### **Alembic Pharmaceuticals Limited**



Touching Lives... ...over 100 years...

### **Corporate overview**

www.alembic-india.com

# Key facts



- Rich history with > **107 years of experience** in Pharmaceutical Industry
- Vertically integrated operations with corporate headquarter in India
- Presence across **75 countries worldwide**, including US and Europe
- Established business in **Europe** through licensing partners
- **Diversified product portfolio** across various therapies
- In-house development, bio-equivalence and regulatory capabilities forming backbone of state-of-the-art manufacturing facilities
- Consistent growth in India as well as with **global generics business**
- Significant growth potential through future plans and strategies

## **R&D** capabilities

- Two state-of-the-art research centers in Vadodara & Hyderabad
- BE facility<sup>1\*</sup> with experience in POC and first-to-file studies
- 350+ scientists engaged in developing advanced APIs & Formulations
- Region specific, dedicated Regulatory and IP teams
- 818\* patent applications relating to formulations & APIs; 87\* patents granted

<sup>1</sup> Approvals from USFDA, BfArM, MPA, ANVISA, Turkish MoH \* As on February 2016



# Manufacturing capabilities



### **API Facilities:**

- 3 Multi-product API facilities
  - Reactors' capacities ranging from 39KL to 200KL across facilities
  - Each facility has approval from one or more from US-FDA, EDQM, ANVISA, PMDA, TGA, BfArM, KFDA, WHO Accreditations



### Formulations Facilities:

### • 2 Formulation facilities

- One dedicated facility for Regulated markets having annual capacity of 5 Billion units
- Focus on Solid orals Tablets, Capsules & Pellets
- USFDA, MHRA, TPD, MCC, ANVISA, WHO Accreditations
- Another facility in north of India, to cater India & other non-regulated markets



# Quality... our core strength



#### PEOPLE

- Experienced technical team
- Continuous training
- Employee retention

#### **SYSTEMS**

• Quality Policy

- Cross functional quality reviews
- Time bound complaint-handling



### PROCESS

- Adherence to SOPs
- Data integrity practices
- Discipline

#### DOCUMENTATION

- Dedicated department
- Software based system

# **Growth Strategies**



- Organic growth through existing capacity expansion and setting up new facilities for other dosage forms
- Introduction of **new delivery systems**
- Increased focus on **'high value'** and **'difficult to manufacture'** products
- Aggressive investments in R&D to build robust pipeline of products for regulated markets
- Leverage front-end marketing presence in USA by launching 7-9 products every year for next 3 years
- Filing Dossiers in other regulated markets like Europe, Australia, Canada, Brazil and South Africa for further out-licensing

## Europe... a key market



- Robust pipeline of Formulations and APIs, dedicated for Europe
- Present in **20+ countries of Europe** through **40+ local partners**
- Flexibility in adopting different business models to establish a long term sustainable business relationships
- Helping partners launch products on **Day 1** of patent expiry
- Actively supporting Partners for securing competitive Tenders (in Germany, UK, the Netherlands, Scandinavia etc.)
- Service oriented dedicated demand planning team handling 450+ SKUs of different products meant specifically for European partners

## Alembic... your Licensing Partner



Alembic

Touching Lives over





Nurturing global well being ... Since 1907

### Looking forward to discuss **business opportunities** for **Europe**:

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