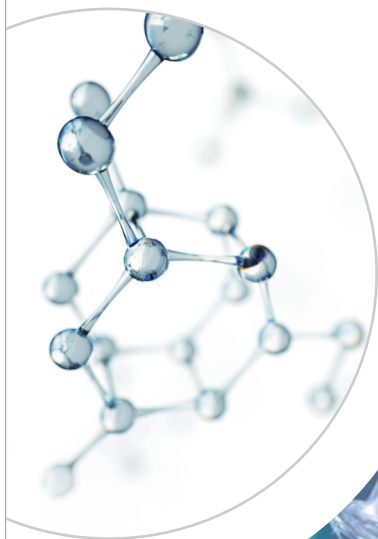




***Mangalam Drugs and Organics Limited***



## ABOUT US



Mangalam Drugs & Organics Limited commenced its manufacturing of Active Pharmaceutical Ingredients (APIs) and Intermediates at VAPI – Gujarat in 1977. It has a multi-product manufacturing facility on two locations, and an in-house Research & Development laboratory recognized by the Department of Scientific & Industrial Research, Delhi Govt. of India (DSIR).

Over the last four decades, Mangalam has acquired worldwide reputation as a single stop destination for frontline Anti-malaria. We also have a diversified product range having synergies in operations and economies of scale. Mangalam is amongst the top companies in Asia in all the products it makes; and is also the largest manufacturer of some of its products in the world.



*Indian Pharma Manufacturers Roundtable  
with Bill Gates, Co-Chair - Gates Foundation*

Along with the **WHO-GENEVA GMP**, **MFDS Korea** Certification and **EDQM** approval for its API manufacturing plant, the company is also in an agreement with the prestigious **Clinton Health Access Initiatives (CHAI)** under its Fight Malaria Program for supply of anti-malaria APIs worldwide.



*Mr. G. M. Dhoot [MD and Chairman of MDOL]  
with Founder of CHAI, President Clinton*

## VISION & MISSION

To be a persistently customer engaged API manufacturing company in the healthcare business and thereby achieving growth in the industry by:

- ▶ Transparency in business
- ▶ Attaining globally competitive cost of all our products by offering the best quality
- ▶ Enhancing the value we deliver to our stakeholders
- ▶ Commitment to Corporate Social Responsibility
- ▶ Creating an environment that fosters ideas, growth and excellence

## QUALITY POLICY & SYSTEM

We are committed to satisfy our customers' needs and expectations. We understand and believe we can meet commitments to customers by:

- ▶ Employee - Vendor Involvement
- ▶ Adopting Current Good Manufacturing Practices
- ▶ Quality management system with continual improvement
- ▶ Emphasis on environmental protection

Our Quality Assurance department encompasses alert and untiring professionals who ensure and implement the above.

## LIST OF PRODUCTS

Sr. No.	Active Pharmaceutical Ingredients (Grades)	Stringent Regulatory Agencies (SRAs) and DMF status
		Approved for
Anti-Malaria		
1	Amodiaquine Hydrochloride (USP/IP/IH)	WHO-Geneva
2	Artemether (USP/Ph.Int./IP)	WHO-Geneva
3	Artesunate (Ph.Int./IP)	WHO-Geneva
4	Dihydroartemisinin (Ph.Int.)	WHO-Geneva and EMA
5	Lumefantrine (USP/Ph.Int./IH)	WHO-Geneva
6	Primaquine Phosphate (USP/EP/BP/IP)	WHO-Geneva
7	Piperaquine Phosphate (IH)	WHO-Geneva and EMA
8	Pyrimethamine (USP/EP/Ph.Int./IP/IH)	WHO-Geneva
9	Pyronaridine Tetra Phosphate (IH)	WHO-Geneva
10	Sulfadoxine (USP/EP/Ph.Int./IP/IH)	WHO-Geneva and EDQM
11	Chloroquine Phosphate (EP/BP/IP)	-
Anti-Retroviral		
12	Atazanavir Sulfate (Ph. Int./IP/IH)	-
13	Dolutegravir Sodium (IH)	WHO-Geneva
14	Efavirenz (USP/Ph. Int./IP/IH)	WHO-Geneva
15	Emtricitabine (USP/Ph. Int./IP/IH)	WHO-Geneva
16	Tenofovir Disoproxil Fumarate (Ph.Int./IP/IH)	WHO-Geneva
17	Tenofovir Alafenamide Fumarate (IP / IH)	-
Anti-Hypertensive		
18	Bisoprolol Fumarate (USP/EP/IP)	-
19	Furosemide (USP/EP/BP/IP)	BfArM, Germany, EDQM
Anti-Inflammatory		
20	Nimesulide (EP/BP)	EDQM
Anti-Convulsant		
21	Pregabalin (EP/IP)	EDQM
Anti-Viral		
22	Acyclovir (Aciclovir) (EP/IP/USP/Ph.Int.)	EDQM
Anti-Rheumatic Arthritis Agent		
23	Hydroxy Chloroquine Sulfate (USP/EP/BP/IP)	EDQM
Anti-Bacterial		
24	Nitrofurantoin (USP/EP/IP)	EDQM
25	Nitrofurantoin Macro crystal (USP / EP)	EDQM

## PRODUCTS

No	Intermediates	CAS Number	Name of Related APIs
1	4,7-Dichloroquine (IH)	86-98-6	Hydroxy Chloroquine Sulphate, Chloroquine Phosphate, Amodiaquine Hydrochloride, Piperaquine Tetra Phosphate
2	Ortho phenoxy methane sulfonanilide (IH)	51765-51-6	Nimesulide
3	Tenofovir Alafenamide Base (IH)	379270-37-8	Tenofovir Alafenamide Fumarate
4	Tenofovir Disoproxil Base (IH)	201341-05-1	Tenofovir Disoproxil Fumarate
5	[2-Dibutylamino-1-(2,7-dichloro-9H-fluorene-4-yl)]-ethanol (DBA)	69759-61-1	Lumefantrine
6	4,6-dichloro-5-methoxy pyrimidine (DCMP)	5018-38-2	Sulfadoxine

Sr. No.	Active Pharmaceutical Ingredients (Grades)	CAS No.
Pipeline APIs (Developed at R & D)		
1	Bictegravir Na (IH)	1611493-60-7
Pipeline APIs (Under Development)		
1	Ganaplacide (IH)	1261113-96-5
2	Tafenoquine Succinate (IH)	106635-80-7
3	Pretomanid (IH)	187235-37-6
Future APIs		
1	Risedronate Na	115436-72-1
2	Etodolac	41340-25-4

## R&D

At Mangalam, we strongly believe that Research & Development is the 'backbone' and 'game changer' of the pharma industry. Having this certainty helps us stay constantly passionate and thus making the 50 scientists at our facility precise, proactive and market responsive. Our team boasts of an excellent blend of doctorates and dynamic post graduates who are productive at the bench and are simultaneously capable to address any formidable synthetic or analytical challenge.

The department's aptitude spans right from performance testing & optimization to meeting with most stringent stability and quality requirements. Our state of the art pilot plant and analytical services facility are an extended arm of the R&D department thereby providing continuous support to the team.

Our R&D Lab is approved by the Department of Scientific & Industrial Research (DSIR), Delhi Govt. of India.





## MANUFACTURING FACILITY



- ▶ RO Water plant coupled with EDI and online TOC (Capacity 2KL/hr with circulation system)
- ▶ Air Handling Unit for Microbiology lab and Production area
- ▶ Air Handling Unit with temperature and humidity control in Powder Processing area
- ▶ Reaction Temperatures from  $-10^{\circ}\text{C}$  TO  $275^{\circ}\text{C}$
- ▶ Pilot Plant Facility with S.S. & GL Reactors, Drier, Filtration Equipment etc. able to handle Pressure Reactions upto To  $10\text{ Kg/cm}^2$
- ▶ Total Reactors: 60
- ▶ Total Capacity:  $175\text{M}^3$
- ▶ M.O.C.: SS, GL, MS
- ▶ Equipment for Filtration, Drying, Flash Distillation Etc.
- ▶ Manufacturing Capacity-1500 TPA



## ACCREDITATIONS



World Health  
Organization



European Directorate for the  
Quality of Medicines & HealthCare



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



Ministry of Food and  
Drug Safety



NATIONAL MEDICAL PRODUCTS ADMINISTRATION  
國家藥品監督管理局



## ***Mangalam Drugs and Organics Limited***

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**2 Manufacturing Units at Vapi, Gujarat - INDIA**