

Gracure Pharmaceuticals Ltd.







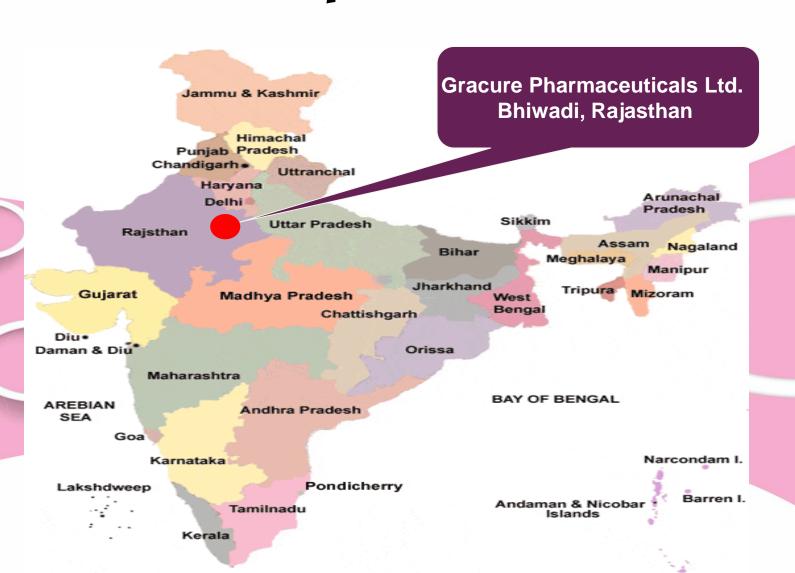


Our Vision

To Grow Sales by 25% YOY through active participation of Our Creative People & support of Our Partners

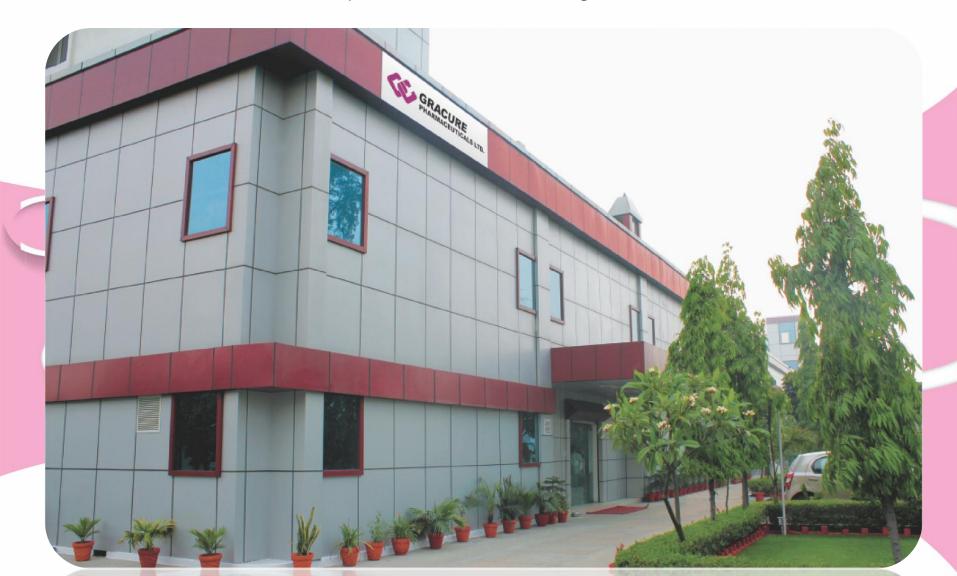


Location of Plant & R&D





Manufacturing Plant







2014 GMP, Ukraine re-approved

2014 GMP, Australia re-approved

2014 EU-GMP, Belgium re-approved

2014 GMP approved by FDA, Ethiopia

2013 GMP approved by FDA, Ghana

2013 GMP approved by Ukraine

2013 GMP approved by TGA, Australia

2011 GMP approved by Tanzania, Nigeria

2011 EU-GMP approved by FAMHP, Belgium

2010 GMP Approved by PPB, Kenya

2007 Expansion & renovation as per EU Standards

1997 1st WHO-GMP approval

1992 Operations started



Certifications & Accreditations











Tanzania











Food, Medicine and Health Care Administration and Control Authority of Ethiopia



National Agency for Food and Drug Adminstration and Control Nigeria



Plant Capabilities



Quality Assurance



Production

Manufacturing plant

Quality Control



Engineering





Manufacturing Capabilities

Solid Orals

- Tablets (uncoated & coated)
- Capsules (hard gelatin capsule)



- Syrup
- Suspension

Dry Syrups

Dry power Syrups



Gels/Creams/Ointments









Salient Features of the Facility

- ☐ Total buildup area is 8,000 sq.mt.
- Qualified, trained and dedicated work force
- Unidirectional flow of men & material
- □ Separate air locks for entry of personnel& material into operational areas
- □ Operation wise hygiene zones
- □ Adequate premises and space
- Approved procedures and instructions
- ☐ Suitable storage and transportation





Quality Policy

"We strive for

Total customer satisfaction through continuous improvements in processes and systems, delivering consistent quality meeting International standards"

Our Motto

On Time In Full



Quality Management Systems

Well established quality management systems and procedures provided.

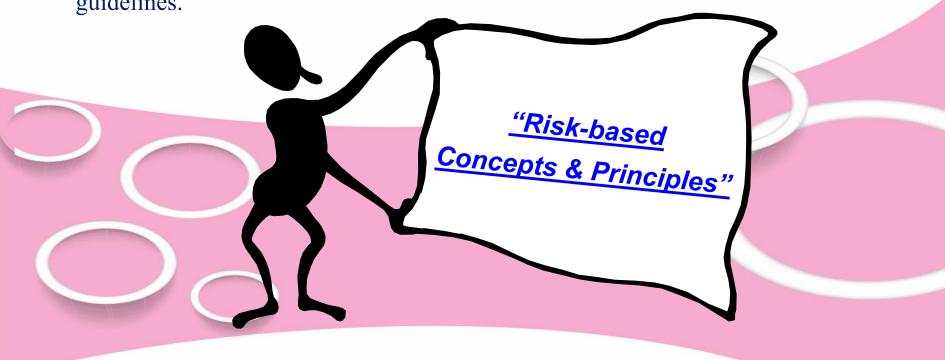
- ✓ Qualification and validation of equipment and systems.
- ✓ Process Validation of all products.
- ✓ Water System Validation.
- ✓ HVAC / CLEAN ROOMS Validation.
- Validation Master Plan Executed.
- ✓ SOP for cleaning, operation, calibration & maintenance is being followed.

Training on cGMP, GLP, GDP and Clean area behavior has been imparted to all concerned.

Quality Risk Assessment (QRM)



Risk assessment is done as per Annexure 20 of EU GMP Guideline and ICH guidelines.





Research & Development



Gracure Pharmaceuticals Ltd. is having fully equipped Research and Development Laboratory headed by highly qualified & experienced persons to develop different formulations according to buyers /market









Development Capabilities

- □ Product Development
- □ Analytical Development
- ☐ Microbiology
- □ Regulatory Support
- □ Project Management
- □ Pilot Plant / scale-up production
- ☐ Stability Studies as per ICH guidelines





R & D Infrastructure

- ☐ Total build up area of 2,500 sq.ft.
- ☐ Qualified persons in Product development &

Analytical development

■ Regulatory and Project support to file dossiers

for various territories

☐ Certified and approved Research &

Development Center by DSIR, Government

of India

☐ Capability to develop 10 products per year



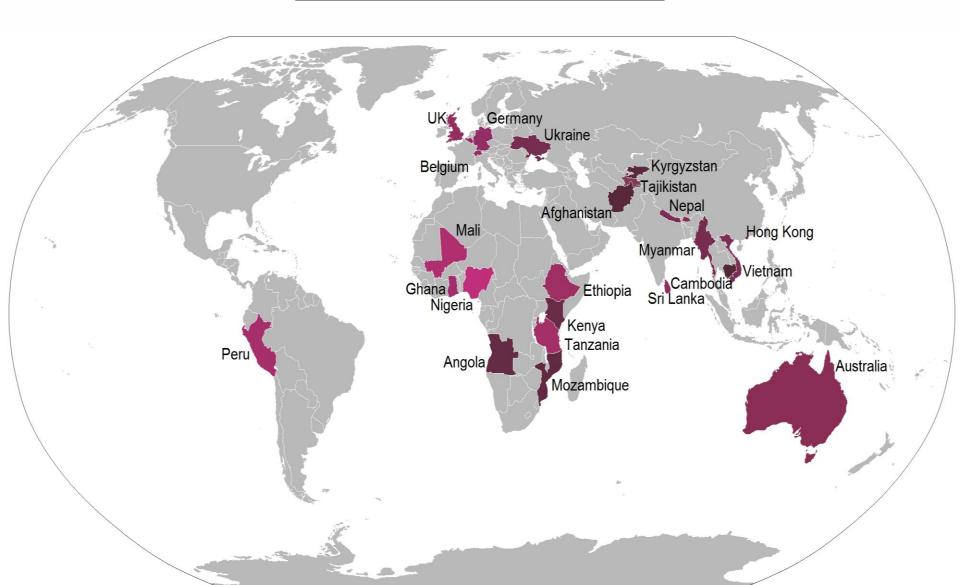


Business Models



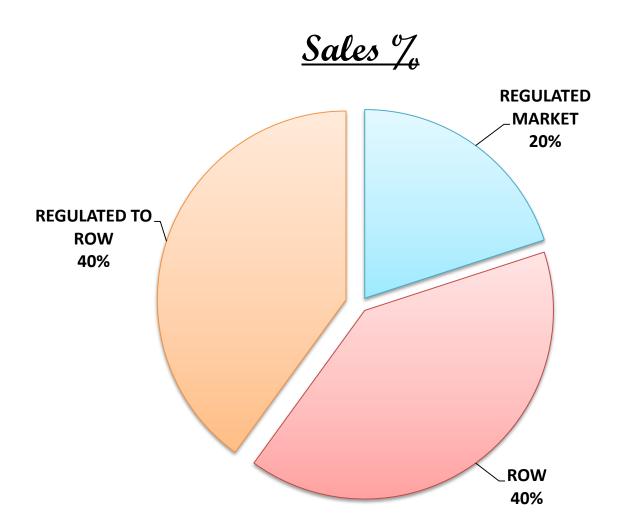


Our Presence





Business Distribution





Our Values

- □ We "TRUST & RESPECT" each other and work as a team
- □ We "ANALYZE DATA" thoroughly to make decisions which are implemented quickly
- We always "DELIVER THE PROMISE"
- We "COMMUNICATE" openly and speedily
- ☐ We will "LEARN CONTINUOUSLY" to improve quality, productivity

and customer satisfaction



Competitive Advantage

Quality medicines at competitive cost ☐ EU-GMP & TGA approved manufacturing facility ☐ Large installed capacities for manufacturing to meet increased customer's requirements ☐ Certified and approved Research & Development Center by DSIR, Government of India ☐ Integrated operation including R&D, scale up, manufacturing & supply chain ■ Long experience of developing & supplying products to regulated markets.



Thank You

For more details visit us at www.gracure.com
For further enquiry please write us at info@gracure.com