An Aqueous Pathway Leading to Patient Friendly Solutions

MKPPL

MURLI KRISHNA PHARMA PVT. LTD.

A Profile

Message from the CMD

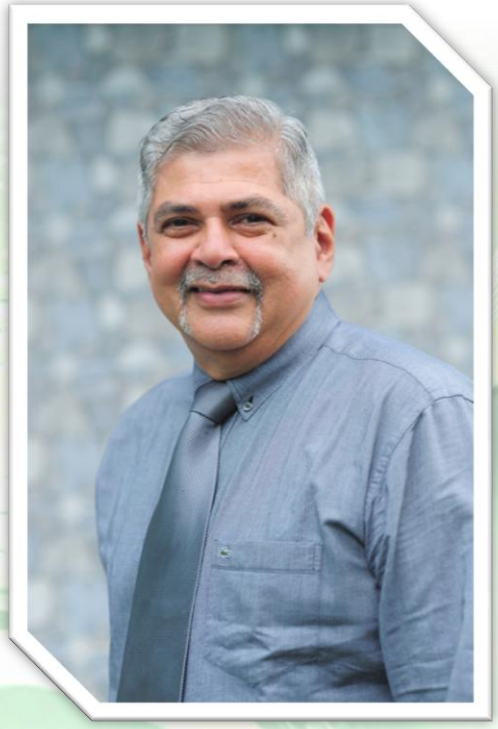
At Murli Krishna Pharma, it is our endeavor to provide the best quality products to the Industry at competitive prices that will provide cost effective therapeutic agents to the developed as well as under developed world.

We have a definite vision and we need achieve our vision through cogent strategies and conduct a periodical review of the same to ensure that we do not deviate from the track. Ethical business practices is the MANTRA of our company and through our innovations and research, we would like to grow and support the clients in their growth mission too.

These values will spurt the growth of Murli Krishna Pharma and make Murli Krishna Pharma a Global Leader in Drug Delivery Technologies

Satya Vadlamani

Message from the Director- Technical



To be a Global Leader in Drug Delivery Technologies, we need to be ahead of the competition. For this, we have committed ourselves to constant innovation and maintaining World Class Quality Standards .

Our goal is to ease the patient's discomfort and lead them to heal faster. With a complete focus on the customer, continuous improvement on processes combined with teamwork and collaboration, we are destined to spur exponential growth for our company in terms of value and revenue.

Dr Vijay Shastri

Murli Krishna Pharma Pvt. Ltd. – (MKPPL)

MKPPL is a Manufacturer of Pre-finished formulation Intermediates accredited by the European Union & WHO for GMP compliance. Our USP is manufacturing of Bioequivalent products using an Aqueous-layering system.

Established in the year 2004, MKPPL had initiated its operations with a single thereuptic group with its supplies to certain semi-regulated markets. With the EU approval in the year 2007, MKPPL had transmuted its operations into a regulatory compliant manufacturer and today, MKPPL is one of the leading manufacturers of PFI's from India.

With a lineup of more than 34 products, Our Therapeutic segment includes Anti-Ulcerants, Anti Fungal, Antibiotics, Anti Obesity, Anti Depressant, Anti Inflammatory, Alpha-blockers, Immune Suppressants and Anti-emetic (during chemotherapy) in the developed/commercialized category and development pipeline includes Mitotic Inhibitors, Carbonic anhydrase inhibitors and Triazole anti-fungals.

MKPPL which had already mastered the Macro, Micro & MUPS arenas is now quickly taking its steps towards Nano Technology which would be a major breakthrough in NDDS.

R&D

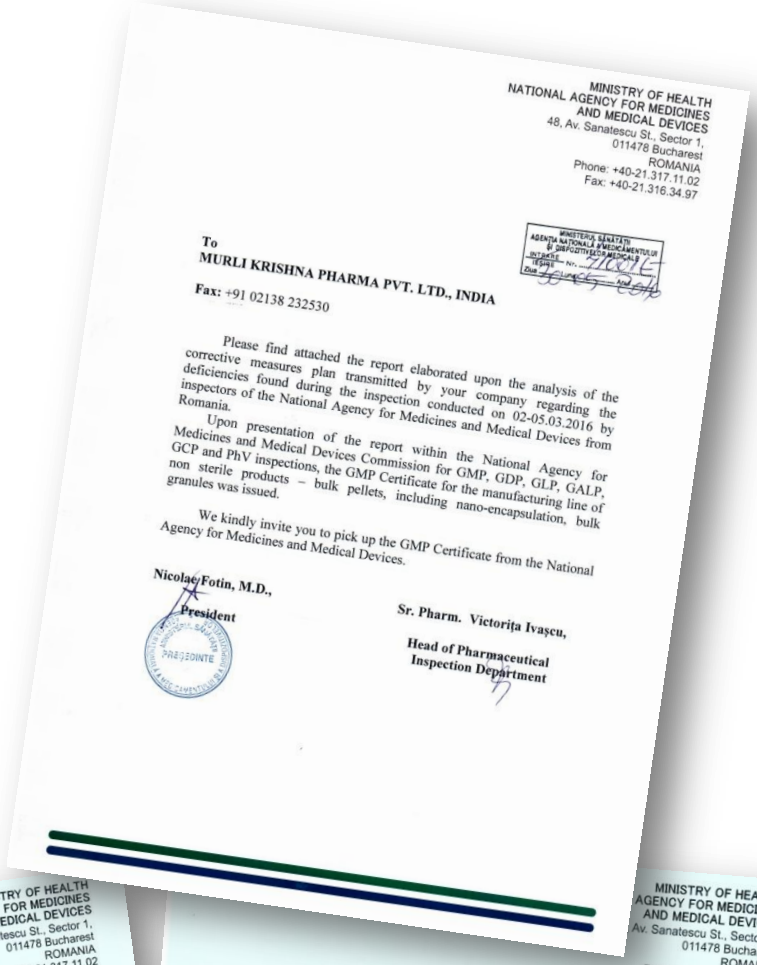
MKPPL which is a DSIR Certified/Recognized R&D, is actively engaged for devising innovative drugs solutions with thoughtful selection of Excipients using a congent Matrix. The R & D team has devised unique techniques to layer poorly soluble drugs using aqueous media.

A pellet based approach has been employed for immune suppressants. The pilot results indicate that the in vivo results match with the innovator in case of Tacrolimus.

A dedicated team has been engaged for devising Nano based developments (Nano Particles) for applications including Injectables, Respules etc. covering the Oncological, Ophthalmological and Corticosteroid categories.

Approvals & Certifications

EU - Union



MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES
48, Av. Sanatescu St., Sector 1,
011478 Bucharest
ROMANIA
Phone: +40-21.317.11.02
Fax: +40-21.316.34.97

To
MURLI KRISHNA PHARMA PVT. LTD., INDIA

Fax: +91 02138 232530

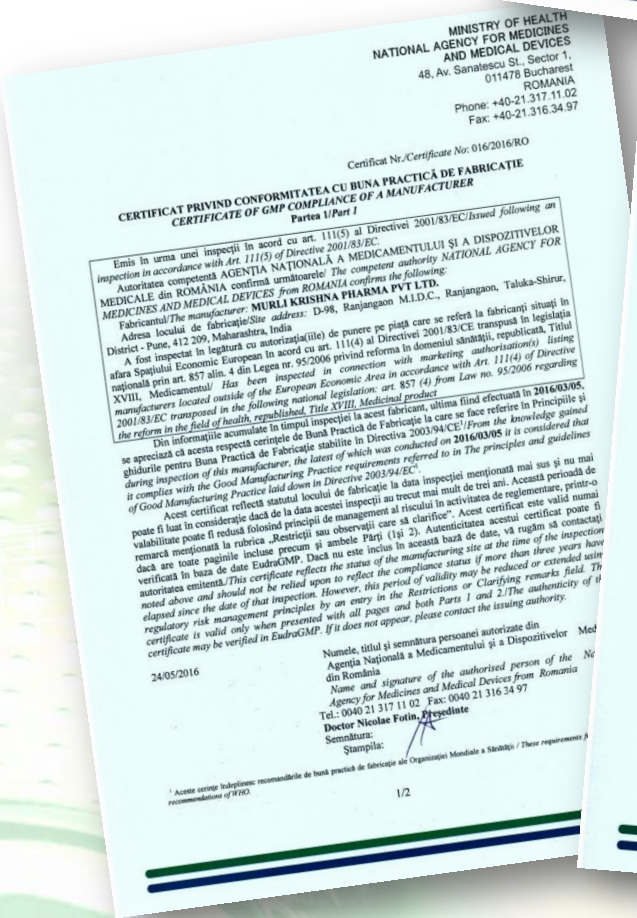
Please find attached the report elaborated upon the analysis of the corrective measures plan transmitted by your company regarding the deficiencies found during the inspection conducted on 02-05.03.2016 by inspectors of the National Agency for Medicines and Medical Devices from Romania.

Upon presentation of the report within the National Agency for Medicines and Medical Devices Commission for GMP, GDP, GLP, GALP, GCP and PhV inspections, the GMP Certificate for the manufacturing line of non sterile products – bulk pellets, including nano-encapsulation, bulk granules was issued.

We kindly invite you to pick up the GMP Certificate from the National Agency for Medicines and Medical Devices.

Nicolae Fotin, M.D.,
President

Sr. Pharm. Victorița Ivașcu,
Head of Pharmaceutical Inspection Department



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Certificat Nr./*Certificate No:* 016/2016/RO

CERTIFICAT PRIVIND CONFORMITATEA CU BUNA PRACTICĂ DE FABRICAȚIE
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Partea 1/*Part 1*

Emis în urma unei inspecții în acord cu art. 111(5) al Directivei 2001/83/EC/*Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.*

Autoritatea competentă AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE din ROMÂNIA confirmă următoarele/ *The competent authority NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES from ROMANIA confirms the following:*

Fabricantul/*The manufacturer:* **MURLI KRISHNA PHARMA PVT LTD.**
Adresa locului de fabricație/*Site address:* D-98, Ranjangaon M.I.D.C., Ranjangaon, Taloka-Shirur, District - Pune, 412 209, Maharashtra, India

A fost inspectat în legătură cu autorizația(ile) de punere pe piață care se referă la fabricanți situați în afara Spațiului Economic European în acord cu art. 111(4) al Directivei 2001/83/CE transpusă în legislația națională prin art. 857 alin. 4 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată, Titlul XVIII, Medicamentul/ *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: art. 857 (4) from Law no. 95/2006 regarding the reform in the field of health, republished, Title XVIII, Medicinal product*

Din informațiile acumulate în timpul inspecției la acest fabricant, ultima fiind efectuată în **2016/03/05**, se apreciază că acesta respectă cerințele de Bună Practică de Fabricație la care se face referire în Principiile și ghidurile pentru Buna Practică de Fabricație stabilite în Directiva 2003/94/CE/*From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on* **2016/03/05** *it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC*[1].

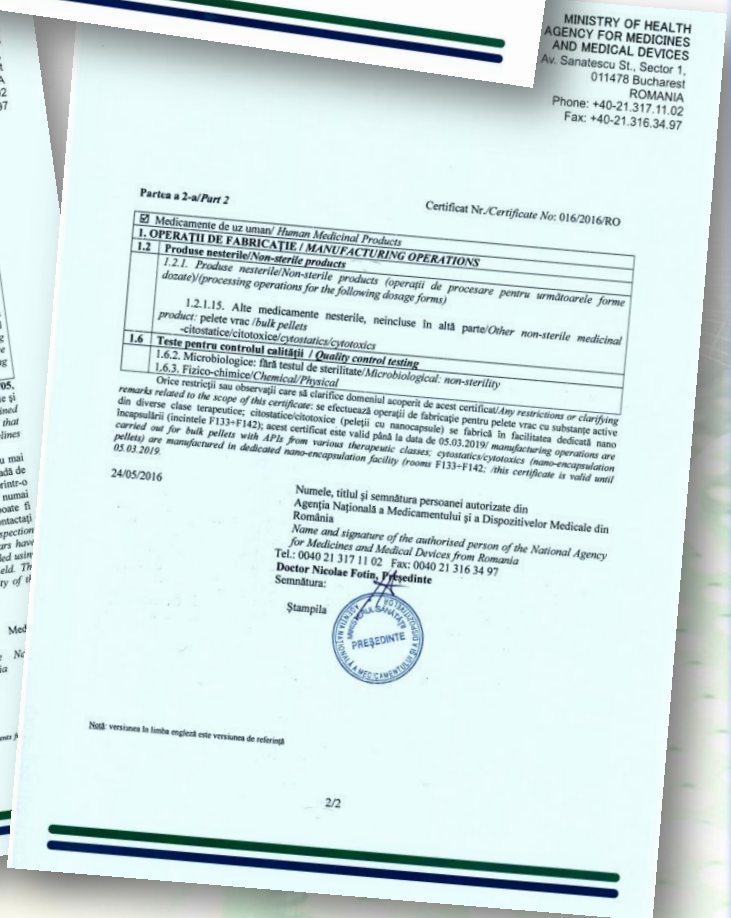
Acest certificat reflectă statutul locului de fabricație la data inspecției menționată mai sus și nu mai poate fi luat în considerație dacă de la data acestei inspecții au trecut mai mult de trei ani. Această perioadă de valabilitate poate fi redusă folosind principii de management al riscului în activitatea de reglementare, printr-o remarcă menționată la rubrica „Restricții sau observații care să clarifice". Acest certificat este valid numai dacă are toate paginile incluse precum și ambele Părți (I și 2). Autenticitatea acestui certificat poate fi verificată în baza de date EudraGMP. Dacă nu este inclus în această bază de date, vă rugăm să contactați autoritatea emitentă./*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. The certificate is valid only when presented with all pages and both Parts 1 and 2./The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.*

24/05/2016

Numele, titlul și semnătura persoanei autorizate din Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România
Name and signature of the authorised person of the National Agency for Medicines and Medical Devices from Romania
Tel.: 0040 21 317 11 02 Fax: 0040 21 316 34 97
Doctor Nicolae Fotin, Președinte
Semnătura:
Ștampila:

[1] Aceste cerințe îndeplinesc recomandările de bună practică de fabricație ale Organizației Mondiale a Sănătății / *These requirements fulfil the recommendations of WHO.*

1/2



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Partea a 2-a/*Part 2*

Certificat Nr./*Certificate No:* 016/2016/RO

☑ Medicamente de uz uman/ *Human Medicinal Products*

1. OPERAȚII DE FABRICAȚIE / *MANUFACTURING OPERATIONS*	
1.2	**Produse nesterile/*Non-sterile products***
	1.2.1. Produse nesterile/Non-sterile products (operații de procesare pentru următoarele forme dozate)/(processing operations for the following dosage forms)
	1.2.1.15. Alte medicamente nesterile, neincluse în altă parte/*Other non-sterile medicinal product:* pelete vrac /*bulk pellets*
1.6	**Teste pentru controlul calității / *Quality control testing***
	1.6.2. Microbiologice: fără testul de sterilitate/*Microbiological: non-sterility*
	1.6.3. Fizico-chimice/*Chemical/Physical*

Orice restricții sau observații care să clarifice domeniul acoperit de acest certificat/*Any restrictions or clarifying remarks related to the scope of this certificate:* se efectuează operații de fabricație pentru pelete vrac cu substanțe active din diverse clase terapeutice; citostatice/citotoxice (peleții cu nanocapsule) se fabrică în facilitatea dedicată nano încapsulării (incintele F133+F142); acest certificat este valid până la data de 05.03.2019/ *manufacturing operations are carried out for bulk pellets with APIs from various therapeutic classes; cytostatics/cytotoxics (nano-encapsulation pellets) are manufactured in dedicated nano-encapsulation facility (rooms F133÷F142; /this certificate is valid until 05.03.2019.*

24/05/2016

Numele, titlul și semnătura persoanei autorizate din Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România
Name and signature of the authorised person of the National Agency for Medicines and Medical Devices from Romania
Tel.: 0040 21 317 11 02 Fax: 0040 21 316 34 97
Doctor Nicolae Fotin, Președinte
Semnătura:

Ștampila

Notă: versiunea în limba engleză este versiunea de referință

2/2

Approvals & Certifications

JFDA – Jordan Food & Drug Administration

المؤسسة العامة للغذاء والدواء

الرقم ٢٨٨٧٩/٢٠١٤/١١/٤
التاريخ
الموافق

المدير الفني المسؤول عن شركة الحياة للصناعات الدوائية

تحية طيبة وبعد ،،،

الموضوع: اعتماد موقع تصنيع

لاحقاً لكتابنا رقم ٢٩٤/٢٩/١٦/٢ تاريخ ٢٠١٤/١/٦ بخصوص الموقع التصنيعي لشركة Murli Krishna Pharma PVT Ltd/ India والمقدم للاعتماد تحت الرقم 30/ACom/2012 تاريخ ٢٠١٢/٥/٢٩.

وبناءً على قرار لجنة اعتماد مواقع التصنيع في جلستها المنعقدة بتاريخ ٢٠١٤/١٠/٢٧ وبعد الاطلاع على تقرير التفتيش الذي جرى على الموقع من قبل فريق التفتيش في الفترة ١٩-٢٠١٤/٨/٢٢ نحيطكم علماً بقبول اعتماد الموقع التصنيعي لشركة Murli Krishna Pharma PVT Ltd/ India

وعنوان المكاتب الرئيسية وموقعها التصنيعي:

D-98, Ranjangaon MIDC, Tal Shirur
Dist. Pune 412209, Maharashtra State, India

لخط انتاج:

Bulk Drugs (Pellets)

رقم التسجيل: 43/Com/2014

وتفضلوا بقبول فائق الاحترام ،،،

المدير العام
الدكتور هايل محمد عبيدات

الصيدلاني قاسم الحديدي
مديرية الدواء / المكلف
التاريخ ٣/ ١١/ ٢٠١٤

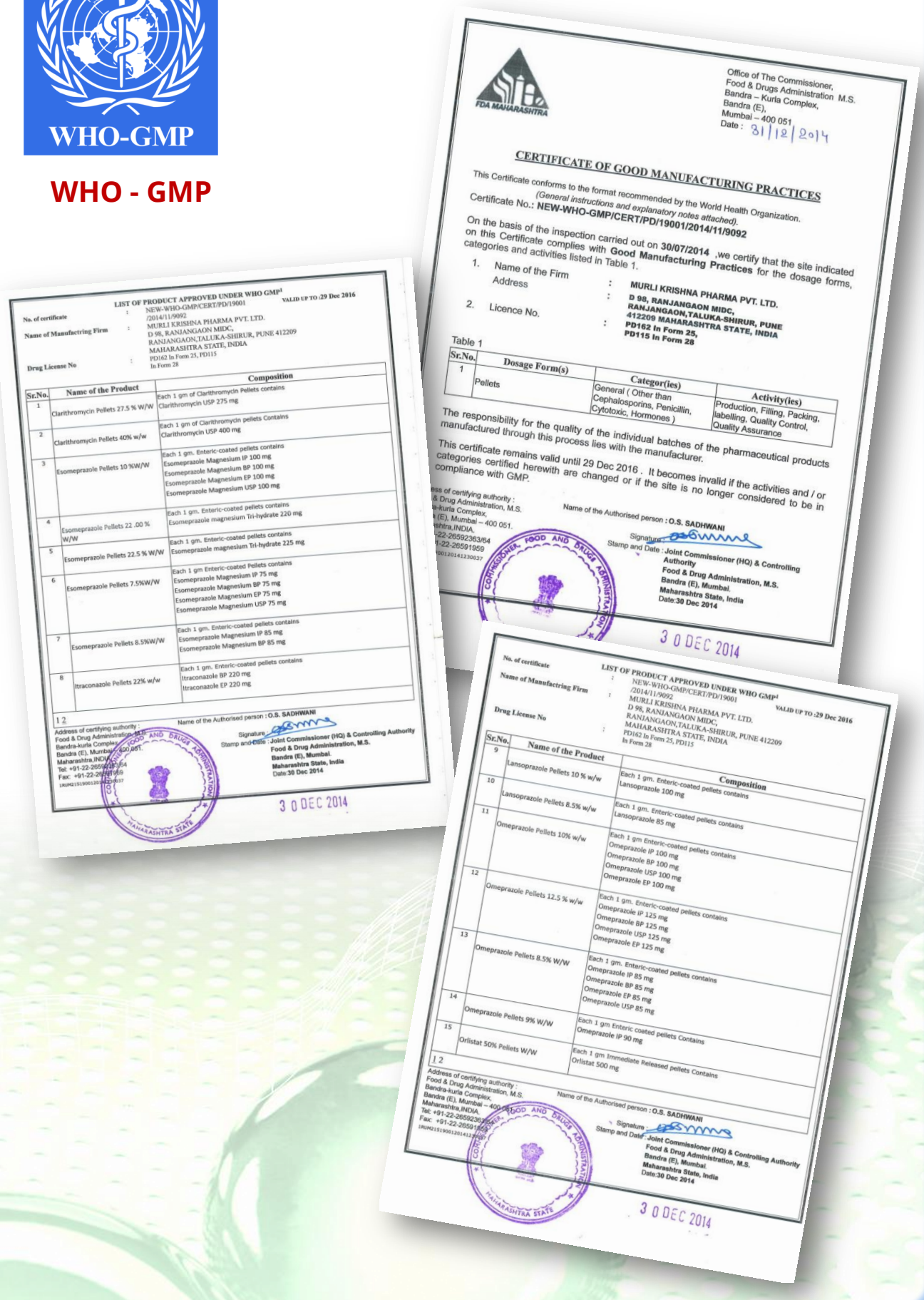
نسخة/ لقسم التسجيل
نسخة/ لمختبر الرقابة الدوائية
نسخة/ م. م. الشؤون المخبرية
نسخة/ لسيم الاستيراد والتصدير
نسخة/ للحاسوب

N-184-2014

المملكة الأردنية الهاشمية
هاتف: ٥٦٣٢٠٠٠ ٦ ٩٦٢+ فاكس: ٥١٠٥٩١٦ ٦ ٩٦٢+ ص.ب: ٨١١٩٥١ عمان ١١١٨١ الأردن الموقع الإلكتروني: www.jfda.jo

Approvals & Certifications

WHO - GMP



FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051.
Date : 31/12/2014

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/PD/19001/2014/11/9092**

On the basis of the inspection carried out on **30/07/2014** ,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 of the Firm : **MURLI KRISHNA PHARMA PVT. LTD.**
   Address : **D 98, RANJANGAON MIDC, RANJANGAON,TALUKA-SHIRUR, PUNE 412209 MAHARASHTRA STATE, INDIA**
2. Licence No. : **PD162 In Form 25, PD115 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Pellets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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 29 Dec 2016 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1RUM215190012014123003?

Name of the Authorised person : **O.S. SADHWANI**
Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:30 Dec 2014

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

30 DEC 2014

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

VALID UP TO :29 Dec 2016

No. of certificate : NEW-WHO-GMP/CERT/PD/19001 /2014/11/9092
Name of Manufacturing Firm : MURLI KRISHNA PHARMA PVT. LTD. D 98, RANJANGAON MIDC, RANJANGAON,TALUKA-SHIRUR, PUNE 412209 MAHARASHTRA STATE, INDIA
Drug License No : PD162 In Form 25, PD115 In Form 28

Sr.No.	Name of the Product	Composition
1	Clarithromycin Pellets 27.5 % W/W	Each 1 gm of Clarithromycin Pellets contains Clarithromycin USP 275 mg
2	Clarithromycin Pellets 40% w/w	Each 1 gm of Clarithromycin pellets Contains Clarithromycin USP 400 mg
3	Esomeprazole Pellets 10 %W/W	Each 1 gm. Enteric-coated pellets contains Esomeprazole Magnesium IP 100 mg Esomeprazole Magnesium BP 100 mg Esomeprazole Magnesium EP 100 mg Esomeprazole Magnesium USP 100 mg
4	Esomeprazole Pellets 22 .00 % W/W	Each 1 gm. Enteric-coated pellets contains Esomeprazole magnesium Tri-hydrate 220 mg
5	Esomeprazole Pellets 22.5 % W/W	Each 1 gm. Enteric-coated pellets contains Esomeprazole magnesium Tri-hydrate 225 mg
6	Esomeprazole Pellets 7.5%W/W	Each 1 gm Enteric-coated Pellets contains Esomeprazole Magnesium IP 75 mg Esomeprazole Magnesium BP 75 mg Esomeprazole Magnesium EP 75 mg Esomeprazole Magnesium USP 75 mg
7	Esomeprazole Pellets 8.5%W/W	Each 1 gm. Enteric-coated pellets contains Esomeprazole Magnesium IP 85 mg Esomeprazole Magnesium BP 85 mg
8	Itraconazole Pellets 22% w/w	Each 1 gm. Enteric-coated pellets contains Itraconazole BP 220 mg Itraconazole EP 220 mg

1 2

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1RUM215190012014123003?

Name of the Authorised person : **O.S. SADHWANI**
Signature :
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Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:30 Dec 2014

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

30 DEC 2014

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

VALID UP TO :29 Dec 2016

No. of certificate : NEW-WHO-GMP/CERT/PD/19001 /2014/11/9092
Name of Manufacturing Firm : MURLI KRISHNA PHARMA PVT. LTD. D 98, RANJANGAON MIDC, RANJANGAON,TALUKA-SHIRUR, PUNE 412209 MAHARASHTRA STATE, INDIA
Drug License No : PD162 In Form 25, PD115 In Form 28

Sr.No.	Name of the Product	Composition
9	Lansoprazole Pellets 10 % w/w	Each 1 gm. Enteric-coated pellets contains Lansoprazole 100 mg
10	Lansoprazole Pellets 8.5% w/w	Each 1 gm. Enteric-coated pellets contains Lansoprazole 85 mg
11	Omeprazole Pellets 10% w/w	Each 1 gm Enteric-coated pellets contains Omeprazole IP 100 mg Omeprazole BP 100 mg Omeprazole USP 100 mg Omeprazole EP 100 mg
12	Omeprazole Pellets 12.5 % w/w	Each 1 gm. Enteric-coated pellets contains Omeprazole IP 125 mg Omeprazole BP 125 mg Omeprazole USP 125 mg Omeprazole EP 125 mg
13	Omeprazole Pellets 8.5% W/W	Each 1 gm. Enteric-coated pellets contains Omeprazole IP 85 mg Omeprazole BP 85 mg Omeprazole EP 85 mg Omeprazole USP 85 mg
14	Omeprazole Pellets 9% W/W	Each 1 gm Enteric coated pellets Contains Omeprazole IP 90 mg
15	Orlistat 50% Pellets W/W	Each 1 gm Immediate Released pellets Contains Orlistat 500 mg

1 2

Address of certifying authority :
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Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
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Fax: +91-22-26591959
1RUM215190012014123003?

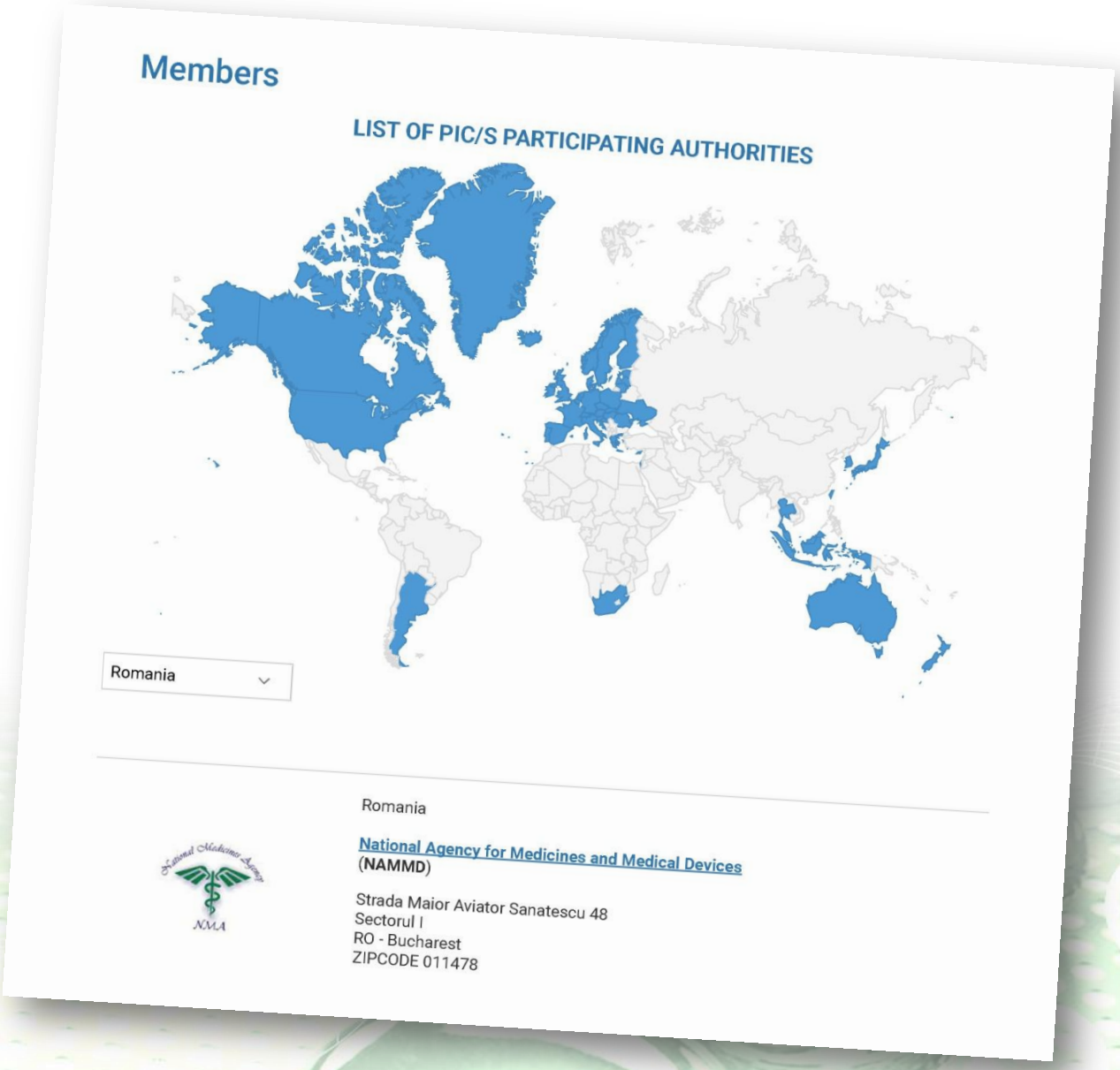
Name of the Authorised person : **O.S. SADHWANI**
Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:30 Dec 2014

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

30 DEC 2014

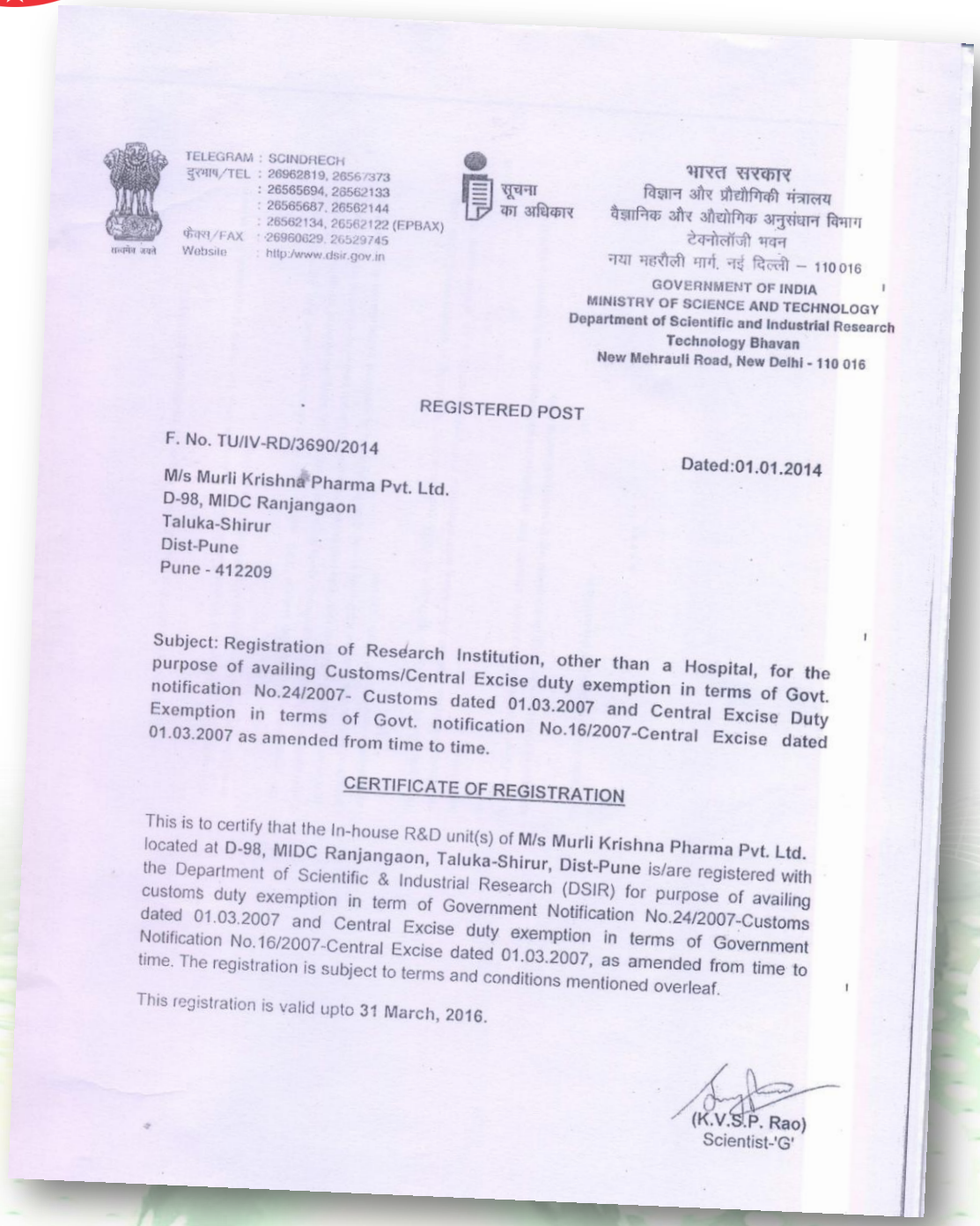
Approvals & Certifications

Member
(Pharmaceutical Inspection Co-operation Scheme)



Approvals & Certifications

DSIR
Department for Scientific & Industrial Research



TELEGRAM : SCINDRECH
दूरभाष/TEL : 26962819, 26567373
: 26565694, 26562133
: 26565687, 26562144
: 26562134, 26562122 (EPBAX)
फैक्स/FAX : 26960629, 26529745
Website : http://www.dsir.gov.in

सूचना का अधिकार

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
वैज्ञानिक और औद्योगिक अनुसंधान विभाग
टेक्नोलॉजी भवन
नया महरौली मार्ग, नई दिल्ली – 110 016

GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
Department of Scientific and Industrial Research
Technology Bhavan
New Mehrauli Road, New Delhi - 110 016

REGISTERED POST

F. No. TU/IV-RD/3690/2014

Dated:01.01.2014

M/s Murli Krishna Pharma Pvt. Ltd.
D-98, MIDC Ranjangaon
Taluka-Shirur
Dist-Pune
Pune - 412209

Subject: Registration of Research Institution, other than a Hospital, for the purpose of availing Customs/Central Excise duty exemption in terms of Govt. notification No.24/2007- Customs dated 01.03.2007 and Central Excise Duty Exemption in terms of Govt. notification No.16/2007-Central Excise dated 01.03.2007 as amended from time to time.

CERTIFICATE OF REGISTRATION

This is to certify that the In-house R&D unit(s) of **M/s Murli Krishna Pharma Pvt. Ltd.** located at **D-98, MIDC Ranjangaon, Taluka-Shirur, Dist-Pune** is/are registered with the Department of Scientific & Industrial Research (DSIR) for purpose of availing customs duty exemption in term of Government Notification No.24/2007-Customs dated 01.03.2007 and Central Excise duty exemption in terms of Government Notification No.16/2007-Central Excise dated 01.03.2007, as amended from time to time. The registration is subject to terms and conditions mentioned overleaf.

This registration is valid upto **31 March, 2016.**

(K.V.S.P. Rao)
Scientist-'G'

Awards

INDIA TODAY GROUP

INDIA TODAY
MAKE IN INDIA
EMERGING ENTREPRENEUR AWARDS
Winner
Biotech & Pharma

National Award for CSR & Sustainability

Awards

Certificate of Appreciation for Export Category in the Small Scale Industry

Accolades

Rated as the Women Entrepreneur of the year By

BBC WORLD NEWS

https://www.youtube.com/watch?v=Lobg8n8BIHM

Mission, Vision & values

To **provide** the **best quality** products at **competitive prices** through **integration, research, innovation & development.**

To be an **ethically** responsible company and work towards the **growth** of our clients, our **country** and our **employees**

To continually **innovate** and **develop indigenous drug delivery** systems that shall propel the company as one of the **leading** drug manufacturing companies in the **world**

To be a **GLOBAL LEADER** in **Drug Delivery** Technologies through **RESEARCH & INNOVATION**

- **Innovation**
- **Ensure Quality**
- **R&D**
- **Customer Focus**
- **Continuous Improvement**
- **Ambition to succeed**
- **Collaboration**
- **Teamwork**

An Aqueous Pathway Leading to Patient Friendly Solutions

MKPPL

MURLI KRISHNA PHARMA PVT. LTD.

D - 98, Ranjangaon MIDC, District Pune,
Maharashtra,
India – 412209
Email: ?????
www.mkppl.com