Challenging the Frontiers in Healthcare

Pharmaceuticals Limited

Mumbai, INDIA

Macleods Overview

9th ranked Pharmaceutical Company in India *(IMS-ORG April'14)

Vertically Integrated Pharmaceutical Company Developing & Manufacturing APIs & Finished Dosage Forms

- 11 Finished Dosage Manufacturing Facilities
- One API Manufacturing Site – 4 Manufacturing Facilities
- Supported by state- of-the- art R&D Centre & In- House Bioequivalence Centre

Over 10,000 employees are at service to provide uninterrupted care

Annual turnover of US$ 557 million (2014-2015)

Presence in more than 100 countries

Milestones

1985 • **Incorporation**

1992 • Started new facility at Palghar

2000 • Started new facility at Daman

2003 • **Established New R&D Facility**

2005 • Established CRO in Mumbai

2007
- **UKMHRA Approval of FDF Oral Dosage facility located at Daman**
- **Established new API Manufacturing Facility & became vertically integrated**
- **Became one of the top 25 Indian Pharma Companies**

2008
- **USFDA Approval of FDF Oral Dosage facility**
- **Established New FDF facility in Baddi (North India)**
- **CRO Facility Approved by USFDA**

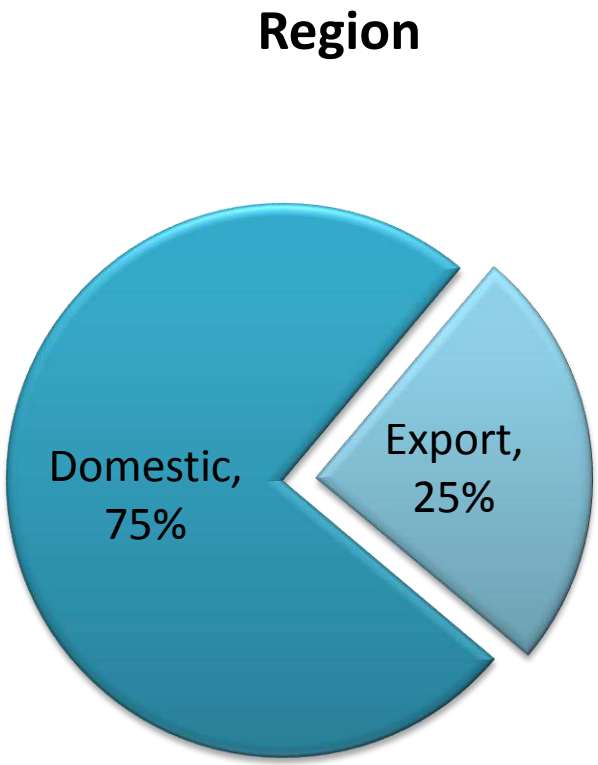
2009 • **Clinical Facility Approved by ANVISA Brazil**

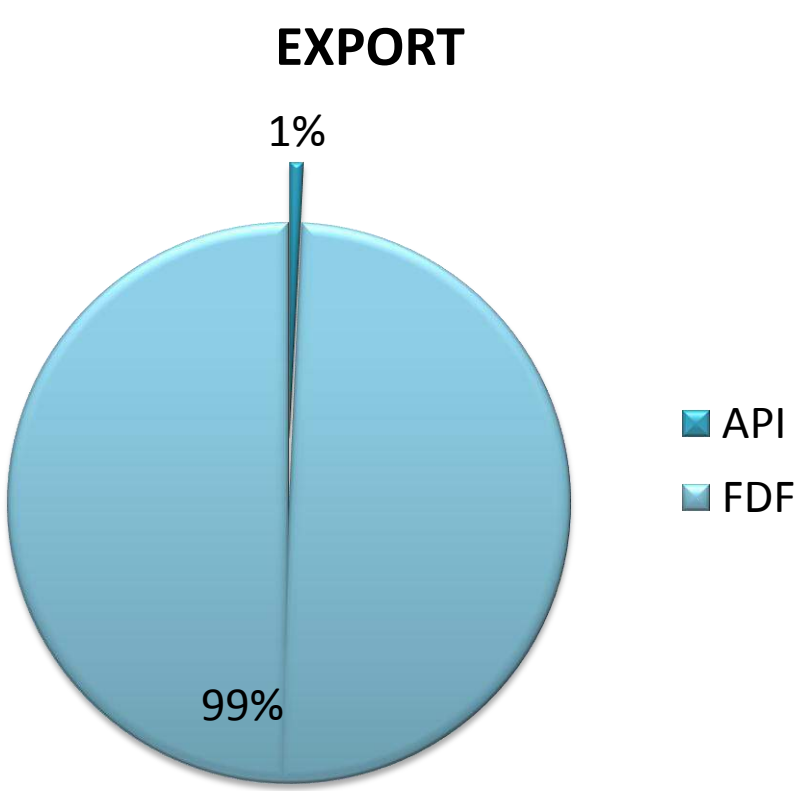
2011 • API facility approved by US FDA

2012 • Launched own operations in USA

2013 • Launched own operations in South Africa

2013-14 Sales





Dossiers & Approvals

API DMF /CEP Application

- US :- Filed **48** API DMFs, Target to file **10-15** APIs every year
- EU :- CEP application: **11** APIs and Received**: 9** CEP approval

USA Filing

- Filed **93** ANDAs, Received **18** approvals
- Target to file **20** ANDAs every year

Europe Filing

- **17** DCPs and Received **13** MA's mainly in UK, Germany, Spain and Italy
- Macleods has over **1,500** registrations across the globe

Wings across the globe….

Presence in more than 100 countries

Subsidiaries in 6 Countries

- USA, UK, South Africa, Ukraine, Peru, Kazakhstan

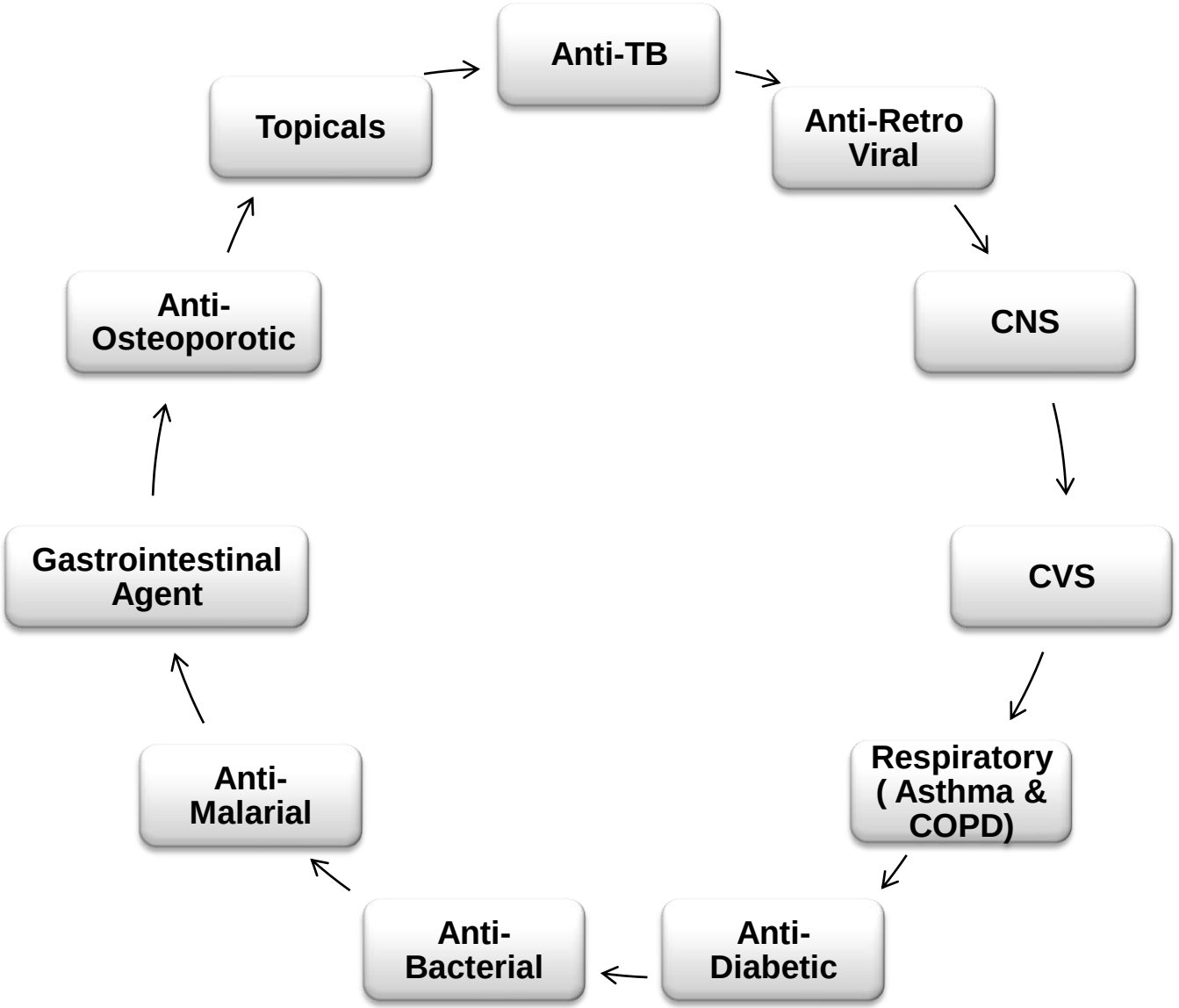
Various Business Models

- Private Market
- Licensing and Formulation Supply
- Technology Transfer with API supply
- API Supply
- Joint Venture
- Tenders

Presence in regulated market

- USA,
- CIS,
- Germany,
- Spain,
- Italy,
- UK,
- Romania,
- Serbia & many more

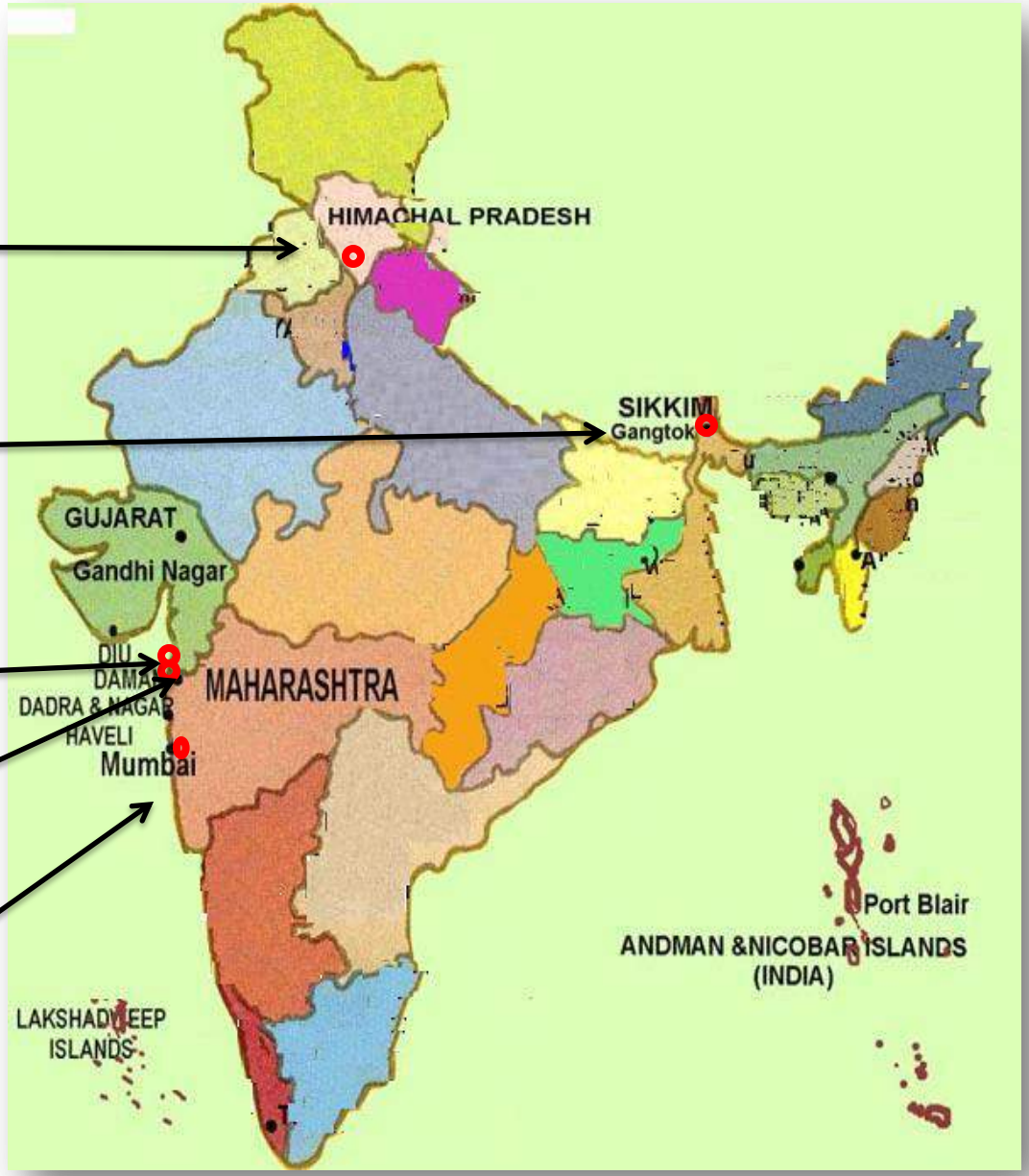
Presence in Various Therapies



Finished Dosage

Manufacturing Facilities

- 6 Formulation Facilities- Baddi
- 1 Formulation Facility- Sikkim (Under Construction)
- 4 Formulation Facilities-Daman
- 1 API Facility- Sarigam
- R & D & Corporate Office- Mumbai



FDF* Quality Achievements

US FDA

SOUTH AFRICA MCC

UK MHRA

MCAZ-ZIMBABWE

WHO-Geneva

MOH-SAUDI ARABIA

وزارة الصحة

and many others…

FDF: Finished Dosage Form

Formulation Facility
Daman

Approved by USFDA, UKMHRA,
WHO Geneva, ANVISA Brazil,
MCC South Africa,TGA Australia, SSMMD Ukraine
& many other regulatory agencies.

Formulation Facility
Baddi

Approved by USFDA, UKMHRA, WHO Geneva,
MCAZ Zimbabwe, MCC South Africa, Saudi Arabia
& many other Regulatory Agencies.

Production Capacity (Formulations)

Formulations	Per Year
Tablets	7,750 Million
Capsules	500 Million
Injectables	55 Million
Granules	60,000 Kg
Dry Powder for Injection	34 Million
Soft gels	175 Million
Liquids	28 Million
DPI	2 Million
MDI	2 Million

API Facility

API Quality Achievements

WHO-Geneva

US FDA

TGA-AUSTRALIA

PMDA Japan

Accredited

and many others…

API Facility Sarigam

Equipment List (API Facility)

Equipment Name	Number
Glass Line Reactor	38
Stainless Steel Reactor	37
Centrifuge	43
Vacuum Tray Dryer	18
Tray Dryer	13
Rotary cone dryers	11
Fluid Bed Dryers	5
Multi mills	17
Vibro sifters	14
Jet Mill	13
Blender	4
Agitated Nutch filter	2

R & D center

R & D Center
Various Departments

Chemical Research Department

- 30 Work Stations. Out put: 10-15 DMF/ Year

Analytical Research Department

- API and Finished Dosage development is supported by various instruments such
  - 100 HPLC
  - 12 LCMS
  - XRD
  - Mass spectrometer
  - Particle Size Analyzer
  - Water Content Analyzer

Formulation Development Department

- Well equipped to develop new FDF
- Output: 10-15 Dossiers/ Year.

R & D Center
Various Departments

Regulatory Department

- In- house well experienced regulatory team of more than **40** people .
- Responsible for dossier filings, query responses, approvals & renewals.

Intellectual Property Rights Department

- In-house team of **15** people
- Provide technical guidance on IP
- Decide strategy/process/formula for API & Finished Dosage development

Stability Section (Part of Analytical Research Department)

- All APIs & FDF developed in R & D are charged on to the following Stability conditions .
- Walk in Chambers: 40 C/ 75%RH, 25 C/ 60%RH, 30 C/ 65%RH

Bio-Equivalence Center

In-House Bio-Equivalence Centre

BE center has	GLP &GCP Approval from
• 184 Beds in 4 CPUs	• USFDA • MCC South Africa • WHO Geneva • UK MHRA • MOH Thailand • MOH UAE

184 Beds.
Approved by USFDA, MCC South Africa,
WHO Geneva & MOH UAE.

THANK YOU