# Qualigens Pharma Pvt. Ltd.

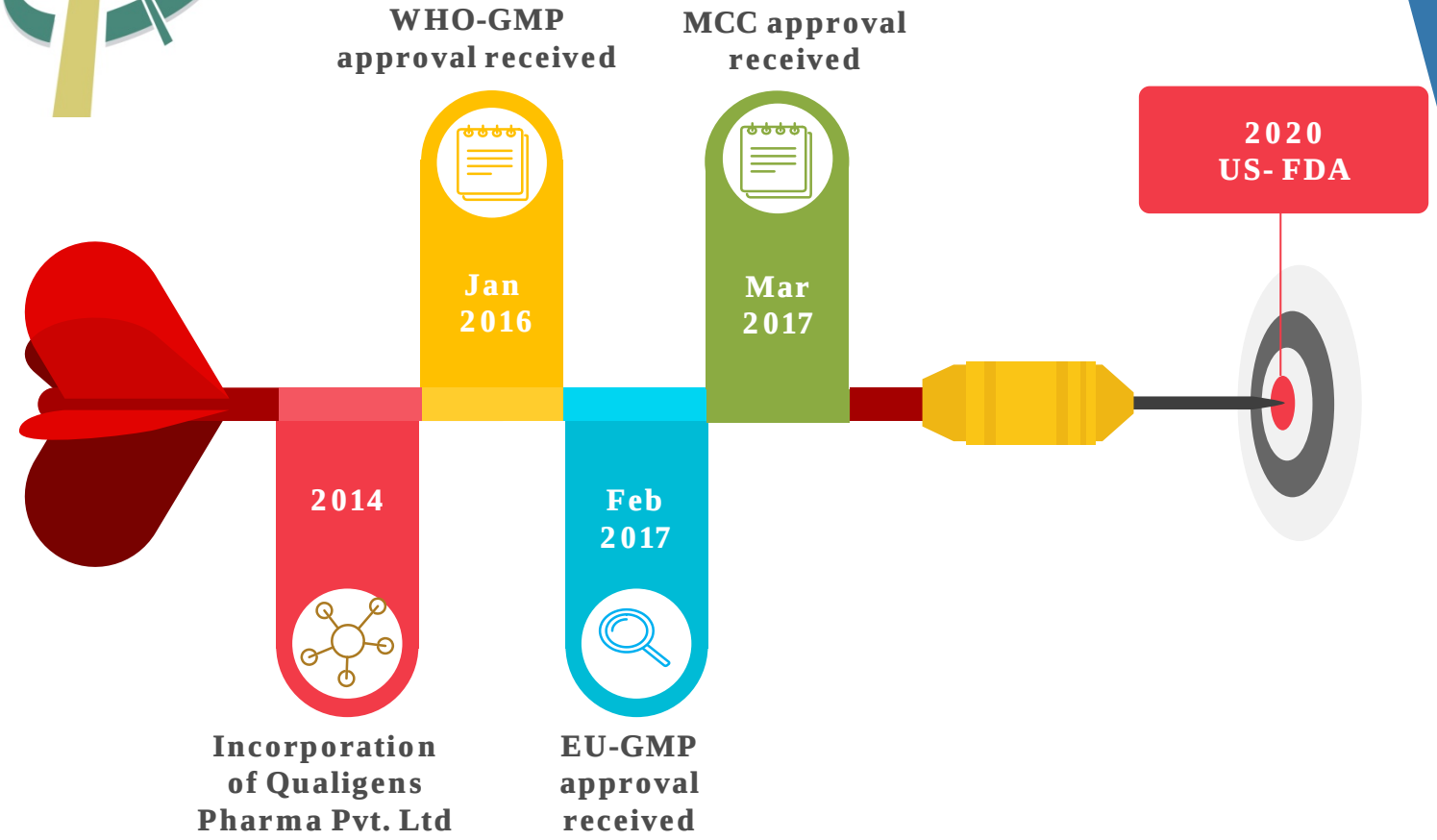
Quality Generics...

Inspired by patients, delivered by Qualigens!

# 1

# About Us

# Company Timeline



# Who are we?

- Qualigens Pharma Pvt. Ltd. is established by professionals with an experience of more than 3 decades in the international Pharma market.

- Qualigens, with its top class manufacturing facility has a substantial scope of products for Marketing and Export in the Regulated and Semi Regulated markets.

- Since our inception we have stood by our values which we believe is the most important factor for a varied client base spread across the world.

# 2.

## Facility

## Salient Features of the Plant:

- The State – of – art manufacturing facility is designed to meet stringent regulations of the regulated markets
- Capacity to produce complex generics in various measurements and shapes
- Computerised and semi robotized operations right from manufacturing to final packing

**The location offers excellent connectivity**

- **Mumbai Pune Expressway : 04 Kms**
- **Nearest Railway Station (Khopoli) : 15 Kms**
- **Nearest Sea Port (JNPT) : 60 Kms**
- **Nearest Airport (Mumbai) : 75 Kms**

# Accrediations:

- EU-GMP certified
- MCC certified
- WHO GMP certified

MEDICINES AUTHORITY

IN012/08 Appendix 01 Version 1

Certificate No: **MT/005HM/2017**

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1,2]**

**Part 1**

**Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC**

The Medicines Authority of Malta confirms the following:

The manufacturer **Qualigens Pharma Pvt. Ltd.**
Site address **S. No. 151/2, Umbre, Khopoli-Pali Road, Taluka-Khalapur, Dist. Raigad – 410 203, Maharashtra State, India.**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation: **Article 101A (10) of the Medicines Act (Chapter 458 of the Laws of Malta).**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25th – 28th November 2016**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3].

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

**7th February 2017**

**Mark Cilia[1]**
**Director Inspectorate & Enforcement Directorate**
**Medicines Authority**
**Tel: 00356 234 39 119**
**Fax: 00356 234 39 161**

1 The certificate referred to in paragraph 111(5) of Directive 2001/83/EC, is also applicable to importers.
2 Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.
3 These requirements fulfil the GMP recommendations of WHO.

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# ANNUAL CAPACITY

- Tablets: 1200 million units
- Capsules: 100 million units

**The formulation facility is constructed with adequate separation to cater:**

- Warehousing
- Production
- Quality Control
- Primary Packaging
- Secondary Packaging
- Tertiary Packaging
- Finished Goods Store

**ORAL SOLID DOSAGE FORMULATIONS**

**TABLETS**

**CAPSULES**

# 3.

# Contract Manufacturing

- Qualigens intends to supply its items under CRAMS to various countries and is constantly extending its reach
- The state – of – art manufacturing facility at Khopoli, Maharashtra, India is certified by EU-GMP, MCC, and different international authorities
- The unit is operational with substantial capacities accessible for tablets & capsules formulations which comply to latest cGMP standards
- Expertise in manufacturing Solid Dose Formulations (Tablets, Capsules)
- Emphasis on Quality Culture and successful alliance with customers for Quality Compliance
- Devoted artwork and packaging development team with mastery of creating fine art and packaging running from Bulk Packs to Mono Packs
- Supportive Purchase and Logistics office
- Dedicated back office group which gives singular regard to every client
- Qualigens attracts Quality. Qualigens is endowed to the world by supplying Quality Generics and serving Human Kind

# Product Therapeutic Area's

| | |
|---|---|
| Analgesics & Antipyretics | Cardiovascular |
| Anthelmintic | Central Nervous System |
| Antibiotic (Non beta-lactum) | Erectile Dysfunction |
| Anti-diabetic | Gastric |
| Antiepileptic | Laxatives |
| Antifungal | Lipid Lowering Agents |
| Antihistamine | NSAID |
| Antimalarial | Sedatives |
| Antihypertensive | Vitamins |
| Bronchodilators | |

# 4.

## Machinery

# Manufacturing - Tablets

RMG

FBD

2 high speed compression machine

- Auto Ganscoater – 60”
- 2 Conventional coater: - 36”

# Manufacturing - Capsules

Octagonal Blender:
600 litres

Double Con Blender:
100 Litres

High Speed Capsule filling Machine
Anchor Mark CF2 XL

# Packing Machinery

| Packing Line | Machine |
|---|---|
| I | Fully Automated Alu/PVC/ PVDC packing with auto cartonator |
| II | 2 Alu/PVC Blister packing machine (Almech 2000) |
| III | |
| IV | Bulk Packaging Machine |
| | Strip packing Machine |

Equipped with on-line printing, camera system and weight check systems

# 5.

# Utilities

# Utilities Capacity

**Raw Water Tank**
25 KL

**Purified Water**
1KL

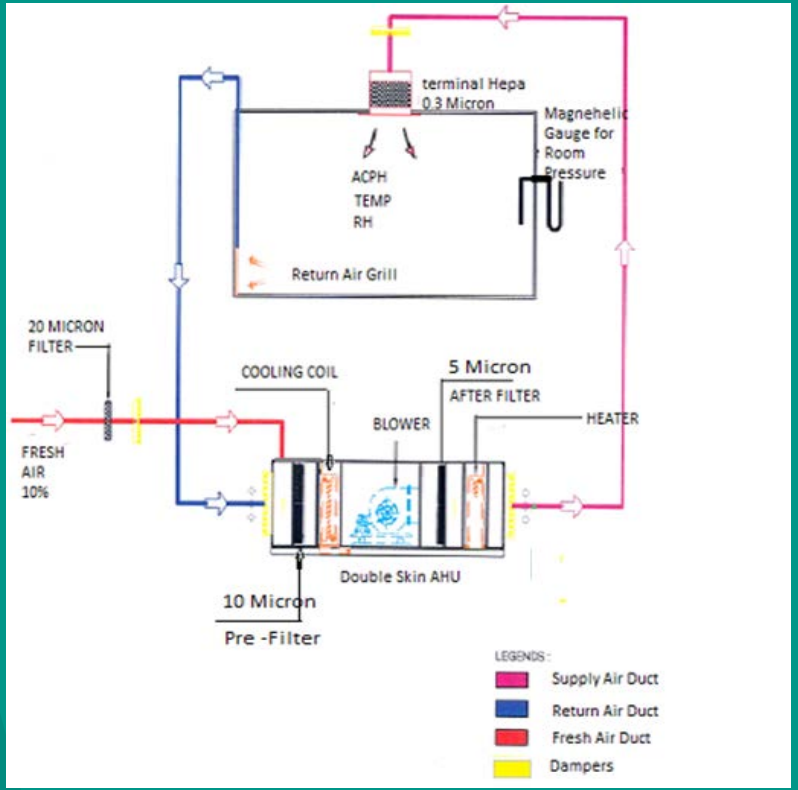
**Air Compressor (Non lubricating)**
175 CFM

**A/C Plant**
75 TR

**Boilers**
850 kgs/cm$^2$

**DG - Sets**
- 320 KVA
- 62.5 KVA

# Air Handling Unit (AHU)



# Air Handling Unit (AHU)

- 31 AHUs
- The production, packaging, storage and QC area are provided with temperature and humidity controlled filtered air through independent air handling units having 0.3 µ [HEPA] terminal filters.
- The AHU is of the recirculation type with 10% of fresh Air
- HEPA terminal filters are provided for critical operations in the manufacturing area to maintain the quality of environment

# Water Systems

Generation of purified water by:

- Reverse Osmosis (RO)
- Electro-De-Ionisation (EDI)

# Compressed Air Systems

- Compressed air is non-lubricated
- Compressed Air is filtered with 0.01 micron filter before it is supplied to user point.

# Water Systems Specifications

**Input Water**
Bore Well

**Purified Water Generation**
By RO & EDI

**Pharmacopoeia Grade**
USP/BP/Ph.Eur./ IP

**Purified Water Specification**

TOC Limit: NMT 500ppb

Conductivity Limit: NMT 1.3µs/cm$^2$

Microbial Limit: TVAC – 100 CFU/ml

**Sanitisation Frequency**
Every Fortnight

# 6.

## Contact Us

## Corporate Office:

204, Anand Estate,
189 Arthur Road, Chinchpokli,
Mumbai – 400011
Tel No: +91-22-23080788

## Factory Address:

No 151/2, Umbre,
Khopoli – Pali Road,
Taluka – Khalapur,
Dist. Raigad, 410203
Tel: +91-2192-277027

**Email Id: management3@qualigenspharma.com**


Looking forward to hear from you!