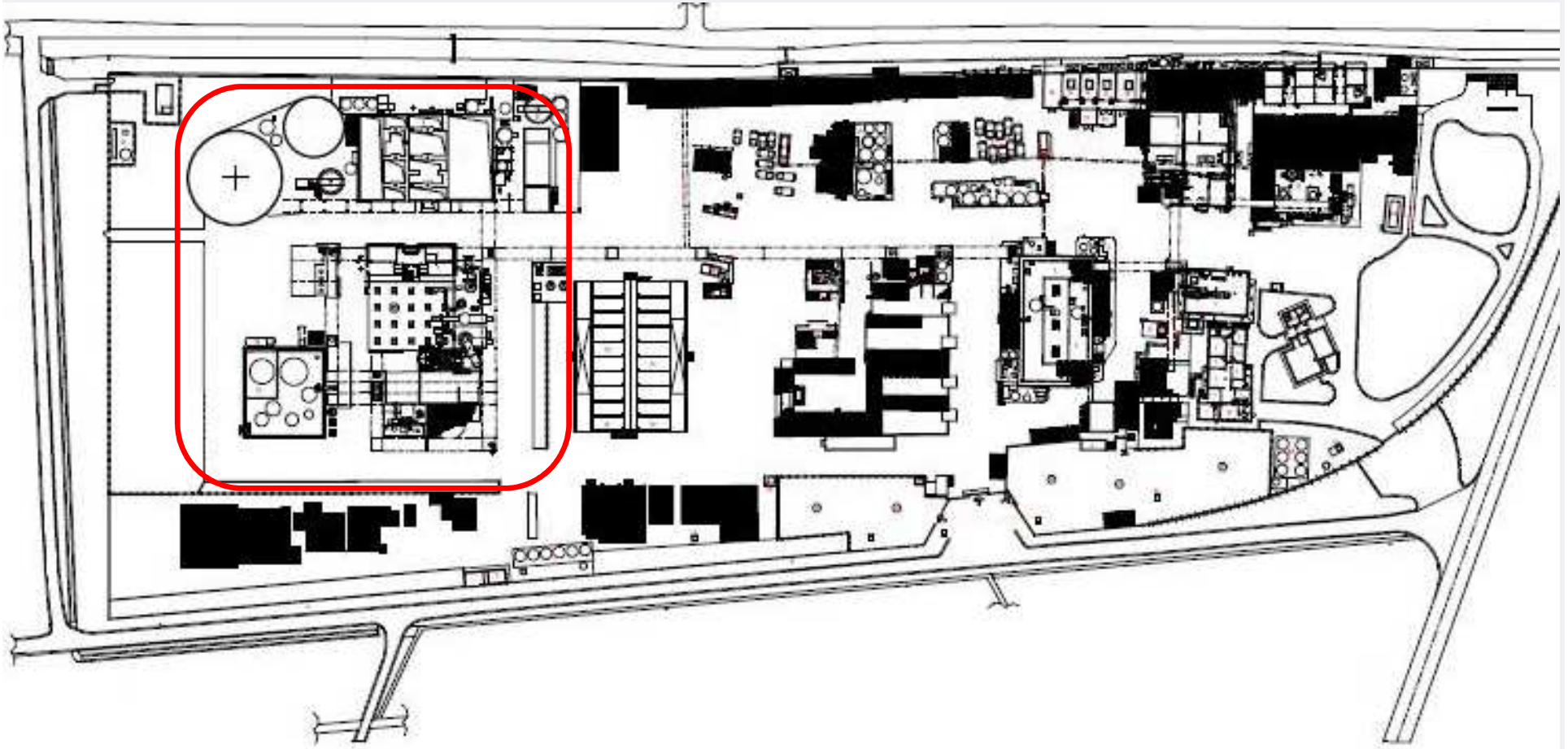
Farchemia Site MAP

Waste treatment plant



Safety & Environment

FARCHEMIA pays great attention to environmental and industrial safety, employing advanced techniques in order to comply with national legislation and environmental regulation

The waste treatment station

The Waste Water Biological Treatment plant has been in operation since January 1992.

It has a capacity of about 5 tons/day of COD (*Chemical Oxygen Demand*)

Safety & environment

The incinerator has been operating since 1990. It is able to incinerate about 60 tons/day of waste streams

The waste treatment station

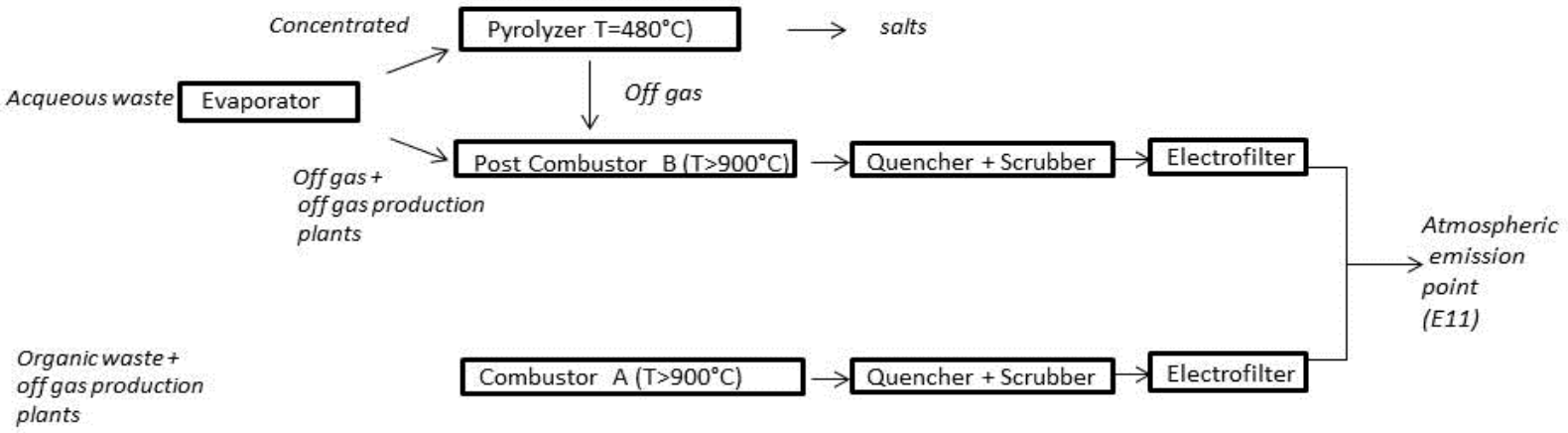
The incineration plant consists of:

- A pre-concentration stage
- Rotating pyrolysis oven
- 2 incineration ovens
- Heat recovery facility (steam generators)

Safety & environment

WASTE DEPARTMENT

1. INCINERATOR (60 Mt/day of waste streams)



Safety & environment

A fire prevention network serves all the installed reactors, operating with water and extinguishing foam sprayed at 7 bars of pressure, guaranteed by 2 independent pumps

A fire fighting gun placed on a tower 15m high serves the flammable solvents warehouse, it is also equipped with a fire *sprinkler system*

Health & Safety Training

Farchemia staff participate in the training program which is organized as required by current legislation

(Italian law D. Lgs n° 81 April 9th 2008 e s.m.i.; D. Lgs. n° 334 August 17th 1999 e s.m.i.)

Safety Management System Certificate

which fulfills the requirements of the standard

OH SAS 18001:2007

Issued on: 2013/07/16

Expire on: 2016/07/15

Training courses for the technicians operating in the plants are regularly organised.

Specific courses are also organized for:

- Licenses for toxic gas handling
- Steam generator operators
- Firefighting emergencies
- First aid & emergencies
- Foreign languages
- GMP training (annual)
- Ethics (Law 231/2001)

Health care program

The site MD is the Director of the Unit of Occupational Medicine of the Hospital Papa Giovanni XXIII in Bergamo.

In compliance with the D. Lgs. 81/2008 and subsequent amendments, the occupational physician has prepared a health monitoring plan and an individual medical record for each worker who undergoes health surveillance

The health monitoring plan provides for periodic assessments depending on the specific risks identified in the "Document on Risk Assessment" conducted according to the D. Lgs. 81/2008, as amended, for all staff,; these assessments and periodic medical examination, if indicated by the doctor in charge, can be integrated with in-depth by instrumental tests, laboratory and specialist medical examinations.

Health care program

The health monitoring program includes:

- X- rays
- Ear tests
- Spyrometric tests
- Blood tests
- Biological monitoring

In the factory there is always a team of First Aid: A group of trained persons to carry out the necessary first aid and emergency medical care.

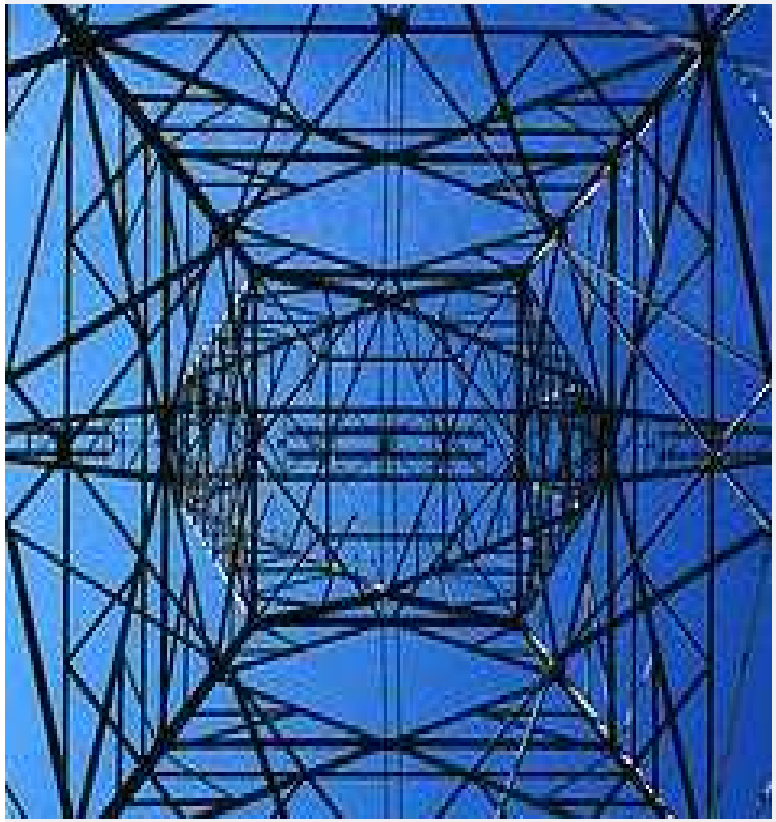
The training of the staff of First Aid and was conducted in accordance with DM 388/2003.

Inside Farchemia

- R&D
- Engineering & Maintenance
- Warehouses
- Production
  - Plant A
  - Plant B
  - Drying & Packaging Plant
- Quality Assurance
- Regulatory Affairs
- Quality Control
- Safety & Environment
- Utilities

Utilities

Energy



Installed electrical power: 4100 KvA

Two different rings connected to the external 15.000 V network

Emergency power generator of 700 KvA (Diesel Power Engine) - turns on automatically in case of black-out

Emergency lighting, temperature indicators, process computers, fire hydrants and equipment are directly connected to the emergency generator

On-site generated electrical power can be distributed to the different units

Utilities

Industrial water

- The water supply is pumped at a rate of up to 390 m3/h, using a system consisting of 3 different wells up ot 42 meters in depth.
- Water is pumped into a piezometric tower providing a constant pressure of 2.8 bar

Utilities

Purified water

- Purified water is obtained using drinking water supplied by the municipality of Treviglio, which is filtered through a two step reverse osmosis plant.
- The quality of our purified water compliant with USP and EP monographs.

Utilities

Cooling system

- Brine utility: 40% Ethylene Glycol
- The cooling unit is equipped with screw compressors, an evaporator and a condenser which produce 380.000 Frig/h at -20° c

Utilities

Heating system

- 3 steam generators produce circa 10 tons/h of saturated steam at 10 bar of pressure using fuels.
- 50% of the heat is recovered from the incineration plant
- Heat generation: up to 17.000.000 Cal/h