



# Mac-Chem Products (I) Pvt. Ltd

# Accreditation



USFDA



EDQM



ANVISA



COFEPRIS



MFDS – KOREA



WHO-GMP

WC (Written Confirmation)

# Introduction

**Mac-Chem Products (India) Pvt. Ltd, Established in 2010, has set up the state of art, cGMP compliant manufacturing facility at Boisar which is 100Km away from financial capital of India – Mumbai.**

**Mac- Chem is a part of NMM Group (Naprod, Mac-Chem & Miraculus). Naprod was started in 1985 with manufacturing of general injectables and OSD.**

**In 1992 Naprod started manufacturing of Oncology injectables. API manufacturing was commenced in 1996.**

**Mac-Chem Products (India) Pvt. Ltd., specializes in the field of oncology & lyophilized bulk sterile products supported by integrated manufacturing, regulatory, sales, marketing & distribution set up.**

**Over the years the company has emerged as a global player in the field of oncology and sterile products by providing high quality products at affordable prices supported by superior customer services.**



# What we do???

**Oncology APIs**

**Lyophilized Bulk Sterile**

**General APIs**

**Generics  
Company**

**What we  
aim for...**

**Quality driven**

**Cost effective**

**Delivery**

**Development & Manufacturing excellence**

# Mac-Chem Products (I) Pvt. Ltd.

## Global Presence

Presence in over 40 Countries



CEP approved for 7 API's



CEP applied for 5 new API's



USDMF Submission for 12 API's



API DMF's/CEP's already filed by leading formulation manufacturers in EU, LATAM, MENA, CIS, SEA Markets



DMF available in CTD Format

# OUR MILESTONES

2010

- Qualification and Validation activities completed.
- API Production started.

2011

- Local FDA GMP and GLP certification.

2012

- Certification by ISO14001 and OSHAS 18001 received.
- WHO GMP certification received by CDSCO India.

2013

- Manufacturing of Sterile API started.
- Received CoS for Dacarbazine , Suxamethonium and Carboplatin.

2014

- Manufacturing Site approved by MFDS Korea
- Received CoS for Letrozole.

2015

Received CoS for Cytarabine

2016

Received COFEPRIS approval for Dacarbazine  
 Received ANVISA approval for Acyclovir sterile, Carboplatin, Cisplatin  
 Received EDQM approval for Suxamethonium

2018

Received USFDA approval for General Block

2019

Received CoS for Gefitinib & Ropivacaine Hydrochloride





# Regulatory : DMF's / CEP's

Sr. No.	Product Name	Category	US DMF No.	CEP NO.
1.	Succinylcholine Chloride	General API	25440	R1-CEP2012-025-Rev.00
2.	Dacarbazine	Oncology API	25624	R1-CEP2012-066-Rev.00
3.	Carboplatin	Oncology API	26029	R1-CEP2012-147-Rev.00
4.	Letrozole	Oncology API	26550	R0-CEP2012-350-Rev.00
5.	Cytarabine	Oncology API	26281	R0-CEP2012-251-Rev.01
6.	Pemetrexed disodium heptahydrate	Oncology API	-	R0-CEP 2015-141-Rev.00
7.	Bicalutamide	Oncology API	26355	-
8.	Irinotecan HCl Trihydrate	Oncology API	26554	CEP Applied
9.	Anastrozole	Oncology API	26581	-
10.	Docetaxel Trihydrate	Oncology API	26580	-
11.	Capecitabine	Oncology API	27026	-
12.	Oxaliplatin	Oncology API	27028	-
13.	Gefitinib	Oncology API	-	R0-CEP 2017-164-Rev 00
14.	Gemcitabine Hydrochloride	Oncology API	-	CEP Applied
15.	Methotrexate	Oncology API	-	CEP Applied
16.	Neostigmine MethylSulfate	General API	-	CEP Applied
17.	Ropivacaine Hydrochloride	General API	27027	R0-CEP 2017-246-Rev 00

# Manufacturing Portfolio – Oncology

Sr. No.	Description	CAS No.	Pharmacopeia
1	Abiraterone Acetate (Pure)	[154229-18-2]	IP/USP
2	Anastrozole	[120511-73-1]	IP/USP
3	Bendamustine Hydrochloride	[3543-75-7]	IH/IP
4	Bicalutamide	[90357-06-5]	USP
5	Capecitabine	[154361-50-9]	IP/USP
6	Carboplatin	[41575-94-4]	IP/BP/USP/PH.EUR.
7	Cisplatin	[15663-27-1]	IP/BP/PH.EUR.
8	Cladribine	[4291-63-8]	USP
9	Cytarabine	[147-94-4]	IP/BP/USP/PH.EUR.
10	Dacarbazine	[4342-03-4]	BP/USP/PH.EUR.
11	Docetaxel Trihydrate	[148408-66-6]	IP/USP/PH.EUR.
12	Erlotinib Hydrochloride	[183319-69-9]	IH/IP
13	Fludarabine Phosphate	[75607-67-9]	IP/USP/PH.EUR./BP
14	Gefitinib	[184475-35-2]	IP/PH.EUR./PN
15	Gemcitabine Hydrochloride	[122111-03-9]	IP/BP/USP/PH.EUR.
16	Imatinib Mesylate	[220127-57-1]	PN/IP/EP
17	Irinotecan Hydrochloride	[136572-09-3]	IP/USP/PH.EUR.
18	Lenalidomide API	191732-72-6	IH
19	Letrozole	[112809-51-5]	BP/USP/PH.EUR.
20	Methotrexate	[59-05-2]	IP/BP/USP/PH.EUR.
21	Oxaliplatin	[61825-94-3]	BP/PH.EUR./USP
22	Paclitaxel	[33069-62-4]	IP/USP/PH.EUR.
23	Pemetrexed Disodium Heptahydrate	[357166-29-1]	IP/USP/PH.EUR.
24	Temozolomide	[85622-93-1]	IP/USP
25	Zoledronic Acid	[165800-06-6]	IP/PN



# Manufacturing Portfolio – General

Sr. No.	Description	CAS No.	Pharmacopeia
1.	Aprepitant	[170729-80-3]	USP
2.	Atracurium Besylate	[64228-81-5]	IP/USP
3.	Colistimethate Sodium	[8068-28-8]	IP/USP
4.	Dexmedetomidine HCl*	[145108-58-3]	IH
5.	Fosaprepitant Dimeglumine	265121-04-8	IH
6.	Hydrocortisone Hemisuccinate		
7.	Methylprednisolone Base	[2921-57-5]	IP/BP
8.	Neostigmine Methylsulfate	[51-60-5]	PH.EUR./BP/USP/IP
9.	Neostigmine Bromide	[114-80-7]	PH.EUR./BP/USP/IP
10.	Ropivacaine Hydrochloride	[132112-35-7]	PH.EUR./BP/USP
11.	Vecuronium Bromide	[50700-72-6]	BP/USP
12.	Suxamethonium Chloride / Succinyl Choline Chloride	[6101-15-1]	PH.EUR./BP/USP/IP

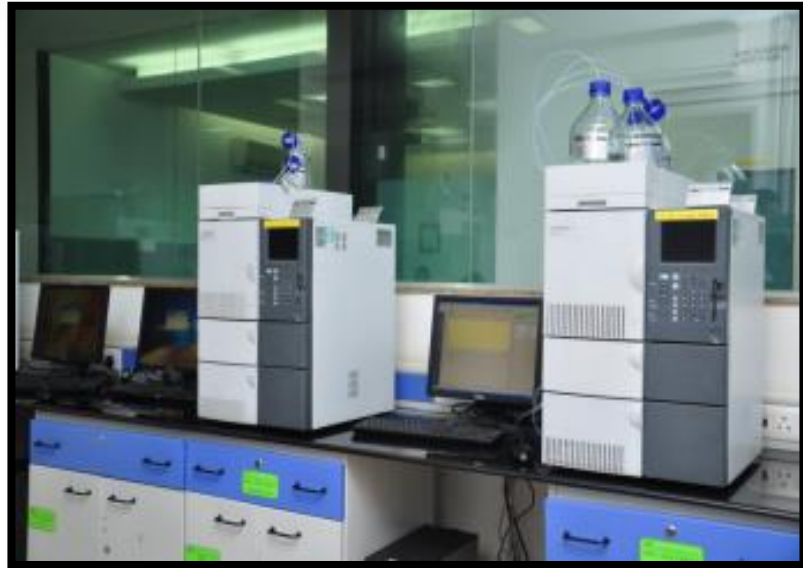
# Manufacturing Portfolio - Sterile

Sr. No.	Description	CAS No.	Pharmacopeia
1	Acyclovir	[69657-51-8]	USP
2	Chloramphenicol Sodium Succinate	[56-75-7]	IP/BP
3	Clarithromycin for Infusion	[81103-11-9]	BP
4	Colistimethate Sodium	[8068-28-8]	IP/USP
5	Esomeprazole Sodium	[161796-78-7]	IH
6	Glutathione	[70-18-8]	IH
7	Hydrocortisone Sodium Succinate	[125-04-02]	IP/USP
8	Methylprednisolone Sodium Succinate	[2375-03-3]	USP
9	Omeprazole Sodium	[95510-70-6]	IH
10	Pantoprazole Sodium	[102625-70-7]	IH
11	Succinyl Choline Chloride	[71-27-2]	IH
12	Tenoxicam	[59804-37-4]	BP

# PRODUCT UNDER DEVELOPMENT

Sr. No.	Description	Category
1	Polymyxin B Bulk Sterile	General
2	Etoposide	Oncology
3	Azacitidine	Oncology
4	Bortizomib	Oncology
5	Cabazitaxel	Oncology
6	Dexmedetomidine HCL	General
7	Fosfomycin Sodium Bulk Sterile	General
8	Hydrocortisone Acetate	General
9	Lapatinib	Oncology
10	Midazolam	General
11	Rocuronium Bromide	General
12	Enzalutamide	Oncology
13	Sorafenib Tosylate	Oncology
14	Dasatinib Monohydrate	Oncology
15	Sunitinib	Oncology
16	Ibrutinib	Oncology
17	Decitabine	Oncology
18	Caspofungin	General
19	Micafungin	General
20	Adrenaline	General
21	Noradrenaline	General
22	Afatinib	Oncology
23	Tigecycline Sterile	General
24	Vancomycin Sterile	General
25	Pralatraxate	Oncology

# API Manufacturing Facility, Boisar



# API Manufacturing Facility, Boisar



# INTERNATIONAL TOP CUSTOMERS



STADA – Germany



Laboratorio Teuto (Pfizer Group) – Brazil



Jelfa (Vivatis) – Germany



Martindale Pharma – United Kingdom



Laboratorios Almiro, S.A. (LABESFAL) –  
Portugal



Laboratorios Pisa S.A. de C.V. – Mexico



Laboratoire Aguettant – France

# INTERNATIONAL TOP CUSTOMERS



Amino AG – Switzerland



**BRAUN**  
SHARING EXPER

B. Braun Medical, S.A. – Spain



**FRESENIUS  
KABI**  
caring for

Fresenius Kabi – South Africa



**Blau**  
FARMACEUTICA

Blau Farmaceutica S.A. – Brazil



*Marcyrl*

Marcyrl Pharmaceutical Industries – Brazil



**AMGEN**  
BRAS

Amgen – Brazil



**AIKMA**  
A.I.I.

Hikma – Egypt



**enma**  
y for a

Glenmark Generics SA – Argentina

## DOMESTIC TOP CUSTOMERS



Dr. Reddys Laboratories Limited



Fresenius Kabi Oncology Ltd.



Glenmark Pharmaceuticals Ltd



Sun Pharmaceutical Industries Ltd.



Cipla Ltd



Hetero Labs Ltd



Macleods Pharmaceuticals Limited



Thank

you

