

IPOCHEM Sp. z o.o.

ORGANIC SYNTHESIS



POLAND

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www.ipochem.com.pl

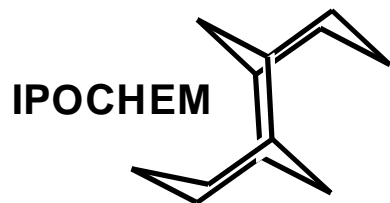
tel: +48 22 519 47 40

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ISO 9001:2008

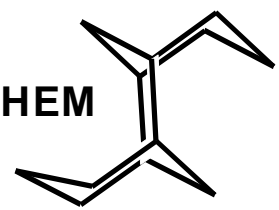
www.tuv.com
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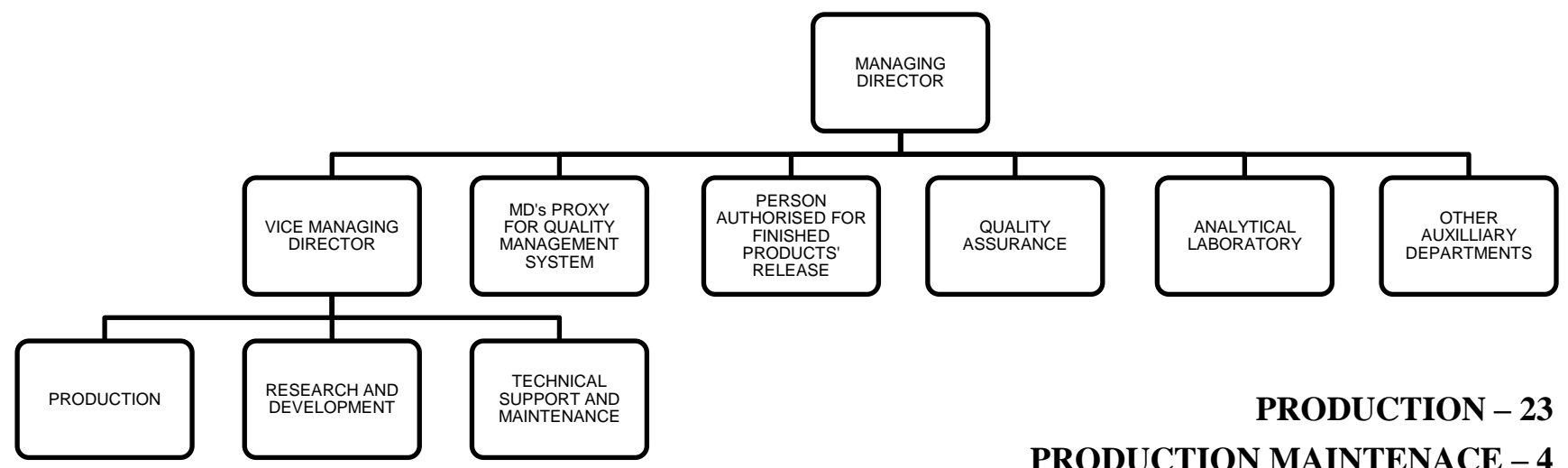
HISTORY

- **1988 – FOUNDATION
BY THE INSTITUTE OF INDUSTRIAL ORGANIC CHEMISTRY**
- **1998 – WARSAW PHARMACEUTICAL WORKS POLFA AS THE BIGGEST
SHAREHOLDER WITH 80% OF SHARES**
- **2001 – NEW GMP-COMPLIANT FACILITY FOR POST-CRITICAL STAGES
IN APIs' PRODUCTION**
- **2005 – ISO 9001:2000 CERTIFICATION BY TÜV RHEINLAND,
LATER UPHELD ACCORDING TO ISO 9001:2008**
- **2007 – NEW GMP-COMPLIANT FACILITY FOR APIs' PHYSICAL
PROCESSING**
- **2011/2014/2017 –SUCCESFUL GMP INSPECTIONS
BY THE POLISH MAIN PHARMACEUTICAL INSPECTOR (GIF)**
- **2012 – PART OF THE POLPHARMA GROUP**

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STAFF

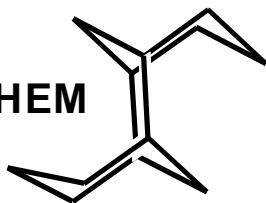


HIGHLY SKILLED AND EXPERIENCED TEAM EDUCATIONAL BACKGROUND:

- PHD (2)**
- UNIVERSITY DEGREE (26)**
- SECONDARY TECHNICAL EDUCATION (12)**
- PROFESIONAL EDUCATION (8)**

- PRODUCTION – 23**
- PRODUCTION MAINTENACE – 4**
- RESEARCH & DEVELOPMENT – 3**
- ANALITYCAL LABORATORY – 5**
- QA AND QC – 4**
- SALES AND PURCHASING – 3**
- ACCOUNTING – 2**
- INVESTMENTS – 1**
- ENVIRONMENT PROTECTION -1**
- MANAGING BOARD - 2**

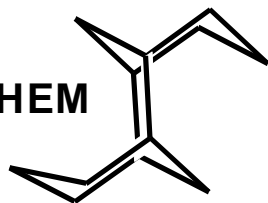
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SCOPE OF OFFER

- **ACTIVE PHARMACEUTICAL INGREDIENTS**
 - **QUALITY COMPLIANT WITH CURRENT MONOGRAPHS : EP / BP / USP**
 - **ASMF DOCUMENTATION IN CTD FORMAT**
- **CHEMICAL INTERMEDIATES FOR PHARMA INDUSTRY**
- **CUSTOM SYNTHESIS**
- **POWDERING AND MICRONIZATION**
 - **AIR JET MILLS**
 - **PARTICLE SIZE DISTRIBUTION LASER ANALYSIS**
- **DEVELOPMENT AND TRANSFER OF PROCESSES AND TECHNOLOGIES**
 - **DEFINING AND IMPLEMENTING COMPLETE MANUFACTURING METHODS**

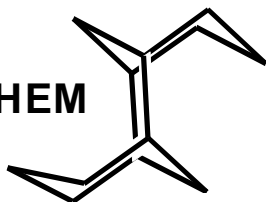
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FIELDS OF EXPERTISE

- **SYNTHESIS OF CHIRAL ACTIVE PHARMACEUTICAL INGREDIENTS**
- **SYNTHESIS WITH CHIRAL SUBSTRATES**
- **SYNTHESIS INCLUDING ALKALINE CYANIDES APPLICATION**
- **SYNTHESIS OF 5-MEMBERED HETEROCYCLIC RINGS**
- **GRIGNARD REACTIONS**
- **REACTIONS UTILIZING Cl_2 , Br_2 , KCN , SOCl_2**
- **CATALYTIC HYDROGENATION (50 ATM)**
- **DIAZOTIZATION**
- **MICRONIZATION**

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EQUIPMENT

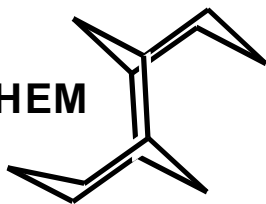
REACTORS	CAPACITY	QUANTITY
Steel glass-lined	1300 L	5
	500 - 600 L	10
	250 L	6
Hastelloy	1600 L	1
	70 L	1

PROCESSING SETS	CHARACTERISTICS	QUANTITY
Vacuum distillations 50, 150, 250 L	$T_{max} = 200^{\circ}\text{C}$; $p_{min} = 3-30 \text{ Tr}$	5
Azeotropic distillations 250, 600 L	$T_{max} = 200^{\circ}\text{C}$	2
p_{atm} distillations 250, 500, 1000 L	$T_{max} = 150^{\circ}\text{C}$	4
Rectifications 100, 250 L	$T_{max} = 150 - 200^{\circ}\text{C}$	4
Crystallizations 150, 250, 500 L		3
Rotary evaporators 10, 20, 50 L	$p_{min} = 30 \text{ Tr}$	4

PLANT INSTALLATIONS	CHARACTERISTICS
Central Vacuum	$p_{min} = 30 \text{ Tr}$
Low Vacuum	$p_{min} = 2 - 3 \text{ Tr}$
Central Process Steam	$p_{max} = 6 \text{ atm}$
Compressed Air	$p_{max} = 6 \text{ atm}$
Cooling (ethylene glycol)	-35°C
Heating (process steam, oil)	$160^{\circ}\text{C}, 250^{\circ}\text{C}$

OTHER EQUIPMENT	CHARACTERISTICS
Filters (pressure, vacuum, flow)	20 - 300 L
Dryers (tray vacuum, shelves, fluid bed)	$T_{max} = 130^{\circ}\text{C}$
Grinders (jet mill, oscillating granulator)	
Ultra-filtration set - dedicated for Iron (III) Dextran	

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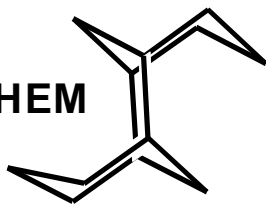


PREMISES

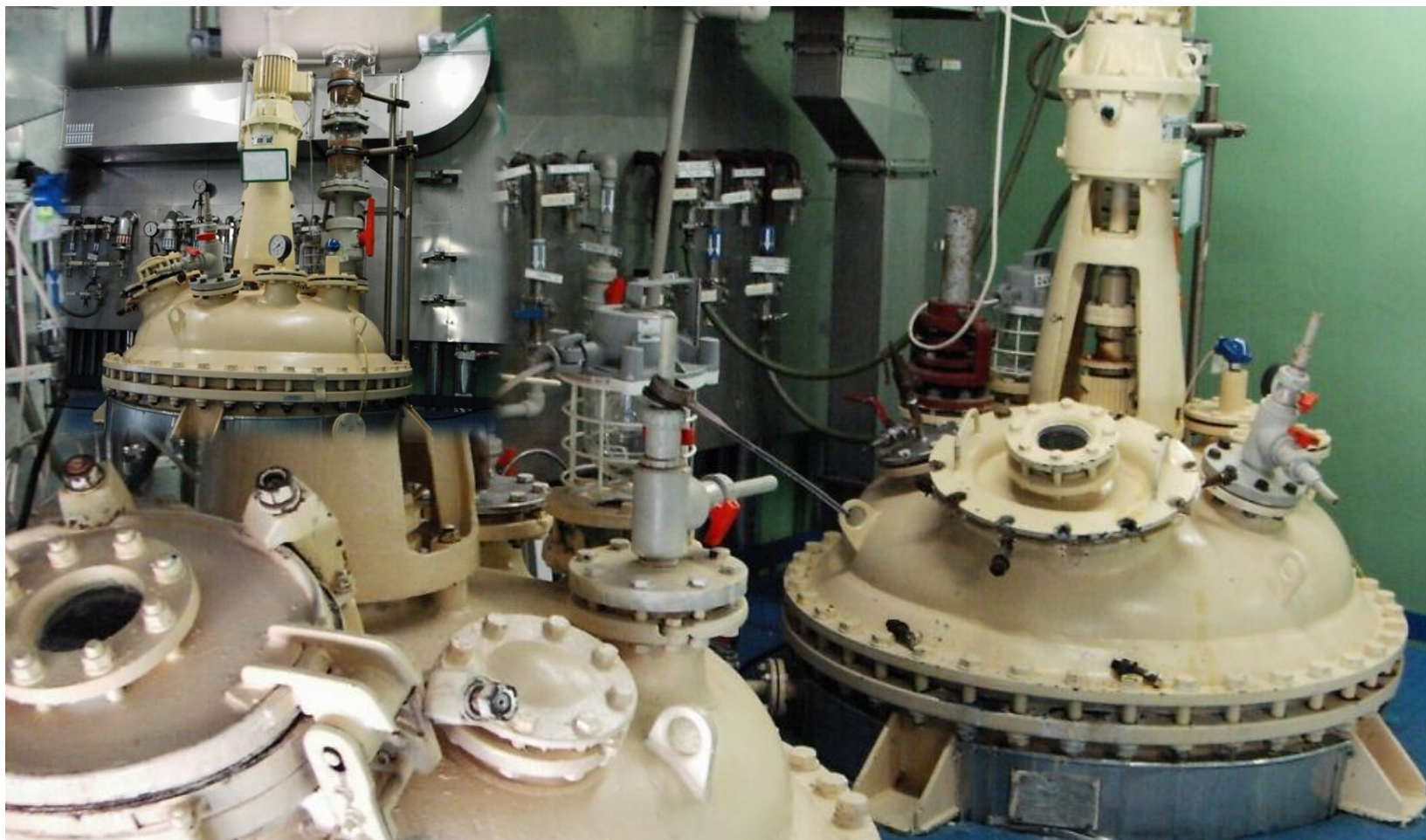


PRODUCTION FACILITY FOR APIS' PHYSICAL PROCESSING

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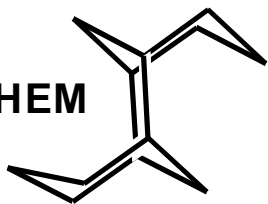


PREMISES



TWO-STOREY PLANT FOR POST-CRITICAL STAGES IN APIS' PRODUCTION

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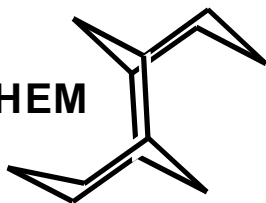


PREMISES



FOUR-STOREY SYNTHESIS PLANT FOR OPERATIONS IN CONDITIONS: -30 - 200°C / 3 TR-50 ATM

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LIST OF PRODUCTS

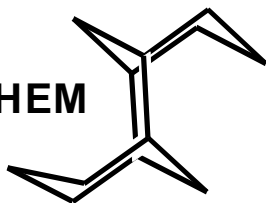
ACTIVE PHARMACEUTICAL INGREDIENTS:

ACENOCOUMAROL
ANTAZOLINE HYDROCHLORIDE
ANTAZOLINE MESYLATE
ANTAZOLINE SULPHATE
CHLORMIDAZOL
CLEMASTINE FUMARATE
CLOPAMIDE
DIISOPROMINE HYDROCHLORIDE
IRON (III) DEXTRAN
ITCL-DENOTIVIR
MOLSIDOMINE
NEFOPAM HYDROCHLORIDE
UNDECYLENAMIDE MEA
XYLOMETAZOLINE HYDROCHLORIDE

INTERMEDIATES:

2-(2-CHLOROETHYL)-1-
METHYLPYRROLIDINE
HYDROCHLORIDE
DIMEPRANOL ACEDOBN
4-HYDROXYBENZYL ALCOHOL
8-HYDROXYQUINALDINE
1-METHYL-2-PYRROLIDINEETHANOL
3-MORPHOLINOSYDNONIMINE, HCL
POTASSIUM ETHYL CARBONATE
N-(p-TOLUENESULFONYL)-
L-GLUTAMIC ACID
2,3,5-TRICHLOROBENZALDEHYDE

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CORE PRODUCTS

ACENOCOUMAROL

CAS RN: 152-72-7
BP current edition

ANTAZOLINE HYDROCHLORIDE

CAS RN: 3131-32-6
EP current edition

ANTAZOLINE SULPHATE

CAS RN: 24359-81-7
Internal specification

CLEMASTINE FUMARATE

CAS RN: 14976-57-9
EP current edition

CLOPAMIDE

CAS RN: 636-54-4
EP current edition

XYLOMETAZOLINE HYDROCHLORIDE

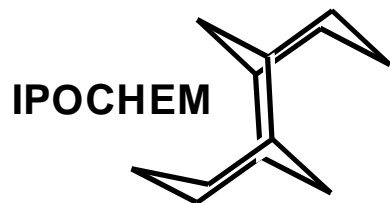
CAS RN: 1218-35-5
EP current edition

MOLSIDOMINE

CAS RN: 25717-80-0
EP current edition

1-METHYL-2- PYRROLIDINEETHANOL

CAS RN: 67004-64-2
Internal specification



KEY CUSTOMERS

GLAXOSMITHKLINE PHARMACEUTICALS (POLAND)

VALEANT - ICN POLFA RZESZÓW (POLAND)

VALEANT - JELFA S.A. (POLAND)

HASCO-LEK S.A. (POLAND)

THERABEL PHARMACEUTICALS (IRELAND)

TOYOTA TSUSHO CORPORATION (JAPAN)

STADA ARZNEIMITTEL AG (GERMANY)

PHARCO PHARMACEUTICALS (EGYPT)

SANDOZ – SALUTAS (GERMANY)

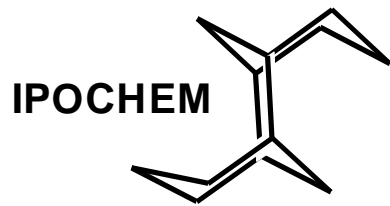
ARROW GENERIQUES (FRANCE)

NOVARTIS PHARMA PAKISTAN

SEKISUI MEDICAL (JAPAN)

SANOFI-AVENTIS (SPAIN)

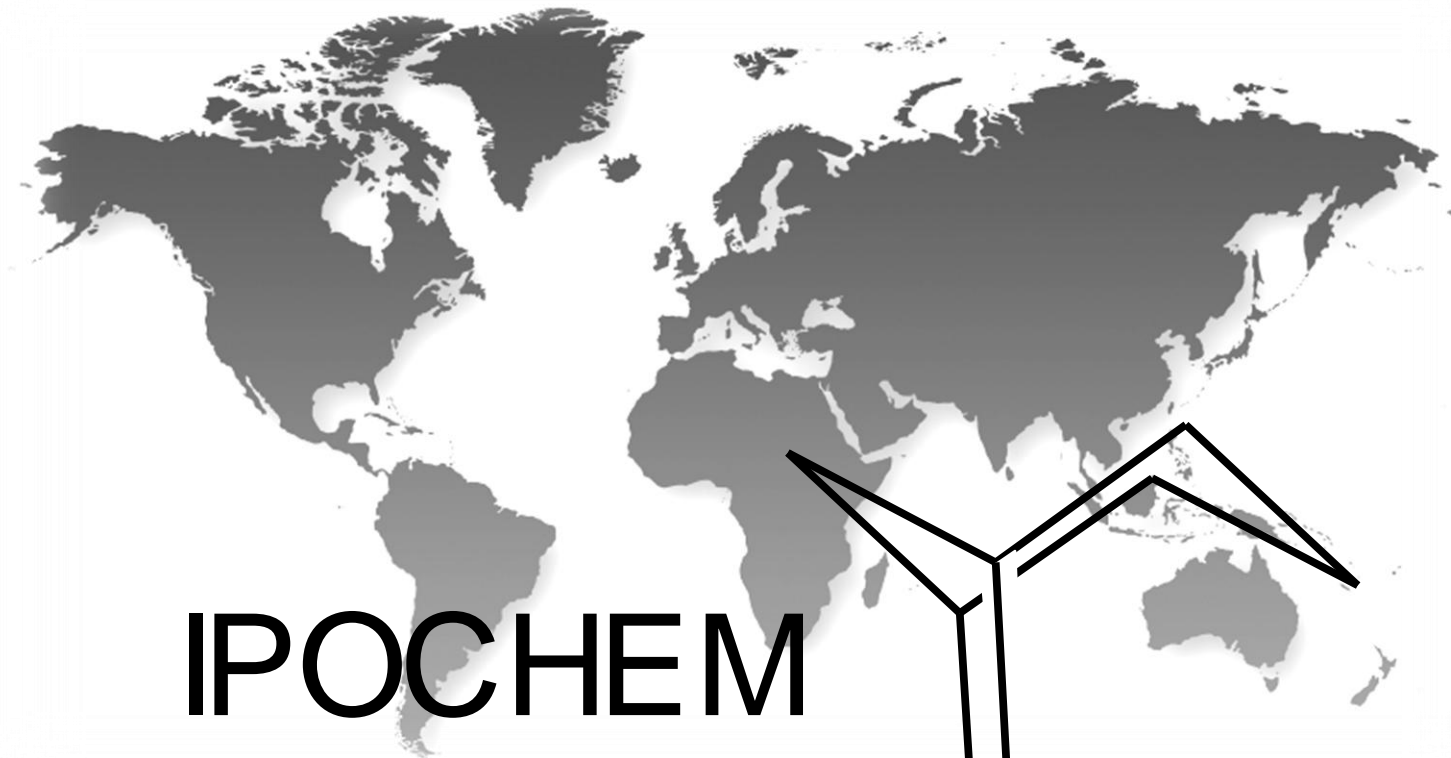
MYLAN (FRANCE)



CERTIFICATES APPROVALS

- **GMP COMPLIANCE CERTIFICATES
(OF POLISH MAIN PHARMACEUTICAL INSPECTOR):
GIF-IW-400/0394_01_01/04/208-1/14
GIF-IW-400/0394_01_01/04/21/17**
- **TÜV RHEINLAND ISO 9001:2008 CERTIFICATE
FOR QUALITY MANAGEMENT SYSTEM**
- **CUSTOMERS' AUDITS AND APPROVALS:
VALEANT, POLFA, POLPHARMA, PHARMACEUTICAL
RESEARCH INSTITUTE, GSK, SANOFI-AVENTIS, SANDOZ,
MYLAN, STADA ARZNEIMITTEL, NOVARTIS.**

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