

Company Profile

2023



Wellous Pharma

Private Limited

WHO GMP Certified Company

ISO 9001:2015 & ISO 22000:2018



About Company



About Wellous Pharma

Wellous Pharma Private Limited is a professionally managed Pharmaceutical Company established in the year 2016, Operating from NavamalMarutur Village, Kandamangalam Block, Villupuram District, Tamil Nadu, India. Wellous Pharma Private Limited is the flagship company promoted by Mr.A.KARUNAKARAN, the Managing Director. The Facility dedicated to Non-Betalactum oral solid dosage forms and Topical formulation is commissioned in the year March-2018. The plant area is spread over 3.6 acres and the built up area is 30000 Sq.Ft in two floors conforming to the global regulatory requirements. The objective of the company is to manufacture drugs including latest molecules of highest standards at reasonable prices & to full fill the growing needs of its customers.

Pharmaceutical



Wellous Portfolio



Wellous Portfolio



WHO GMP Certificate



DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF TAMILNADU
359, Anna Salai, Chennai - 600 006, Tamil Nadu.

CERTIFICATE OF GOOD MANUFACTURING PRACTICES*

Certificate No: K Dis. No: 17414/D1/4/2021, Dated: 07.04.2022

On the basis of the inspection carried out on 12.01.2022, 13.01.2022 and 23.03.2022 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

- 1 Name and address of site: **M/s. Wellous Pharma Private Limited,
R.S. No.333-2A & 2B2, Navamal Maratur Village,
Kandamangalam Block, Villupuram District,
Tamil Nadu - 605102 .**
- 2 Manufacturer's licence number: Form 25 Bearing No: TN00004921 Dated: 20.03.2018
Form 28 Bearing No. TN00004922 Dated: 20.03.2018

3 Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
Tablets, Hard Gelatin Capsules, External Preparation	General (Other Than Betalactum, Sex Hormones & Cytotoxic	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 31.12.2024 It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name and function of responsible person:

K.Sivabalan, B.Pharm.,



K.Sivabalan
21/4/22
Director of Drugs Control
K. SIVABALAN B.Pharm
Tamil Nadu.
Director of Drugs Control
359, Anna Salai, Chennai - 600 006.

Email: indcad@gmail.com

Telephone No: 44-2433 5068

*This certificate is issued as per WHO norms

ISO 9001: 2015 Certificate



Certificate

**Breakthrough Management Quality Registrar
(BMQR)**

Certifies that the Quality Management System of

WELLOUS PHARMA PRIVATE LIMITED

R.S.No. 333-2A & 2B2, Navamal Marutur Village,
Kandamangalam Block, Villupuram District – 605 102.
Tamilnadu, India.

has been assessed and found to be in accordance with the requirements of the quality standards

ISO 9001:2015

for the following scope of certification

**MANUFACTURING OF PHARMACEUTICAL AND
NUTRACEUTICAL FORMULATIONS FOR
DOMESTIC AND EXPORTS**

Original Certification Date : 08/03/2022
Current Certification Date : 08/03/2022
First Surveillance Due On : 07/03/2023
Second Surveillance Due On : 07/03/2024
Certificate Expiration Date : 07/03/2025



Surveillance Audit

Due On 07/03/2023 Due On 07/03/2024



This certificate is invalid
if surveillance audit is not completed



Certificate No : AB09IS224542



Stamp

For BMQR

No.5, 2nd Floor, Sathyamoorthy Road, Thiruvalluwarar Nagar, Thirumangalam,
Anna Nagar West, Chennai - 600 040, Tamilnadu, India.
email: iso@bmqr.com, Web : www.bmqr.com

The certificate will remain current subject to the company maintaining its system to the required standard(s). This will be monitored regularly by BMQR Certifications Pvt. Ltd.
This Certification details and effectiveness are listed at www.bmqr.com. Registration does not assure the quality of products produced by a Quality System.
This Certificate is granted based on the limited sampling audit as per ISO 19011:2011 and BMQR is not responsible for client's failure to maintain documented quality system.
This certificate is the property of BMQR Certifications Pvt. Ltd. and to be returned upon request.

ISO 22000: 2018 Certificate



Certificate

**Breakthrough Management Quality Registrar
(BMQR)**

Certifies that the Food Safety Management System of

WELLOUS PHARMA PRIVATE LIMITED

R.S.No. 333-2A & 2B2, Navamal Marutur Village,
Kandamangalam Block, Villupuram District – 605 102.
Tamilnadu, India.

has been assessed and found to be in accordance with the requirements of the HACCP and food safety standards

ISO 22000:2018

for the following scope of certification

**MANUFACTURING OF PHARMACEUTICAL AND
NUTRACEUTICAL FORMULATIONS FOR
DOMESTIC AND EXPORTS**

Original Certification Date : 08/03/2022
Current Certification Date : 08/03/2022
First Surveillance Due On : 07/03/2023
Second Surveillance Due On : 07/03/2024
Certificate Expiration Date : 07/03/2025



Surveillance Audit

Due On
07/03/2023

Due On
07/03/2024



This certificate is invalid
if surveillance audit is not completed



Certificate No: AB22IS224543



Blair

For BMQR

No.5, 2nd Floor, Sathyamoorthy Road, Thiruvallieswarar Nagar, Thirumangalam,
Anna Nagar West, Chennai - 600 040, Tamilnadu, India.
email: iso@bmqr.com, Web : www.bmqr.com
PH- 044-26152595

The certificate will remain current subject to the company maintaining its system to the required standard(s). This will be monitored regularly by BMQR Certifications Pvt. Ltd.
This Certification details and effectiveness are listed at www.bmqr.com. Registration does not assure the quality of products produced by a Quality System.
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FORM 25 LICENSE

R.Dis.No. 18081/011/2017 dt. 20.3.18 GRANT

FORM 25
(See rule 70)

License to manufacture for sale or for distribution of drugs other than those specified in Schedules C, C(1) and X

Number of License TN00004921 and Date of Issue 20.3.2018

1. Directors of M/s. Wellous Pharma
private limited

is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Schedules C, C(1) and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at R.S. NO. 333-2A & 2B2

Navamal Martur Village, Kandamangalam
Block, Villupuram district, Tamilnadu

under the direction and supervision of the following competent technical staff: - 605102

a) Competent technical staff (Names):

1. Thiru. T.G. Venkatesan Bpharm - for Manu
facturing
2. Thiru. V. Barathbushan B.Sc (chem) - for Testing

b) Names of Drugs (each item to be separately specified):

Vide List attached

- The license authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the license, subject to the conditions applicable to license for sale.
- The license unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.
- The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.



Signature [Handwritten Signature]

Designation **Director of Drugs Control**
Chennai-600 006

Licensing Authority

[Handwritten Signature]
20.3.18

[Handwritten Signature]
20.3.18

FORM 28 LICENSE

R.Dis.No. 18081/01/1/2017 dt. 20.3.18

FORM 28
(See rule 76)

Grant

License to manufacture for sale or for distribution of drugs specified in Schedules C and C (1) excluding those specified in Schedule X

Number of License TN00004922 and Date of Issue 20.3.2018

1. Directors of M/s. Kellous Pharma private Limited

is hereby licensed to manufacture at the premises situated at R.S. No. 333-2A + 2B2 Navamal Marudor Village kandamanga Block, Villupuram District, Tamilnadu - 605102

the following drugs, being drugs specified in Schedules C and C (1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

Names of Drugs : Vide List attached

2. Names of approved competent technical staff :

1. Thiru. T. G. Venkatesan B.pharm - For 11/9
2. Thiru. V. Barathbuehan B.sc(chem) - For 0 Testing

- The License authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the License subject to the conditions applicable to Licenses for sale.
- The License unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of License and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.
- The License is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Signature 

Designation **Director of Drugs Control**
Chennai-600 006



Licensing Authority


20.3.18

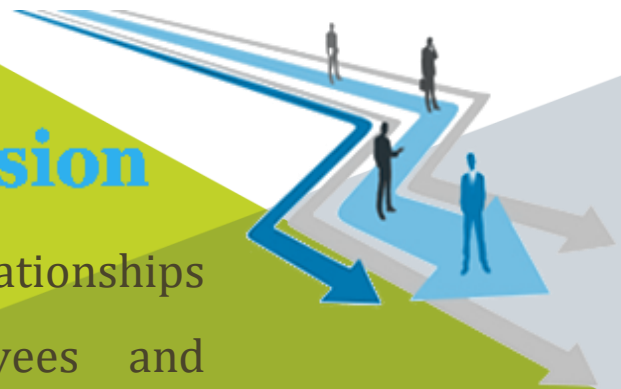
Vision \$ Mission



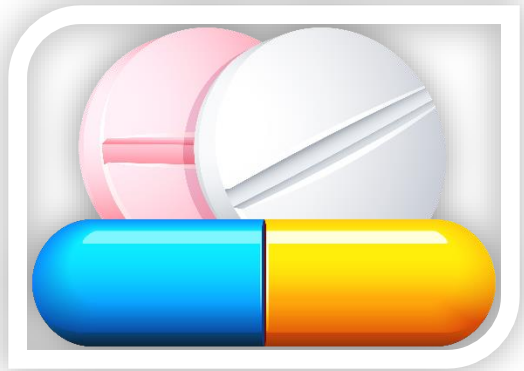
Developing Innovative and Quality Product to continuously create new opportunities for growth in our strategic business.

Our Mission

To develop high integrity relationships with our customer employees and suppliers. Constant innovations, consistent quality, creative solution these are our identity. Wellous Pharma Private Limited committed to strive for total customer satisfaction by conforming to their requirements through continuous improvement in Product, Process and Quality System.



Our Capacity



Tablets
Preparation - 900
Millions / Annum

Capsules
Preparation - 100
Millions / Annum



Powder
Preparation - 12
Millions / Annum

Ointment
Preparation - 10
Millions / Annum



Our Leading Customer



CAPLIN POINT
LABORATORIES LTD.



A Unit of the Orbit Group



NEMUS
Pharmaceuticals Pvt. Ltd.



Flamingo
Pharmaceuticals Limited

apex



Our Leading Customer



Our Departments

Production



The production facility is designed to manufacture oral solid dosage forms includes Tablets, Hard gelatin Capsules, Oral powders and external preparation includes Ointments.

The production area is equipped with advanced manufacturing technology containing automated and PLC based sophisticated equipment as per GMP standard. All process areas are designed to meet the controlled Temperature and Humidity.

Packing

Packing section is equipped to handle all the packing requirements from Alu / Alu, Blisters, Strip and Sachet packing. Barcoding on Primary & Secondary packing is an additional feature to meet the global packing standards.



Our Departments



Quality Assurance

Quality Assurance is a wide ranging concept which covers all matters which individually or collectively influence the quality of a product. It is the total sum of the organized arrangements made with the object of ensuring that medicinal products are of the quality required for the intended use

Quality Control

Quality Control is that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out to meet the specification.

The Quality Control lab is provided with exclusive chemical, Instrumentation and Microbiology labs for the testing of Raw materials, Packaging materials, In-process materials and Finished drug products. The Quality Control Lab is furnished with sophisticated instruments including UV Spectrophotometer, HPLC, FTIR, Auto Titrator and Dissolution test apparatus.



Our Departments

Engineering

Plant is designed to provide uninterrupted services and support for the manufacturing requirements with respect to Electrical, Mechanical, compressed air and allied engineering requirements.

Dedicated Air Handling Units are provided for each process area to prevent cross contamination. The entire plant is equipped with 21 AHU and 1 ventilation unit. Differential pressure is maintained in the process area to restrict the contamination in respective processing area with appropriate cascade air locks. The water plant is designed to deliver Purified water complying with the IP/BP.



Warehouse (Stores)

Warehouse is designed to store Raw materials, Packing materials, Empty hard gelatin capsules and finished goods. Sampling and dispensing activities are carried out in classified area under class 100 environment.

Dynamic pass boxes provided in the sampling area, dispensing area, Empty capsules storage area and Days stores of raw and primary packing materials. Solvents are stored in dedicated flame proof area.



Tablets

METHYLCOBALAMIN, ALPHA LIPOIC ACID, BENFOTIAMINE,
INOSITOL, CHROMIUM PICCOLINATE, PYRIDOXINE HYDROCHLORIDE,
FOLIC ACID, VITAMIN D3, CALCIUM CARBONATE TABLETS

SAMION-CD3
सामिअन सीडी ३

arinna
Lifesciences

10 x 10 Tablets

L- Arginine, Lycopene,
Grape seed Extract,
Multivitamins, Multiminerals
& Trace Elements Tablets

LENOVA-F™

INTRA
LIFE SCIENCES

1 x 10 Tablets

Cetirizine Tablets BP 10 mg

RIZIN

10 x 10 Tablets

ACE

Lycopene, L-Carnitine, Coenzyme Q10
Zinc Ascorbate & Astaxanthin Tablets

LENOVA-M™

INTRA
LIFE SCIENCES

10 x 1 x 10 Tablets

10 x 10 Tablets

Aceclofenac & Thiocolchicoside Tablets

Thiogesic-A

INTRA
LIFE SCIENCES

25 x 10 Tablets

ACECLOFENAC AND
PARACETAMOL TABLETS

ACE-PLUS
एस-प्लस

Aaram

New & Improved
Ultra Fortification

Ascorbic Acid (Vitamin C) Zinc & Vitamin D3 Tablets

**ELBRIT
C+ZD™**

10 x 10 Tablets

ELBRIT

Tablet of Active Vitamins,
Natural Extracts, Minerals
and Amino acids

Fourts B² Plus

Fourts

Net Content: 1x10 Tablets

10 X 10 Tablets

Ascorbic Acid (Vitamin C),
Zinc & Vitamin D₃ Tablets

WAR VIT™

CARUS

20 X 15 Tablets

Paracetamol Tablets IP 650mg

Lumen's™
Pa 650

Lumen
LIFE
SCIENCES

Lumen
LIFE
SCIENCES

Ascorbic Acid (Vitamin C) Chewable Tablets 500 mg

POPCEE™

20 x 10 Tablets
Alu Alu

Lumen
LIFE
SCIENCES

Probiotic & Vitamin C Chewable Tablets

PROBIO C™

1 x 10 Tablets
Alu Alu

10 x 10 Tablets

Selenium
Zinc
Chromium
Folic Acid
Iron

Multivitamins & Minerals Tablets

AGIMIN-Z

Net Content:
10 x 1 x 10 Tablets

Myo Inositol, D-Chiro Inositol, L-Methyl Folate
Calcium and Vitamin D Chewable Tablets

ChiroCyst DS
क़िरोसिस्ट डी एस

CHIROCYST PRODUCT
Ankara, Turkey

3 x 10 TABLETS

IMMUNE-5

Rx

Sildenafil Citrate Tablets IP 25 mg

PrimiWal-S

प्रिमीवाल-एस

3 x 10 Tablets

N-Acetyl Cysteine,
Myo Inositol, D-Chiro Inositol,
Chromium picolinate and Vitamin D2 Tablets

ChiroCyst
क़िरोसिस्ट

Vanilla
Flavour

25mg
FOLIC ACID (100mcg)

CHIROCYST PRODUCT
Ankara, Turkey

10 x 10 Tablets

Flupirtine Maleate
Sustained Release Tablets


Flubak-100
फ्लुबक-100

ELM

Capsules

10 x 10 Capsules


Rx
Calcium Dobesilate Capsules
DOBIL
डोबिल



3 x 10 CAPSULES

Prebiotic & Probiotic Capsules with Zinc & FOS

Dualac
Good for the Gut



Dualac

Gastro-resistant Omeprazole Capsules BP 20mg

OMEROZ

10 x 10 Capsules

ДУАЛАК ИСТОЧНИК ПРОБИОТИЧЕСКИХ МИКРООРГАНИЗМОВ

КАПСУЛЫ

30 330 мг

БИФИДО - и ЛАКТОБАКТЕРИИ



Rx
Rabeprazole Sodium and Domperidone (SR) Capsules

ESODRIVE-D
इसोड्राइव-डी

10 x 10 Capsules

Rx
Pantoprazole Gastro Resistant and Domperidone Prolonged Release Capsules IP

PANPRAZ-D

10 X 10 Capsules



10 X 10 Capsules Alu/Alu

X
Pantoprazole Gastro Resistant & Domperidone Prolonged Release Capsules IP

POPZ-D SR
पोपस-डी एसआर



10 x 1 x 10 Capsules Alu/Alu

Pregabalin & Methylcobalamin Capsules IP

PREGANAM M



Sachets

Fourrts
 Polyethylene Glycol 3350
 Powder for Oral Solution
LAXOPEG[®] KID
 लॅक्सोपेग किड
 10 x 8.5g Sachet

20 Sachets
ELMA
 L-Arginine, Zinc
 & Folic Acid Granules
LYGENE
 Sachet
 SUGAR FREE

Amino acids, Vitamin, Minerals,
 Co-enzyme Q10, Citric acid,
 Fructose & Lycopene powder
Carni-Q[™] XP
 कारनी-क्यू एक्स पी
 Net Content: 20 x 5 g Sachets

10 Sachets
 L-Arginine, Zinc
 & Folic Acid Granules
LRZin Forte[™]
 एलआरज़िन फोर्ट
 Tasty Orange Flavour
 SUGAR FREE

Probiotic Granules
Happy Pro[®]
 Sachet
SUNAX

1 gm Sachet
 Probiotics with Omega 3 Fatty Acid & Vitamin E
Hepameg
 हेपामेग

New
 10 x 17 g Sachet
 POLYETHYLENE
 GLYCOL 3350
LAXOPEG[®]
 लॅक्सोपेग
Fourrts
 TOP GRADE
 PEG 3350

20 Sachets
 L-Arginine, Zinc
 & Folic Acid Granules
LRZin[™]
 एलआरज़िन
 Lemony Orange Flavour
 SUGAR FREE

Net Quantity:
 30 x 3g sachets
 Myo-Inositol, Folic acid & Vitamin D2 Granules
MyoCyst[™]
 मयोसिस्ट
 SUGAR FREE
 Orange flavour
Issai
 Lic. No.: 1241608000924
 A **HEAL** PRODUCT

10 x 0.84 g Sachets
Saccharomyces Boulardii
 (Lyophilized)
ONEFLORA
 Heilan Medicament

Myo-Inositol, D Chiro Inositol,
 L-Methylfolate, Melatonin
 Co-Enzyme Q₁₀ &
 Vitamin-D3 Sachets
OVARICH OD
 Sachets
 10 x 7g Sachet

10 x 5g Sachets
 SUGAR FREE
 L-Arginine Granules
Rheonitric[®]
 Heilan Medicament
 Orange Flavour

Ointments

Diclofenac Diethylamine, Linseed Oil, 30g
Methyl Salicylate, Capsaicin & Menthol Gel

VOLIGEL™

Lumen
LIFE
sciences



Rx Sucralfate, Metronidazole and Lignocaine Cream 20g

Surect™ सुरेक्ट™ NEMUS



Rx Sucralfate, Metronidazole and Lignocaine Cream 20 g

Sucrabet Ano

Elder
Mupirocin Ointment IP 2.0% w/w

Sofrabact® 5g

Rx Sucralfate, Metronidazole and Lignocaine Cream 20 g

Proctobact™

Elder

Rx Povidone Iodine & Ornidazole Ointment 15 g

Povimen-OR

Microbicidal Water-Soluble Ointment

Lumen
LIFE
sciences

Rx Povidone Iodine & Ornidazole Ointment 15g

POVIKEN

Microbicidal Water-Soluble Ointment

Chemiken

Rx Povidone Iodine & Ornidazole Ointment 15 g

POVI-10™

पोवी-१०

Microbicidal Water-Soluble Ointment

NEMUS

15 g.

Neomycin and Polymyxin B Sulfates and
Bacitracin Zinc Ointment USP

60g

Permethrin
Cream 5% w/w



Contact Details



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9442993737 / 9047005701
karunakarana@wellous.in
www.wellous.in

Factory Address

M/s. Wellous Pharma Private Limited,
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Villupuram District,
Tamil Nadu - 605 102.
Mobile: 9047007606.
Site: www.wellous.in



Pharmaceutical

