



JONAKAYEM

Pharma - Formulation (OPC) Pvt. Ltd.
formerly KAYEM Pharmaceutical Pvt. Ltd
An ISO 9001-2008 Certified Company

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Mission & Vision

JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly **KAYEM Pharmaceutical Pvt Ltd** is a contract manufacturer and marketers of Generic Prescription Drugs having the capacity to manufacture Tablets, Capsules, Liquids, Powder, Ointments and Injectibles including Parental.

Mission - is to harness the possibility engendered by Government of India & Indian Medical Association initiative in regulating Drug prices through making it mandatory for the prescribing Healthcare professional to prescribe Generic name along with its Brand and more particularly the drugs/medicines covered under the DPCO so that it is manufactured at low cost from SME sector to contain the spurt in Prices of the Branded Generic and to make the same formulations affordable to common people.

Vision - "This vision of **JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd-** formerly **KAYEM Pharmaceutical Pvt Ltd** is to garner specializations in manufacture and Market of all segments of Generic Drugs that shall include product through in-house Research & Development maintaining the same & similar bioequivalence. It envisions manufacturing and supplying Generic versions of all Drugs at its most affordable cost by optimizing the scale of production & marketing.

About Us


JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly KAYEM Pharmaceutical Pvt Ltd is a contract manufacturer and marketers of Generic Prescription Drugs having the capacity to manufacture Tablets, Capsules, Liquids, Powder, Ointments and Injectibles including Parenteral/IV Fluids.

JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly KAYEM Pharmaceutical Pvt Ltd envisions greater business possibilities in manufacture and market of Generic Drugs where the Price plays a major role to contain the cost of Branded Products by its substitution through Generic Versions having the same bioequivalence.

JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly KAYEM Pharmaceutical Pvt Ltd Intends to garner specializations in manufacture and Market of all segments of Generic Drugs with its in-house expertise in Research & Development to develop products matching exact bio-equivalence. Therefore, Kayem is capable of manufacture any Formulations in a WHO Certified Manufacturing Plant with globally compatible packaging.

JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly KAYEM Pharmaceutical Pvt Ltd is owned and managed by professionals and is a registered manufacturer and Exporter of Medicines & Appliances within the meaning of Small Scale Industries with the National Small Scale Industrial Corporation- India vide IEM - Part-II Number : 27222200277 and is a Rated SME(Small & Medium Enterprises) by CRISL LTD ,India - a third party performance evaluating agency nominated by the Government of India & an Indian Affiliate of Standard & Poor - UK.

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JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly KAYEM Pharmaceutical Pvt Ltd endeavors to supply medicine at an affordable prices particularly those which are under the Drugs Price Control Ordinance of National Pharmaceutical Pricing Authority of India- Ministry of Chemical - Government of India where the production and supply for the most is uneconomic.

JONAKAYEM Pharma- Formulation(OPC) Pvt. Ltd- formerly KAYEM Pharmaceutical Pvt Ltd intends to harness the possibility engendered by Government of India & Indian Medical Association initiative in regulating Drug prices through making it mandatory for the prescribing Healthcare professional to prescribe Generic name along with its Brand and more particularly the drugs/medicines covered under the DPCO so that it is manufactured at low cost from SME sector to contain the spurt in Prices of the Branded Generic and to make the same formulations affordable to common people.

Our Department

- ◆ Liquid
- ◆ Tablet & Capsule
- ◆ Powder
- ◆ Ointment
- ◆ Injectibles

Liquid

Manufacturing: 5 μ / 10 μ filter air supplied to the manufacturing area. Manufacturing area is divided in two parts. Manufacturing tank hang over the slab at 1st floor and filtration and transfer of liquid is done at ground floor.

Liquid Manufacturing is performed in two compartments, one of 3,000 liters and the other of 500 Liters capacity.

All manufacturing activities are activated from the control room. Liquid manufacturing is a completely closed process, having minimal operator's physical involvement in materials additions.

Transfer of material from vessel to another is through vacuum. These equipments are having on-line homogenizer.

Liquid Filling: Liquid filling area is having independent AHU, these are circulatory type through a bank of 10 μ - / 5 μ and terminal HEPA filter of .3 μ to achieve class 10000. Class 10000 is comprises of air changes of 30 and particle count for viable and non-viable and DOP test, 10% fresh air is used. Filling machine consists of four 6 head filling station & 6 head sealing station. These lines are fully automated, starting from the bottle filling to labeling of bottles.

Packing Department: Labeling of bottle is done on automatic machine. 12 packing conveyor is equipped.



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Tablet & Capsule

Tablet

The flooring in the entire department is coated with epoxy with a clear coat of polyurethane in order to have an impervious microbe resistant floor. The walls of entire department is treated with water base epoxy primer and finally with polyurethane paint.

Positive air pressures are maintained in the air lock between the primary corridor and granulation to ensure that outside air does not enter into areas.

Department is separated as per the process step.

Granulation section: Air supplied to granulation section is filtered through 10 μ filter and 5 μ filter.

All machinery installed is made as per GMP Standards. Main equipments are 150 liter SS 316 Jacketed Paste kettle, 36" SS 316 Vibro sifter, SS316 Communiting mill having 300 kg capacity of pulverization, 600 liter Rapid mixing granulator with PLC, 600 liter Fluid bed dryer with PLC, 1800 liter octagonal blender. This section is equipped to take batch sizes from 100 Kg to 600 Kg.



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Tablet & Capsule

Compression Section: To prevent cross contamination with granulation section & Coating section it is separated with by positive air lock.

Compression Area having independent AHU, these are circulatory type through a bank of 10 μ - / 5 μ and terminal HEPA filter .3 μ to achieve class 10000. Class 10000 is comprises of air changes of 30 and particle count for viable and non-viable and DOP test, 10% fresh air is used. There is total 4 Nos of compression section. Presently 27 stn. D tooling, 35 stn. B tooling machine are installed

Coating section: Section is separated with positive pressure of air with separate AHU's. 2 no. of 48" SS 316 coating pan are installed. SS 316 Jacketed solution preparation tank is provided to prepare the solution between 50-100 ltr. To make controlled release pellets 60 kg of SS 316 Pelletizer (Fluid bed coater) is provide. Additional to maintain the GMP standard, process of loading of raw material is done by IPC Lifter in every step.



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Tablet & Capsule

Capsule

Design : The flooring in the entire department is coated with epoxy with a clear coat of polyurethane in order to have an impervious microbe resistant floor. The walls of entire department is treated with water base epoxy primer and finally with polyurethane paint.

HVAC System: Positive air pressures are maintained in the air lock between the primary corridor and department to ensure that outside air does not enter into manufacturing area.

Design of AHU of the capsules department is made as to maintain the RH between 35-40 and temperature $22^{\circ} \pm 1\%$. Air supplied to Capsules department section is filtered through 10μ filter and 5μ filter and terminal HEPA filter of $.3\mu$ to achieve class 10000. Class 10000 is comprises of air changes of 30 and particle count for viable and non-viable and DOP test, 10% fresh air is used.]

Machine: High speed fully automatic capsule filling machine AF 90t Pam make is installed which gives filling output of 90000 capsules per hour. Online capsules sorting & loading of capsules for filling is done with Sorter Elevator model SE 100, also after filling of capsules sorting of empty capsules & polishing of filled capsules is done online with Empty Capsule Sorter ESC 100. Change part for capsule Size 0,1,2,4 is available.



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Powder

Design : The flooring in the entire department is coated with epoxy with a clear coat of polyurethane in order to have an impervious microbe resistant floor. The walls of entire department is treated with water base epoxy primer and finally with polyurethane paint.

HVAC System: Positive air pressures are maintained in the air lock between the primary corridor and department to ensure that outside air does not enter into manufacturing area.

Design of AHU of the powder department is made as to maintain the RH between 35-40 and temperature $22^{\circ} \pm 1\%$. Air supplied to powder department section is filtered through 10μ filter and 5μ filter and terminal HEPA filter of $.3\mu$ to achieve class 10000. Class 10000 is comprises of air changes of 30 and particle count for viable and non-viable and DOP test, 10% fresh air is used. Manufacturing: Separate area for drying of material is provided with 48 try Steam heated try dryer.

Manufacturing area is equipped with 36" Vibro sifter, Pulverizer, 200 liter capacity planetary blender.

Separate area is provide for blending of material with 1200 liter octagonal blender.

Filling Machine: For pouch filling of powder five no. of volumetric form fill seal (FFS) machine are equipped. Coding of batch is done with ink jet printer.

For dry powder bottle filling separate automatic powder filling and packaging line is equipped.



Ointment

Manufacturing : Cream and Ointment Manufacturing has the facility to produce creams, ointments and gel products.

Main equipments are 500 Kg Mfg. Tank, Aqueous phase Tank, Oil phase manufacturing tank. This unit is design to take batch sizes for 150 Kg to 500 Kg.

Transfer of material from vessel to another is through vacuum. Wax is melted outside and transferred after weighing. These equipments are having on-line homogenizer. Heating of water & melting of wax is done by steam.

Machine is a SS316 equipped with bottom entry stirrer with contra rotary stirring. Transfer of batch material to filling machine is done through transfer pump. Two no. of SS 316 Capacity of 500 liters storage vessels are provided.

Filling Area: GAN Model Wimco make double head high speed filling machine with filling speed of 140 tube/min for 10 g. is equipped with online automatic empty tube loading, air jet cleaning, code embossing done. Machine is equipped to fill products from 3 gm to 100 gm.

For dry powder bottle filling separate automatic powder filling and packaging line is equipped.



Injectibles

Plant Capacity

Sterile Liquid Filling Department
Liquid Vial Filling & Sealing Line.
From 2 ml. To 30 ml Size filling capacity
40,000 Vials per shift.
Ampoule Filling : From 1 ml. To 5 ml.
Six stroke M/C - One
Four stroke M/C - One
Two stroke M/C - Two
Capacity - 100,000 per shift.



Our Clients

- ◆ Nord Services LDA, Luanda, Angola (AFRICA)
- ◆ Under Product Registration with Georgia Pharmacy Board



Our Featured Products

10 ml.

SUCCINYLCHOLINE CHLORIDE INJECTION B.P.

Exported by: **KAYEM**
 Mumbai, India
 info@kayempharma.com
 www.kayempharma.com

Mfg. by:
 Saiis Pharmaceuticals P. Ltd.
 Ahmedabad, Gujarat (INDIA)

20 ml

Bupivacaine Injection 0.5%

Each ml contains:
 Bupivacaine Hydrochloride BP equivalent to anhydrous
 Bupivacaine Hydrochloride5.0 mg
 Sodium Chloride BP8.0 mg
 Methyl Paraben BP1.0 mg
 (As preservative)
 Water for injection BPq.s.

Dosage:
 As directed by Physician.

KEEP OUT OF REACH OF CHILDREN
 Store in cool place, Protected from light.

Exported by: **KAYEM**
 Mumbai, India
 info@kayempharma.com
 www.kayempharma.com

Mfg. by:
 Saiis Pharmaceuticals P. Ltd.
 Ahmedabad, Gujarat (INDIA)

Thiopental Sodium for Injection BP 1g.

Single use vial

Dosage:
 As directed by Physician.

KEEP OUT OF REACH OF CHILDREN
 Store in cool place, Protected from light.

Exported by: **KAYEM**
 Mumbai, India
 info@kayempharma.com
 www.kayempharma.com

Mfg. by:
 Saiis Pharmaceuticals P. Ltd.
 Ahmedabad, Gujarat (INDIA)

Amoxicilina 60ml.
 250mg/5 ml

Suspensão Oral

Agitar bem antes de usar

250

Ampicilina 60 ml.
 250mg/5 ml

Suspensão Oral

250

Fabricado por:
 Kayem Pharmaceutical Pvt Ltd.
 At Vasai (E), Thane, India

amp 112568

Bromhexine Xarope B.P.

100ml

Cada 5 ml contém:
 Bromhexine Hydrochloride BP 10mg
 Xarope aromatizado base q.s.

Cor: Peneau #2

Dosagem: Como dirigida pelo médico.

Fabricado por:
 Kayem Pharmaceutical Pvt Ltd.
 At Vasai (E), Dist. Thane-India.

Mfg. Lic. Nr. KD-168

Co-Trimoxazole Suspensão oral 100ml

Cada 5 ml contém:
 Trimetoprine BP 40 mg
 Sulfametoxazole BP 200 mg
 Xarope aromatizado base q.s.

Cor: eritrosina

Dosagem: Como dirigida pelo médico.

Fabricado por:
 Kayem Pharmaceutical Pvt. Ltd.
 At Vasai (E), Dist. Thane-India.

Mantenha fora da vista e do alcance das crianças.
 Agitar antes de usar.
 Armazenar num local fresco

PARACETAMOL Xarope

Cada 5 ml contém:
 Paracetamol BP 125 mg
 Xarope aromatizado base q.s.
 Cor: eritrosina

Dosagem: Como dirigida pelo médico.

Fabricado Por:
 Kayem Pharmaceutical Pvt. Ltd.
 At Vasai (E), Dist. Thane-India

ARMAZENAMENTO:
 • Conservar em local seco inferior a 25°C.
 • Proteger da luz.
 • Agitar bem antes de usar
 • Manter fora do alcance das crianças

Salbutamol 2mg/5ml

Xarope 100ml

Cada 5 ml contém:
 Salbutamol Sulfato equivalentes 2 mg de salbutamol
 Xarope aromatizado base q.s.

Fabricado por:
 Kayem Pharmaceutical Pvt. Ltd.
 At Vasai (E), Thane, Maharashtra

Mfg. Lic. Nr. KD-621

Mebendazol Suspensão oral 30ml

Cada 5 ml contém:
 Mebendazole USP 100 mg
 Xarope aromatizado base q.s.

Fabricado por:
 Kayem Pharmaceutical Pvt. Ltd.
 At Vasai (E), Thane, Maharashtra

Mfg. Lic. Nr. KD-621

Our Licenses & Permission

Under the Drugs & Cosmetics Act 1940

Wholesale License

20B & 21 B Z-7/103/2135

IEC Code

0307043738

Pharmaxil RCMC No

PXL/ME/VII/RO/KKSC/5297/2008-09

SSI Registration No

IEM Part-II 27222200277

Manufacture License pursuant to FORM 25 F under the Drugs & Cosmetics Act, 1940 & WHO GMP Certificate for manufacture of Pharmaceutical Products at SWISS PARENTRAL PVT LTD- a WHO Certified Plant is under process with the Local FDA, the Company has Schedule -M GMP under the Drugs & Cosmetics Act, 1940.

Our Accreditation



NSIC-CRISIL Performance and Credit Rating for Small Scale Industries

Kayem Pharmaceutical Private Limited, Maharashtra
has been awarded an NSIC-CRISIL Rating of



on June 18, 2010.

This rating indicates 'Moderate Performance Capability and Moderate Financial Strength'.

This rating is valid till June 17, 2011.

A handwritten signature in black ink, appearing to read "Roopa Kudva".

Roopa Kudva
Managing Director and Chief Executive Officer