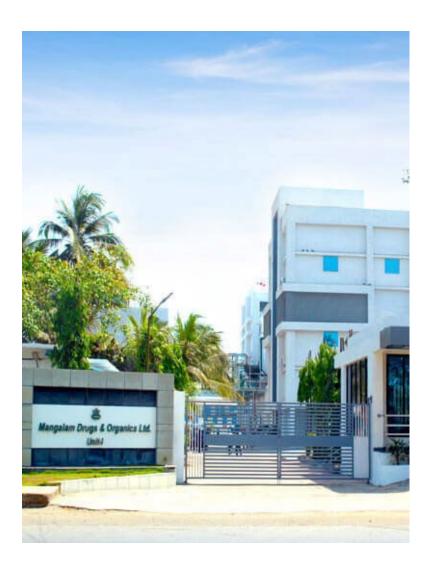
Strategic sourcing of raw material to ensure production continuity and sustainability

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About Mangalam





- ➤ We are one of the largest manufacturers in the world for Anti-Malaria APIs.
- ➤ We have two state of art manufacturing facilities located in Gujarat, INDIA which have different accreditations like WHO-Geneva, EDQM, MFDS-Korea.
- ➤ We are the first company to qualify under WHO's prequalification of API program.
- ➤ We have total 13 WHO prequalified APIs. Besides this we have several CEPs and DMFs at MFDS, Korea.
- For more information, you may visit our website: www.mangalamdrugs.com

Introduction



- ➤ An Active Pharmaceutical Ingredient commonly known as an API, or a Bulk Drug is the part of any medication that produces the intended health effects on the person who consumes it.
- ➤ All medications are made up of two core components ACTIVE & INACTIVE:
 - The API is the central ingredient making it the 'active' substance.
 - o The other 'inactive' components in the final medicine include substances such as excipients, flavors, preservatives, and even fillers that help the tablet stick together.

It is therefore, safe to say, that the role of an API is crucial and key in the pharmaceutical industry. The timely medication is always a priority for patient's health; and to meet their targets, strategic sourcing plays a vital role. It starts with selecting source of starting material/intermediates.

Finding the correct source

Key Points:

- > Quality is one of the most important factors
- > Strong cGMP compliance
- Long-term stability
- Manufacturing capacity
- > High-quality raw materials at a competitive price.
 - The cheapest price is not always the most cost-effective option.
 - Non-compliant product can be costly further down the line.

Criteria once you shortlist the source



- > Years of experience
- Support on vendor qualification activity
- Financial stability
- Prompt delivery times
- Customer reviews
- > Stringent safety and environmental policies

Challenges



- GMP awareness
- Dynamic Market
- ➤ Irregularity in supply chain/ Logistics

 e.g. COVID 19 Pandemic, Natural disaster, War etc.
- > Environmental consciousness and transparency
- Competitive Price
- ➤ Long term contract with Price validity

What API Manufacturer needs to do to ensure a sustainable supply of KSM



- ➤ Well established agreement
- Multiple Source or multiple manufacturing sites of one source
 For better price option, de-risking of your supplies and to get best quality product.
- ➤ Local suppliers Import substitute
- In house manufacturing
- > Frequent visit of suppliers
- > Reliable logistic partners
- Advance production planning of your own production
- ➤ Last but not the least, periodic forecast from the FPP manufacturers which is directly related to long-term sustainability.

Expectation from Regulators



- > Complex regulations Non avaibility of specific guidelines for KSMs.
- ➤ Long Term Contract Help from procurement bodies is expected to make sure all stake holders honour it. e.g Artemisinin.
- ➤ Approval of additional sources of KSM/RM need to hastened to overcome supply constrains, whenever needed.

Thank You!

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