ANUH PHARMA LTD.
3-A Shivsagar Estate, North Wing,
Dr. Annie Besant Road, Worli, Mumbai 400 018
Phone: +91 22 6622 7575; **Fax:** +91 22 6622 7600
Email: anuh@sk1932.com; **CIN:** L24230MH1960PLC011586

FAMILIARISATION PROGRAM FOR INDEPENDENT DIRECTORS FOR THE FINANCIAL YEAR 2016-17

A. PREAMBLE:

Pursuant to the Regulation 25(7) of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015 the listed entity shall familiarise the Independent Directors through various programs about the listed entity, including the following:

(a) nature of the industry in which the listed entity operates;
(b) business model of the listed entity;
(c) roles, rights, responsibilities of independent directors; and
(d) any other relevant information.

B. FAMILIARIZATION PROCESS:

1. All Independent Directors of the Company are made aware of their role, responsibilities and liabilities at the time of appointment/re-appointment through formal letter of appointment, which also stipulates various terms and conditions of their engagement.

2. Each Member of the Board, including the Independent Director have been given complete access to any information relating to the Company, whenever they so request.

3. The Company shall conduct periodical meetings and visits of Independent Directors and make presentations to the Independent Directors to familiarize them with the strategy, operations and functions of the Company;

4. The Company conducts quarterly review meetings and where Independent Directors shall be invited in one of the meetings to interact with the team of senior management of the Company;

5. The programs and presentations will give them insight into the Company's strategy, business model, operations, markets, organization structure, finance, technology, quality, facilities and risk management and such other areas of relevance;

6. The Company may conduct an introductory familiarization program /presentation whenever a new Independent Director comes on the Board.

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7. The Company provides specific regulatory updates, from time to time, and circulates news and articles related to the industry.

C. PROGRAMME AND DISCLOSURE:

1. Presentation was made regarding role & responsibilities of Independent Directors and regarding factory activities and operations of the factory to familarise the Independent Directors of the Company's business model and how the factory runs as & with their roles and responsibilities; (copy of the presentation is enclosed herewith as **Annexure - 1**);

2. Visit to Company's plant was organized for the Independent Directors, where plant heads appraised them of the operational and sustainability aspects of the plants to enabled them to have full understanding on the activities of the Company and initiatives taken on safety, quality, Sustainability etc.;

3. Periodical presentations on operations made to the Board include information on business performance, operations, market share, financial parameters, working capital management, fund flows, senior management change, major litigation, compliances, CSR donations, regulatory scenario etc.;

4. Familiarization program will be conducted on "as needed" basis during the year.

5. As and when familiarization program is conducted, the same will be disclosed on the website of the Company.

D. REVIEW OF THE PROGRAM:

The Board will review this program and make such revisions as may be required or deemed necessary from time to time.

By order of the Board
For **Anuh Pharma Limited**

Sd/-

Bipin Shah
Managing Director
(DIN: 00083244)

Date: 10th March, 2017

ANUH PHARMA LIMITED

ANUH PHARMA LIMITED

FAMILARISATION PROGRAM FOR INDEPENDENT DIRECTORS FOR THE FINANCIAL YEAR 2016-17

Head Office: 3-A, Shiv Sagar Estate, North Wing, Dr. Annie Besant Road, Worli, Mumbai - 400 018
Factory: E 17/3 & 17/4, MIDC, Boisar, Tarapur, Palghar - 401 506

FAMILARISATION PROVISIONS

- Pursuant to Regulation 25(7) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 the listed entity shall familiarise the Independent Directors through various program about the listed entity, including the following:
- Nature of the industry in which the listed entity operates;
- Business model of the listed entity;
- Roles, rights, responsibilities of Independent Directors; and
- Any other relevant information.

KEY INITIATIVES

- Presentation shall be made regarding role & responsibilities of Independent Directors and regarding factory activities and operations of the factory to familarise the Independent Directors of the Company's business model and how the factory runs as & with their roles and responsibilities.

- Visit to Company's plant shall be organized for all the Independent Directors, where plant Heads appraise them of the operational and sustainability aspects of the plants to enable them to have full understanding on the activities of the Company and initiatives taken on safety, quality, Sustainability etc.

- Periodical presentations on operations shall be made to the Board which shall include information on business performance, operations, market share, financial parameters, working capital management, fund flows, senior management change, major litigation, compliances, CSR donations, regulatory scenario etc.

ROLES, RIGHTS, RESPONSIBILITIES OF INDEPENDENT DIRECTORS

- **Section 149, 150 and Schedule IV of the Companies Act, 2013 governs the rules, regulations, duties, role and functions of Independent Directors:**
- **The Independent Directors shall:**

✓ help in bringing an independent judgment to bear on the Board's deliberations especially on issues of strategy, performance, risk management, resources, key appointments and standards of conduct;

✓ bring an objective view in the evaluation of the performance of board and management;

✓ participate constructively and actively in the committees of the Board in which they are chairpersons or members& strive to attend the general meetings of the company.

ROLES, RIGHTS, RESPONSIBILITIES OF INDEPENDENT DIRECTORS

- ✓ determine appropriate levels of remuneration of executive directors, key managerial personnel and senior management and have a prime role in appointing and where necessary recommend removal of executive directors, key managerial personnel and senior management;
- ✓ scrutinise the performance of management in meeting agreed goals and objectives and monitor the reporting of performance
- ✓ seek appropriate clarification or amplification of information and, where necessary, take and follow appropriate professional advice and opinion of outside experts at the expense of the company
- ✓ not disclose confidential information, including commercial secrets, technologies,advertising and sales promotion plans, unpublished price sensitive information, unless such disclosure is expressly approved by the Board or required by law

ABOUT US

- Anuh Pharma's manufacturing activities are carried out under Licence from the Food & Drug Administration, Maharashtra State, India and covered by manufacturing Licence No. 28 KD-990 & 25 KD 1194
- Global presence in 57 countries as exporter.
- Government recognised export house for last ten years.

PRODUCT LIST

- Macrolides

ITEM	SPECIFICATION	PACKING	CAS NO	USE
Erythromycin Base	IP/BP/USP/CP/EP	25 Kg HDPE Drum	114-07-8	Antibacterial
Erythomycin Estolate	IP/BP/USP/EP	25 Kg HDPE Drum	3521-62-8l	Antibacterial
Erythromycin Ethyl Succinate	BP/USP/EP	25 Kg HDPE Drum	41342-53-4	Antibacterial
Erythromycin Propionate	FP	25 Kg HDPE Drum	134-36-1	Antibacterial
Erythromycin Phosphate	IN HOUSE TESTING	25 Kg HDPE Drum	4501-00-2	Antibacterial
Erythromycin Stearate	IP/BP/USP/EP	25 Kg HDPE Drum	643-22-1	Antibacterial
Erythromycin 11,12 Carbonate	IN HOUSE TESTING	25 Kg HDPE Drum	55224-05-0	Antibacterial

PRODUCT LIST

- Intermediates

ITEM	SPECIFICATION	PACKING	CAS NO	USE
Erythromycin Oxime Base	In House	25 Kg HDPE Drum	13127-18-9	Intermediate
Erythromycin Silyl Ester	In House	25 Kg HDPE Drum	119665-76-8	Intermediate
Erythromycin Imino Ether	In House	25 Kg HDPE Drum	99290-97-8	Intermediate

PRODUCT LIST

- Higher Macrolides

ITEM	SPECIFICATION	PACKING	CAS NO	USE
Azithromycin	BP/USP	25 Kg HDPE Drum	83905-01-5	Antibacterial

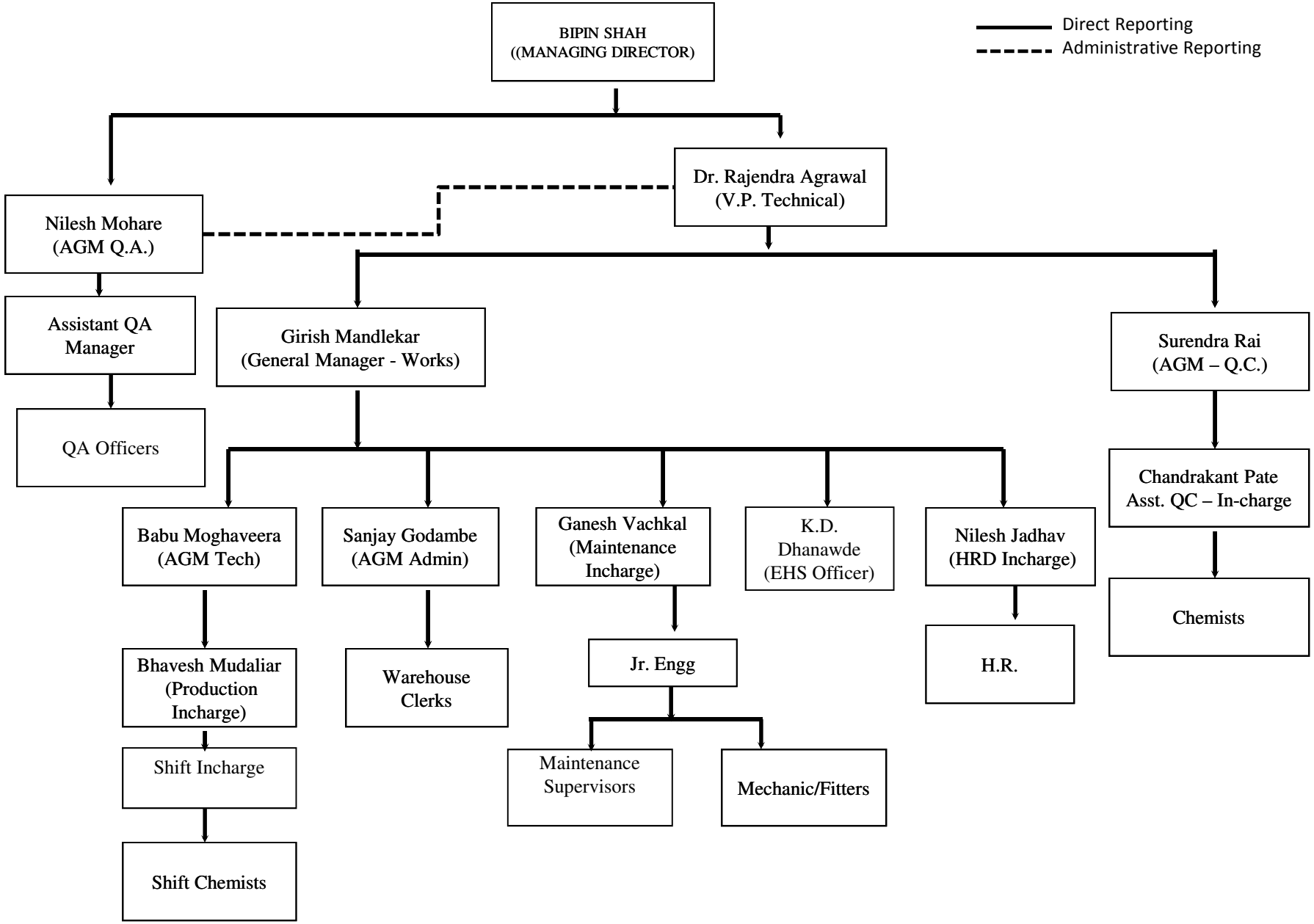
PRODUCT LIST

- Chloramphenicol

ITEM	SPECIFICATION	PACKING	CAS NO	USE
Chloramphenicol	IP/BP/USP/EP	25 Kg HDPE Drum	56-75-1	Antibacterial
Chloramphenicol Palmitate	IP/BP/USP/EP	25 Kg HDPE Drum	530-43-8	Antibacterial

ITEM	SPECIFICATION	PACKING	CAS NO	USE
Pyrazinamide	IP/BP/USP/EP	25 Kg HDPE Drum	98-96-4	Antituberculousis
Sulfadoxine	IP/BP/EP	25 Kg HDPE Drum	2447-57-6	Antimalarial
Ofloxacin	IP/BP/USP	25 Kg HDPE Drum	82419-36-1	Antibacterial
Losartan Potassium	IP/BP/EP/USP	25 Kg HDPE Drum	124750-99-8	Antihypertensive

ORGANOGRAM


Direct Reporting
Administrative Reporting
BIPIN SHAH
((MANAGING DIRECTOR)
Dr. Rajendra Agrawal
(V.P. Technical)
Nilesh Mohare
(AGM Q.A.)
Assistant QA Manager
QA Officers
Girish Mandlekar
(General Manager - Works)
Surendra Rai
(AGM – Q.C.)
Chandrakant Pate
Asst. QC – In-charge
Chemists
Babu Moghaveera
(AGM Tech)
Sanjay Godambe
(AGM Admin)
Ganesh Vachkal
(Maintenance Incharge)
K.D. Dhanawde
(EHS Officer)
Nilesh Jadhav
(HRD Incharge)
H.R.
Bhavesh Mudaliar
(Production Incharge)
Shift Incharge
Shift Chemists
Warehouse Clerks
Jr. Engg
Maintenance Supervisors
Mechanic/Fitters

MANUFACTURING FACILITY

- The plant is situated at Plot No. E-17/3 & 17/4, Tarapur Industrial Area, M.I.D.C., Boisar, - 401 506 Maharashtra (India).
- It is about 125 km from Mumbai.
- The Plot area is 3600 Sq. M.
- The plant has been designed & constructed to meet GMP guidelines.
- The Facility has been approved by WHO GMP for Pyrazinamide & Sulfadoxine & EU GMP for Pyrazinamide & Erythromycin Ethyl succinate.
- The facility has been approved by COFEPRIS (Mexico) for Erythromycin Base, Erythromycin ethyl succinate, Erythromycin stearate, Chloramphenicol & Chloramphenicol palmitate.
- The facility has been approved by Indian FDA & has been granted local GMP Certificate.
- Products manufactured by this facility has been granted with written confirmation for export to European union by CDSCO (Govt. Of India)

MANUFACTURING FACILITY

MANUFACTURING FACILITY

TOTAL BUILT UP AREA IN SQ. METERS	
Change Rooms	37.30
Production Area	1367.00
Warehouse	513.80
Quality Control	104.80
Quality Assurance	41.29
ETP	15.30
AHU Area	180.55
Total	2154.44

MANUFACTURING FACILITY

Capacity

1. Total reactor capacity is 50,000 L

Sr No.	Name of Product	Capacity Per Annum
1	Macrolides & Intermediates	1000 Metric Ton
2	Pyrazinamide	500 Metric Ton
3	Chloramphenicol	100 Metric Ton
4	Ofloxacin	250 Metric Ton
5	Sulphadoxine	100 Metric Ton
6	Losartan Potassium	50 Metric Ton

MANUFACTURING FACILITY

The site comprises of two blocks.

Block - 1 comprises of :

1. Administration Area
2. Quality Control
3. Quality Assurance
4. Two Dedicated Manufacturing Plants
5. Two Dedicated Air Jet Milling Rooms

Block- 2comprises of :

1. Four Dedicated Manufacturing Plants
2. Warehouse

MANUFACTURING FACILITY

Quality Control Lab.

- Anuh Pharma Ltd. currently has 7 HPLCs, 2 GC, 1 UV Spectrophotometer, 1 FTIR and 4 Stability Chambers.
- It also has a Microbiology section which has separate primary and secondary change rooms, and different rooms for Autoclave, Incubators and Laminar Air Flow units.

MANUFACTURING FACILITY

Dedicated Manufacturing Facilities

Ground Floor :

- The ground floor houses 9 dedicated powder processing areas.
- It houses Centrifuge Area, Drying Area, Milling & Sieving, Blending and Packing rooms.

MANUFACTURING FACILITY

First & Second Floor :

- The first and second floor houses the synthesis area.
- The synthesis area houses Reactors with Condensers, Charging Vessels, Sparkler Filters, Pumps etc.

MANUFACTURING FACILITY

Warehouse :

- Raw Material, Packing Material & Finished Goods are stored here.
- 2 Lifts for the movement of Raw Materials, Packing Materials and Finished Products between levels are provided.
- Dedicated temperature controlled areas for specific Raw Materials and Finished Goods are provided.
- The entire passage area with Forced Draft Ventilation.
- Separate dispensing and sampling rooms with Reverse Laminar Airflow are provided.

Purified Water Plant

Purified Water Loop System :

- In its effort to provide good quality medicines Anuh Pharma Ltd. Has commissioned a Loop System for distribution of Purified Water IP/BP/EP in the manufacturing facility.
- The Loop System continuously circulates the Purified Water IP/BP/EP in the plant through SS 316 mirror polished pipelines and zero dead-lag valves so as to completely avoid stagnant water hold up and related growth of microorganisms.
- The Loop System has been setup as per cGMP Guidelines.

QUALITY POLICY

- Manufacturing of Active Pharmaceuticals Ingredient is governed by the philosophy of *Current Good Manufacturing Practices* also known as cGMP. These guidelines cover all the aspects of pharmaceutical manufacturing, storage and distribution, and are aimed at providing quality pharmaceuticals Ingredients to the user pharmaceuticals formulation manufacturing companies.
- Being a firm believer in the cGMP philosophy, Anuh Pharma Ltd. strives for its implementation in all the operations involved.
- The company's policy is to ensure that all products are manufactured to the appropriate Quality and the buyer can trust the product as being consistent in Quality, Reliability and Safety for the purpose for which it is intended.
- To achieve this objective, a Quality Assurance System has been developed and installed to which Management will give their full support.
- We are also committed to continually improve effectiveness of our quality management system & ensure that the basic principles of cGMP shall always be adhered to during manufacturing & distribution activities.

EHS POLICY

- For manufacturing those we shall carry out all the operations in safe manner, follow cGMP and assuring compliance of all legal requirements and achieve for the purpose for which it is intended.
- We believe that all the accidents, occupational health hazards are preventable.
- Conduct all its activates in such a manner as to avoid harm to employees, contractors and the community.
- Utilize energy resources in a responsible and efficient manner so as to reduce emissions and generation of effluent and waste product.
- Comply with all statutory requirement concerning health, safety and Environment.
- Effective use of safe working procedure and practices for operation maintenance, inspection and emergency situation.
- Regular review of these safe working procedures.

…Contd

EHS POLICY

- Providing the personal protective equipments, tools and tackles to conduct all works in a safe manner and to ensure integrity of the assets.
- Investigating all incidents relating to Health, Safety and Environment including minor ones and near misses followed by the implementation of corrective measures.
- Identifying and evaluating Health risk related to its operations and carrying out pre-employment and periodic medical check up of its employees.
- Interaction with local communities regarding its operations, likely hazards and emergency response system.
- We are also committed to continually improve effectiveness of our safety policy and will strive for its implementation in all the operations involved.

BIPIN SHAH
Managing Director

R&D Division

1. "Research & Experience" these two values from the foundation of our growth and success. With Experience comes Expertise and Knowledge, but in an industry that has one of the fastest rates of innovation and technological advances it is Research that differentiates leaders in our industry. Experience needs to be Empowered by Research.

2. Spread across 10,000 square feet in Navi Mumbai, this laboratory has three sections: the Analytical Development lab, Chemical Synthesis Lab and a Pilot Plant. In addition to these facilities the lab derives benefit from the services of excellent professionals and experienced advisors. Our sound infrastructure and systems ensure smooth working of the lab. We receive 30 KVA Uninterrupted Power Supply and we have a 120 KVA diesel generator to ensure continual undisturbed reactions. The Effluent Treatment Plant adheres to environment friendly guidelines. In fact, we use all the treated water for gardening purposes thereby reducing the lab's carbon footprint.

R&D Division

Chemical Synthesis Lab

Analytical Development Lab

Kilo Lab

CERTIFICATES

Star Export House

भारत सरकार
GOVERNMENT OF INDIA
वाणिज्य एवं उद्योग मंत्रालय
MINISTRY OF COMMERCE & INDUSTRY
कार्यालय, मंडलीय संयुक्त महानिदेशक, विदेश व्यापार
OFFICE OF THE ZONAL JOINT DIRECTOR GENERAL OF FOREIGN TRADE
मान्यता प्रमाण पत्र
Certificate of Recognition
स्टार निर्यात सदन
STAR EXPORT HOUSE

मैसर्स _____

STATUS HOLDER No.:03/2/B-0094/20071105

(आई ई सी सं. _____ और आयकर पैन सं. _____)
को विदेश व्यापार नीति, 2004-2009 के प्रावधानों के अनुसार स्टार निर्यात सदन का स्तर प्रदान किया जाता है। यह प्रमाण पत्र 1 अप्रैल _____ से 31 मार्च _____ तक _____ वर्षों की अवधि के लिए वैध है।

M/s _____

ANUH PHARMA LTD. 3-A SHIV SAGAR ESTATE NORTH WING
DR. ANNIE BESANT ROAD WORLI BOMBAY MAHARASHTRA 400018

(IEC No. [illegible] and Income Tax PAN No. [illegible]) are hereby accorded the status of Star Export House in accordance with the provisions of the Foreign Trade Policy, 2004-2009. This Certificate is valid for a period of Two years effective from 1st April 2007 to 31st March 2009

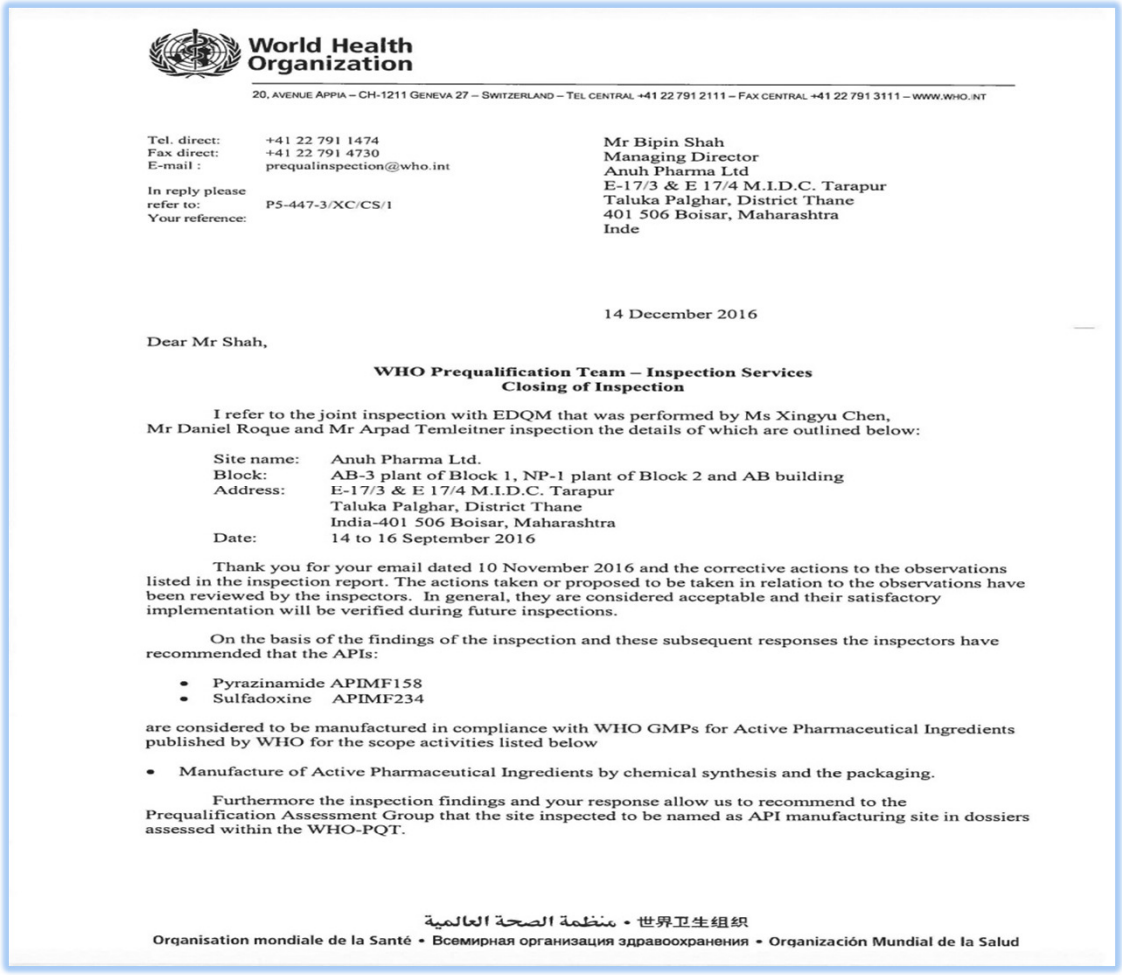
No. B-0094
Date 05.11.2007
Place Mumbai

S.SANDHU
मंडलीय संयुक्त महानिदेशक, विदेश व्यापार
ZONAL JOINT DIRECTOR
GENERAL OF FOREIGN TRADE

फाइल सं. / FILE NO. 03/81/105/00028/A 2168/

CERTIFICATES

WHO CERTIFICATE



World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 1474
Fax direct: +41 22 791 4730
E-mail : prequalinspection@who.int

In reply please refer to: P5-447-3/XC/CS/1
Your reference:

Mr Bipin Shah
Managing Director
Anuh Pharma Ltd
E-17/3 & E 17/4 M.I.D.C. Tarapur
Taluka Palghar, District Thane
401 506 Boisar, Maharashtra
Inde

14 December 2016

Dear Mr Shah,

WHO Prequalification Team – Inspection Services
Closing of Inspection

I refer to the joint inspection with EDQM that was performed by Ms Xingyu Chen, Mr Daniel Roque and Mr Arpad Temleitner inspection the details of which are outlined below:

Site name: Anuh Pharma Ltd.
Block: AB-3 plant of Block 1, NP-1 plant of Block 2 and AB building
Address: E-17/3 & E 17/4 M.I.D.C. Tarapur
Taluka Palghar, District Thane
India-401 506 Boisar, Maharashtra
Date: 14 to 16 September 2016

Thank you for your email dated 10 November 2016 and the corrective actions to the observations listed in the inspection report. The actions taken or proposed to be taken in relation to the observations have been reviewed by the inspectors. In general, they are considered acceptable and their satisfactory implementation will be verified during future inspections.

On the basis of the findings of the inspection and these subsequent responses the inspectors have recommended that the APIs:

- Pyrazinamide APIMF158
- Sulfadoxine APIMF234

are considered to be manufactured in compliance with WHO GMPs for Active Pharmaceutical Ingredients published by WHO for the scope activities listed below

- Manufacture of Active Pharmaceutical Ingredients by chemical synthesis and the packaging.

Furthermore the inspection findings and your response allow us to recommend to the Prequalification Assessment Group that the site inspected to be named as API manufacturing site in dossiers assessed within the WHO-PQT.

منظمة الصحة العالمية • 世界卫生组织
Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud

CERTIFICATES

EU GMP CERTIFICATE

Certification of Substances Department

ATTESTATION OF INSPECTION

Inspected site	Anuh Pharma Ltd E-17/3 & E 17/4 M.I.D.C. Tarapur Taluka Palghar, District Thane India-401 506 Boisar, Maharashtra
Holder of the Certificate of Suitability	Anuh Pharma Ltd 3-A, Shivsagar Estate, North Wing Dr Annie Besant Road, Worli India-400 018 Mumbai, Maharashtra
References of CEP dossier	CEP 2007-235 / Erythromycin ethylsuccinate CEP 2005-059 / Pyrazinamide
Inspection dates	14/09/2016 to 16/09/2016
Inspector / Name of organisation	ROQUE Daniel, AGENCE NATIONALE DE SECURITE DU MEDICAMENT ET DES PRODUITS DE SANTE, France ; Mr TEMLEITNER Arpad, EDQM, Council of Europe.
Scope of the inspection	The inspection focused on the compliance with the information provided in the above-mentioned application for a certificate of suitability, as well as the implementation of a suitable Quality Management System based on the Good Manufacturing Practice as laid down in the EU Rules governing Medicinal Products in the European Union, Volume 4.
Conclusion	The company operates in accordance with the application submitted and the requirements of the Resolution AP-CSP (07) 1. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above.

EDQM Inspection Reference number: INSP 2009-021 P04

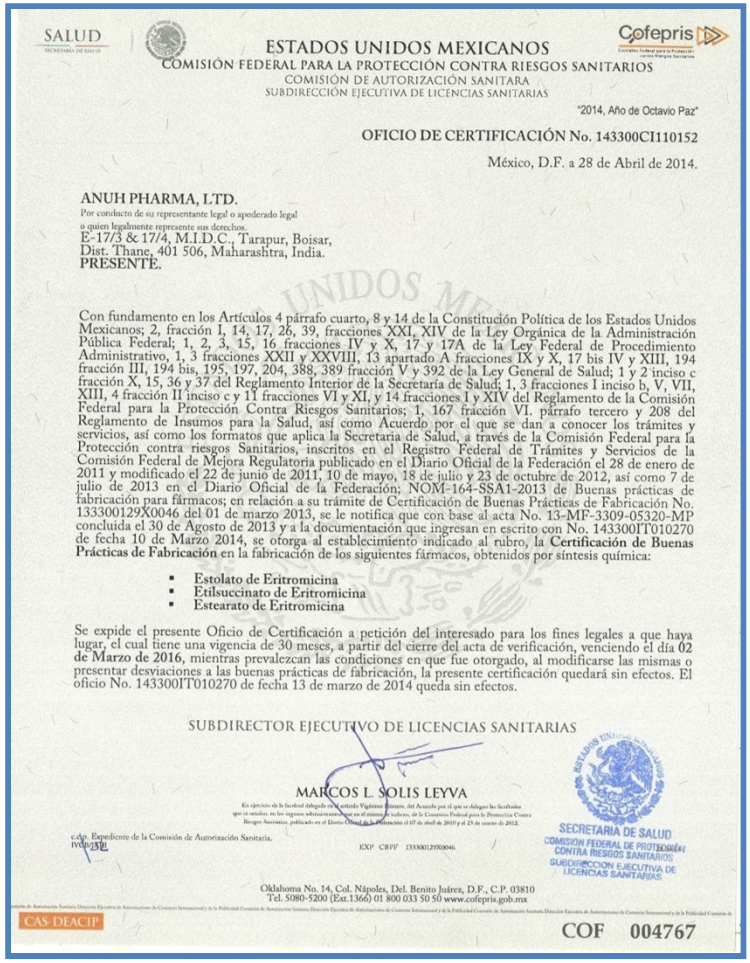
Strasbourg, 19 December 2016

On behalf of the Director of EDQM

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

CERTIFICATES

COFEPRIS GMP



SALUD

ESTADOS UNIDOS MEXICANOS

COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

COMISIÓN DE AUTORIZACIÓN SANITARIA

SUBDIRECCIÓN EJECUTIVA DE LICENCIAS SANITARIAS

Cofepris

"2014, Año de Octavio Paz"

OFICIO DE CERTIFICACIÓN No. 143300CI110152

México, D.F. a 28 de Abril de 2014.

ANUH PHARMA, LTD.
Por conducto de su representante legal o apoderado legal
o quien legalmente represente sus derechos.
E-17/3 & 17/4, M.I.D.C., Tarapur, Boisar,
Dist. Thane, 401 506, Maharashtra, India.
PRESENTE.

Con fundamento en los Artículos 4 párrafo cuarto, 8 y 14 de la Constitución Política de los Estados Unidos Mexicanos; 2, fracción I, 14, 17, 26, 39, fracciones XXI, XIV de la Ley Orgánica de la Administración Pública Federal; 1, 2, 3, 15, 16 fracciones IV y X, 17 y 17A de la Ley Federal de Procedimiento Administrativo, 1, 3 fracciones XXII y XXVIII, 13 apartado A fracciones IX y X, 17 bis IV y XIII, 194 fracción III, 194 bis, 195, 197, 204, 388, 389 fracción V y 392 de la Ley General de Salud; 1 y 2 inciso c fracción X, 15, 36 y 37 del Reglamento Interior de la Secretaría de Salud; 1, 3 fracciones I inciso b, V, VII, XIII, 4 fracción II inciso c y 11 fracciones VI y XI, y 14 fracciones I y XIV del Reglamento de la Comisión Federal para la Protección Contra Riesgos Sanitarios; 1, 167 fracción VI. párrafo tercero y 208 del Reglamento de Insumos para la Salud, así como Acuerdo por el que se dan a conocer los trámites y servicios, así como los formatos que aplica la Secretaría de Salud, a través de la Comisión Federal para la Protección contra riesgos Sanitarios, inscritos en el Registro Federal de Trámites y Servicios de la Comisión Federal de Mejora Regulatoria publicado en el Diario Oficial de la Federación el 28 de enero de 2011 y modificado el 22 de junio de 2011, 10 de mayo, 18 de julio y 23 de octubre de 2012, así como 7 de julio de 2013 en el Diario Oficial de la Federación; NOM-164-SSA1-2013 de Buenas prácticas de fabricación para fármacos; en relación a su trámite de Certificación de Buenas Prácticas de Fabricación No. 133300129X0046 del 01 de marzo 2013, se le notifica que con base al acta No. 13-MF-3309-05320-MP concluida el 30 de Agosto de 2013 y a la documentación que ingresan en escrito con No. 143300IT010270 de fecha 10 de Marzo 2014, se otorga al establecimiento indicado al rubro, la **Certificación de Buenas Prácticas de Fabricación** en la fabricación de los siguientes fármacos, obtenidos por síntesis química:

- Estolato de Eritromicina
- Etilsuccinato de Eritromicina
- Estearato de Eritromicina

Se expide el presente Oficio de Certificación a petición del interesado para los fines legales a que haya lugar, el cual tiene una vigencia de 30 meses, a partir del cierre del acta de verificación, venciendo el día **02 de Marzo de 2016**, mientras prevalezcan las condiciones en que fue otorgado, al modificarse las mismas o presentar desviaciones a las buenas prácticas de fabricación, la presente certificación quedará sin efectos. El oficio No. 143300IT010270 de fecha 13 de marzo de 2014 queda sin efectos.

SUBDIRECTOR EJECUTIVO DE LICENCIAS SANITARIAS

MARCOS L. SOLIS LEYVA

c.c.p. Expediente de la Comisión de Autorización Sanitaria.

EXP. CBPF 133300129X0046

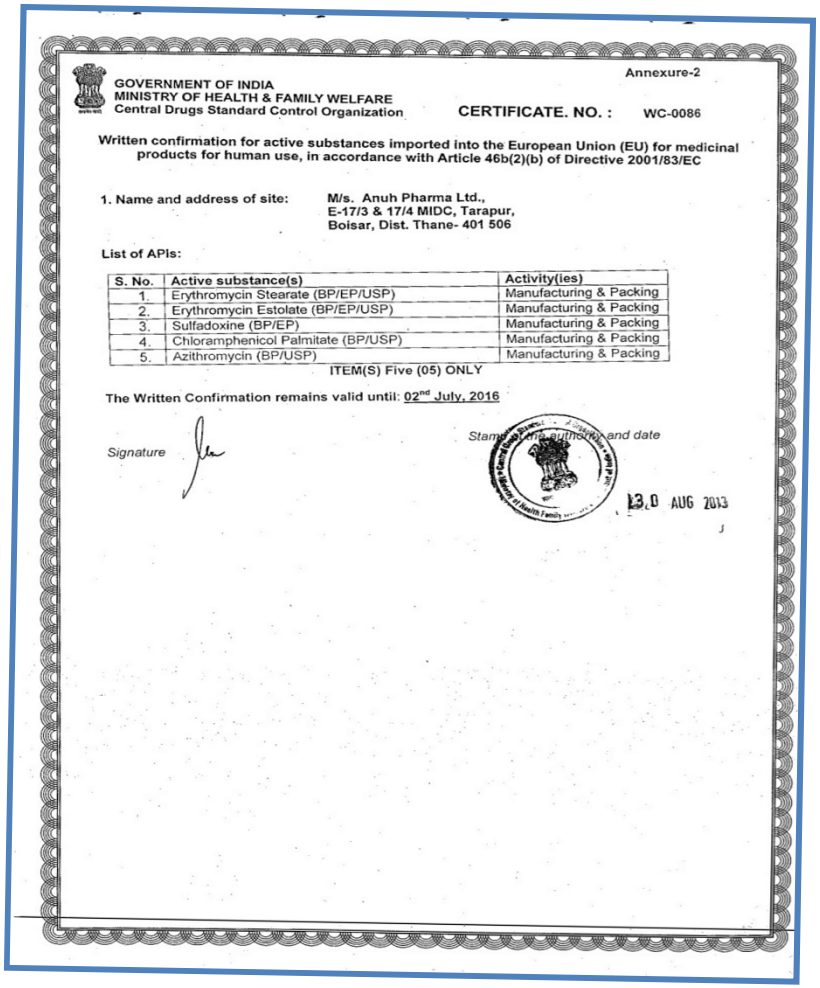
SECRETARÍA DE SALUD
COMISION FEDERAL DE PROTECCIÓN CONTRA RIESGOS SANITARIOS
SUBDIRECCION EJECUTIVA DE LICENCIAS SANITARIAS

Oklahoma No. 14, Col. Nápoles, Del. Benito Juárez, D.F., C.P. 03810
Tel. 5080-5200 (Ext.1366) 01 800 033 50 50 www.cofepris.gob.mx

CAS-DEACIP

COF 004767

Written Confirmation - CDSCO



Annexure-2

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE. NO. : WC-0086

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Anuh Pharma Ltd.,
E-17/3 & 17/4 MIDC, Tarapur,
Boisar, Dist. Thane- 401 506

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Erythromycin Stearate (BP/EP/USP)	Manufacturing & Packing
2.	Erythromycin Estolate (BP/EP/USP)	Manufacturing & Packing
3.	Sulfadoxine (BP/EP)	Manufacturing & Packing
4.	Chloramphenicol Palmitate (BP/USP)	Manufacturing & Packing
5.	Azithromycin (BP/USP)	Manufacturing & Packing

ITEM(S) Five (05) ONLY

The Written Confirmation remains valid until: 02nd July, 2016

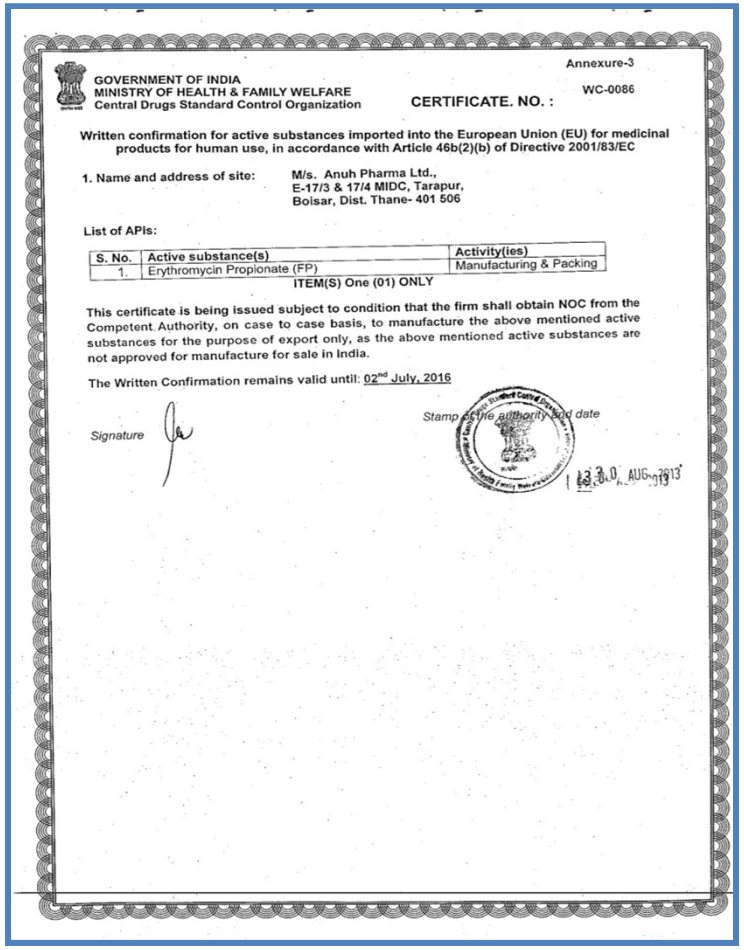
Signature

Stamp with authority and date

13.0 AUG 2013

CERTIFICATES

Written Confirmation - CDSCO



Annexure-3

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE. NO. : WC-0086

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Anuh Pharma Ltd., E-17/3 & 17/4 MIDC, Tarapur, Boisar, Dist. Thane- 401 506

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Erythromycin Propionate (FP)	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 02nd July, 2016

Signature

Stamp of the authority and date

30 AUG 2013

Written Confirmation - CDSCO

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-1

CERTIFICATE. NO. : WC-0086

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Anuh Pharma Ltd., E-17/3 & 17/4 MIDC, Tarapur, Boisar, Dist. Thane- 401 506

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Pyrazinamide (BP/EP/USP)	Manufacturing & Packing
2	Erythromycin (BP/EP/USP)	Manufacturing & Packing
3	Erythromycin Ethyl Succinate (BP/EP/USP)	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 02nd July, 2016

Signature

Stamp of the authority and date

18 JUN 2013

AWARDS

Best Exporter's Award
By Vice Presedent of India

Best Exporter's Award (2002 - 2003)
By Commerce Minister, Govt. of India

Best Exporter's Award (2003 - 2004)
By Commerce Minister, Govt. of India

ANUH PHARMA LIMITED

Thank You.