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 2018-19

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.

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

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Email: anuh@sk1932.com; **CIN:** L24230MH1960PLC011586

C. PROGRAMME AND DISCLOSURE:

1. Presentation was made regarding role & responsibilities of Independent Directors, recent amendments to SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2018 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);

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 shall be conducted on "as needed" basis during the year; and

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

D. REVIEW OF THE PROGRAM:

The Board shall 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: 22nd March, 2019

ANUH PHARMA LTD.

FAMILARISATION PROGRAM FOR INDEPENDENT DIRECTORS FOR THE FINANCIAL YEAR 2018-19

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

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.

ANUH PHARMA LTD.

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;

- ✓ scrutinize 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.

RECENT AMENDMENTS IN SEBI (LISTING OBLIGATIONS AND DISCLOSURE REQUIREMENTS) REGULATIONS, 2018 W.R.T. INDEPENDENT DIRECTORS

- Existing Provisions

There were 7 Criteria for independence in existing Listing Regulations

- Amended Provisions

- Two new criteria have been added as under:

1) Independent Director shall not be member of the promoter group of the listed entity.
2) Independent Director means who is not a non-independent director of another company on the board of which any non - independent director of the listed entity is an independent director:

- (For e.g. If Mr. A is Independent Director of "A" Ltd., (as listed Company) and Mr. "A" is a non independent director of "B" Ltd., in which non-independent director of "A" Ltd., is an independent Director, then Mr. "A" will not be considered as Independent Director of "A" Ltd.,)

ANUH PHARMA LTD.

PROHIBITION ON APPOINTMENT OF ALTERNATE DIRECTOR FOR AN INDEPENDENT DIRECTOR

- **Existing Provisions**

No such provisions in existing Listing Regulations

- **Amended Provisions**

No person shall be appointed or continue as an alternate director for an independent director of a listed entity with effect from October 1, 2018.

ANUH PHARMA LTD.

PERFORMANCE EVALUATION OF INDEPENDENT DIRECTORS

- **Existing Provisions**

The performance evaluation of independent directors shall be done by the entire board of directors

Provided that in the above evaluation the directors who are subject to evaluation shall not participate in the proceedings

- **Amended Provisions**

- The evaluation of independent directors shall be done by the entire board of directors which shall include –
  - performance of the directors; and
  - fulfillment of the independence criteria as specified in these regulations and their independence from the management:

  Provided that in the above evaluation, the directors who are subject to evaluation shall not participate.

ABOUT US

- Established in 1960

ANUH PHARMA LTD.

A public limited company listed on the Bombay Stock Exchange.

ABOUT US

- Established in 1960
- Part of SK Group

ANUH PHARMA LTD.

SK
We Serve Since 1932

ABOUT US

- Established in 1960
- Part of SK Group
- Located in Tarapur, Maharashtra

ANUH PHARMA LTD.

ABOUT US

- Established in 1960
- Part of SK Group
- Located in Tarapur, Maharashtra
- 120 kms from Mumbai

ANUH PHARMA LTD.

ABOUT US

- Established in 1960
- Part of SK Group
- Located in Tarapur, Maharashtra.
- 120 kms from Mumbai
- Area: 3600 Sq. M.

Address:
E-17/3 & 17/4,
Tarapur Industrial Area,
M.I.D.C., Boisar - 401 506
Maharashtra (India).

ABOUT US

- Top line of more than 50 million USD
- Exports to over 57 countries

ANUH PHARMA LTD.

ABOUT US

- Top line of more than 50 million USD
- Exports to over 57 countries
- Facility Approved by Maharashtra FDA and granted Local GMP certification

FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

License No:
28 KD-990 & 25 KD 1194

GMP Certificate No:
6070374

ANUH PHARMA LTD.

ABOUT US

- Top line of more than 50 million USD
- Exports to over 57 countries
- Facility Approved by Maharashtra FDA and granted Local GMP certification
- Facility approved by EDQM, ANSM (France), WHO – PQ.

ANUH PHARMA LTD.

ABOUT US

- Top line of more than 50 million USD
- Exports to over 57 countries
- Facility Approved by Maharashtra FDA and granted Local GMP certification
- Facility approved by Cofepris
- The Plant has been designed to meet cGMP guidelines

ANUH PHARMA LTD.

FACTORY LAYOUT

TOTAL BUILT UP AREA IN SQ. METERS	
Change Rooms	37
Production Area	1367
Warehouse	514
Quality Control	105
Quality Assurance	41
ETP	15
AHU Area	181
Total	2154

ANUH PHARMA LTD.

MANUFACTURING FACILITY

- Manufacturing Capacity

- Total reactor capacity is 50,000 L

SNo	Name of Product	Capacity PA
1	Macrolides & Intermediates	1000 Metric Ton
2	Pyrazinamide	500 Metric Ton
3	Chloramphenicol	100 Metric Ton
4	Ambroxol Hydrochloride	100 Metric Ton
5	Sulphadoxine	100 Metric Ton
6	Pyrimethamine	20 Metric Ton

MANUFACTURING FACILITY

- Manufacturing Capacity
- Quality Control Lab

- Well equipped quality control lab to make sure that our products adhere to the standards of quality prescribed by various pharmacopoeias.
- 7 HPLCs, 2 GC, 1 UV Spectrophotometer, 1 FTIR and 5 Stability Chambers
- Microbiology section which has separate primary and secondary change rooms, and different rooms for Autoclave, Incubators and Laminar Air Flow units

ANUH PHARMA LTD.

MANUFACTURING FACILITY

- Manufacturing Capacity
- Quality Control Lab
- Dedicated manufacturing facility

Ground Floor:

- 9 dedicated powder processing areas with change room and clean corridor
- Separate passages for man and material movement supplied with forced draft ventilation system.
- All powder processing areas have separate and dedicated HVAC Systems.
- Temperature is maintained below 27 ° C
- The air changes in the Centrifuge Area is NLT 30 per hour while other areas are maintained at NLT 20 changes per hour.
- All areas are supplied with air filtered through 0.3 micron terminal HEPA filters.
- After packing, the material is transferred to the quarantine area which opens into the material corridor. From here the material is taken to finish product store.

ANUH PHARMA LTD.

MANUFACTURING FACILITY

- Manufacturing Capacity
- Quality Control Lab
- Dedicated manufacturing facility

First & Second Floor:

- The first and second floor houses the synthesis area.
- Both the floors are accessible from inside the synthesis area.
- Both the synthesis area are supplied with air from forced draft ventilation system with 3 micron filters.
- The synthesis area houses Reactors with Condensers, Charging Vessels, Sparkler Filters, Pumps etc.

ANUH PHARMA LTD.

MANUFACTURING FACILITY

- Manufacturing Capacity
- Quality Control Lab
- Dedicated manufacturing facility
- Warehouse

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 is provided with Ventilation Air Unit with 5 Micron Filters.
- Separate dispensing and sampling rooms with Reverse Laminar Airflow are provided.

ANUH PHARMA LTD.

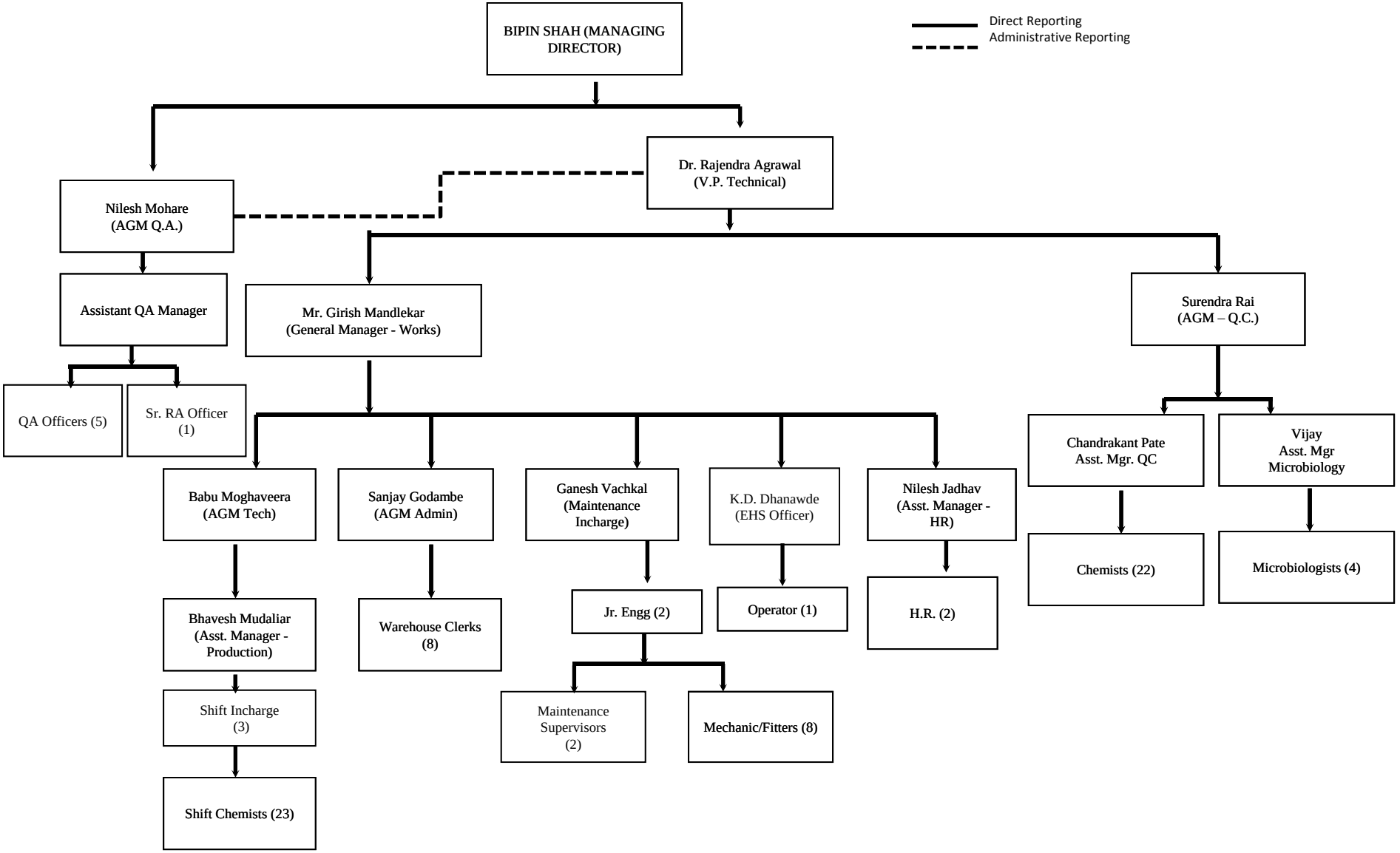
APPROVALS

Sr. No.	Approval	Certificate No.	Date
01	Products manufactured by this facility has been granted with written confirmation for export to European union by CDSCO (Govt. Of India)	WC-0086	01/03/2017
02	The facility has been approved by COFEPRIS (Mexico) for Chloramphenicol & Chloramphenicol palmitate	153300ER020181	11/07/2015
03	The facility has been approved by Indian FDA & has been granted local GMP Certificate.	6061290	20/06/2016
04	The facility has been approved by COFEPRIS (Mexico) for Erythromycin Base, Erythromycin Ethyl Succinate, Erythromycin Stearate.	143300CI110152	28/04/2014
05	The facility has been approved by EDQM for Erythromycin Ethyl Succinate, Pyrazinamide and Erythromycin and has been granted EuGMP by ANSM – France.	16MPP064HPT01	16/12/2016
06	The facility has been approved by WHO – Prequalification for Sulfadoxine and Pyrazinamide.	APIMF-234 & APIMF -158	14/12/2016

LIST OF KEY PERSONNEL

Sr. No.	Name of Person	Designation	Qualification	Experience In Anuh	Total Experience
01	Bipin Shah	Managing Director	B.E. Chemcial	32 Years	45 Years
02	Dr. Rajendra Agrawal	V.P. Technical	PhD. Pharmacy	6 Years	32 Years
03	Girish Mandlekar	General Manager Works	B.E. Chemcial	2 Years	20 Years
04	Nilesh Mohare	AGM QA	B.Sc. Chemistry	5 Years	19 Years
05	Surendra Rai	AGM QC	M.Sc. Chemistry	6 Years	20 Years
06	Prashant Patil	Assistant QA Manager	B.Sc. Chemistry	7 Years	20 Years
07	Chandrakant Pate	Assistant QC Manager	B.Sc. Chemistry	11 Years	17 Years
08	Sanjay Godambe	AGM Admin	B.Com Accounts	21 Years	23 Years
09	Babu Moghaveera	AGM Technical	B.Sc. Chemistry	21 Years	23 Years
09	Bhavesh Mudliyar	Production In-charge	B.Sc. Chemistry	17 Years	20 Years
10	Ganesh Vachakal	Maintenance In-Charge	B.E. Mechanical	9 Years	9 Years
11	K.D. Dhanawade	EHS Officer	B.Sc. Chemistry	4 Years	7 Years
12	Nilesh Jadhav	HRD In-charge	MBA HRD	9 Years	13 Years

ORGANOGRAM



ANUH PHARMA LTD.

PRODUCT LIST

- MACROLIDES

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

- HIGHER MACROLIDES

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

ANUH PHARMA LTD.

PRODUCT LIST

- INTERMEDIATES

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

- CHLORAMPHENICOL

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

ANUH PHARMA LTD.

PRODUCT LIST

- OTHERS

ITEM	SPECIFICATION	PACKING	CAS NO	USE
Pyrazinamide	IP/BP/USP/EP	25 Kg HDPE/Fiber Drum	98-96-4	Antituberculousis
Sulfadoxine	IP/BP/EP	25 Kg HDPE/Fiber Drum	2447-57-6	Antimalarial
Ambroxol Hydrochloride	IP/BP/EP	25 Kg HDPE/Fiber Drum	23828-92-4	Mucolytic Agent
Losartan Potassium	IP/BP/USP	25 Kg HDPE/Fiber Drum	124750-99-8	Anti-Hypertensive
Moxifloxacin Hydrochloride	BP/EP/USO	25 Kg HDPE/Fiber Drum	354812-41-2	Anti-Bacterial
Pyrimethamine	BP/EP	25 Kg HDPE/Fiber Drum	58-14-0	Antimalarial

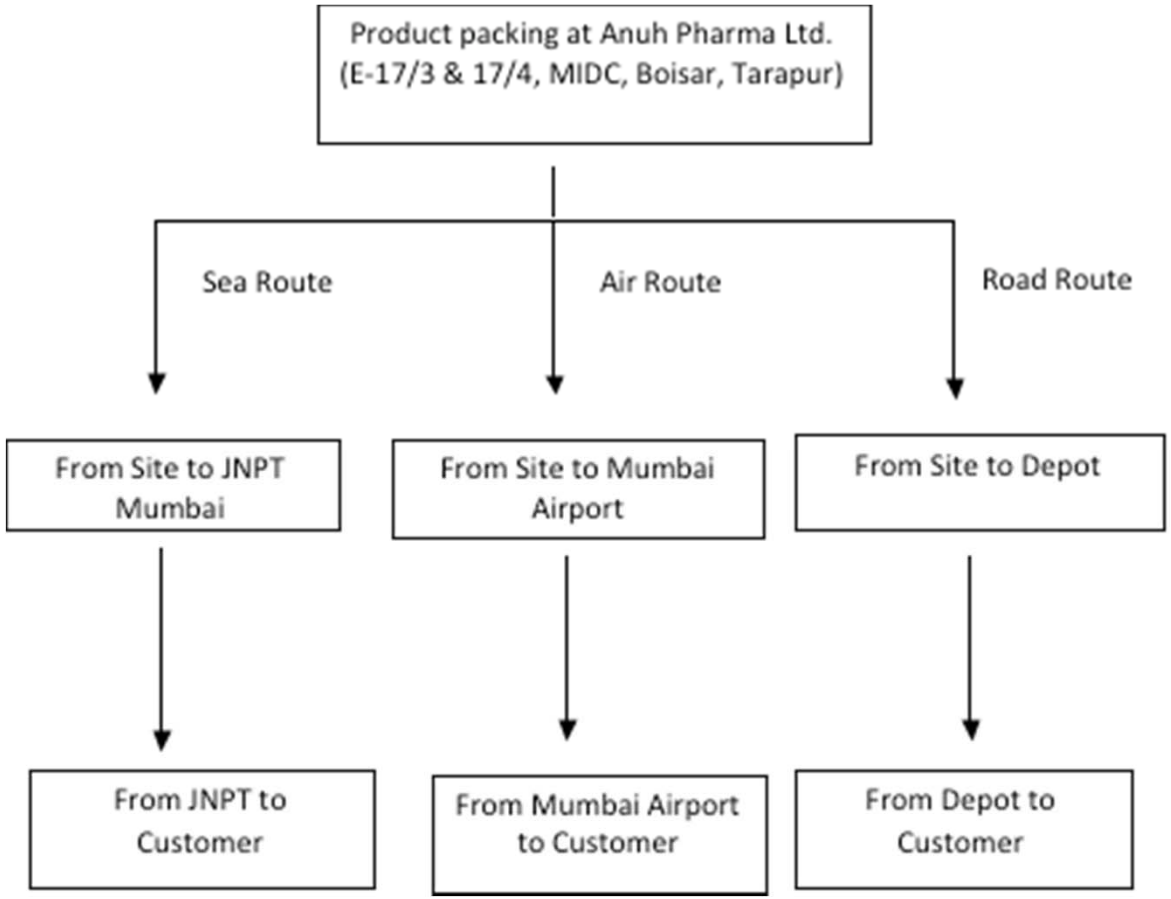
PURIFIED WATER SYSTEM

- Purified Loop
- Water 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 micro-organisms.
- The Loop System has been setup as per cGMP Guidelines.

ANUH PHARMA LTD.

OVERVIEW ON SUPPLY CHAIN



ANUH PHARMA LTD.

QUALITY POLICY

- Consistency of Product in Quality, Reliability and Safety
- Ensure the basic principles of cGMP are followed

ANUH PHARMA LTD.

Quality Policy
Format No.: QS/F/184-00

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.

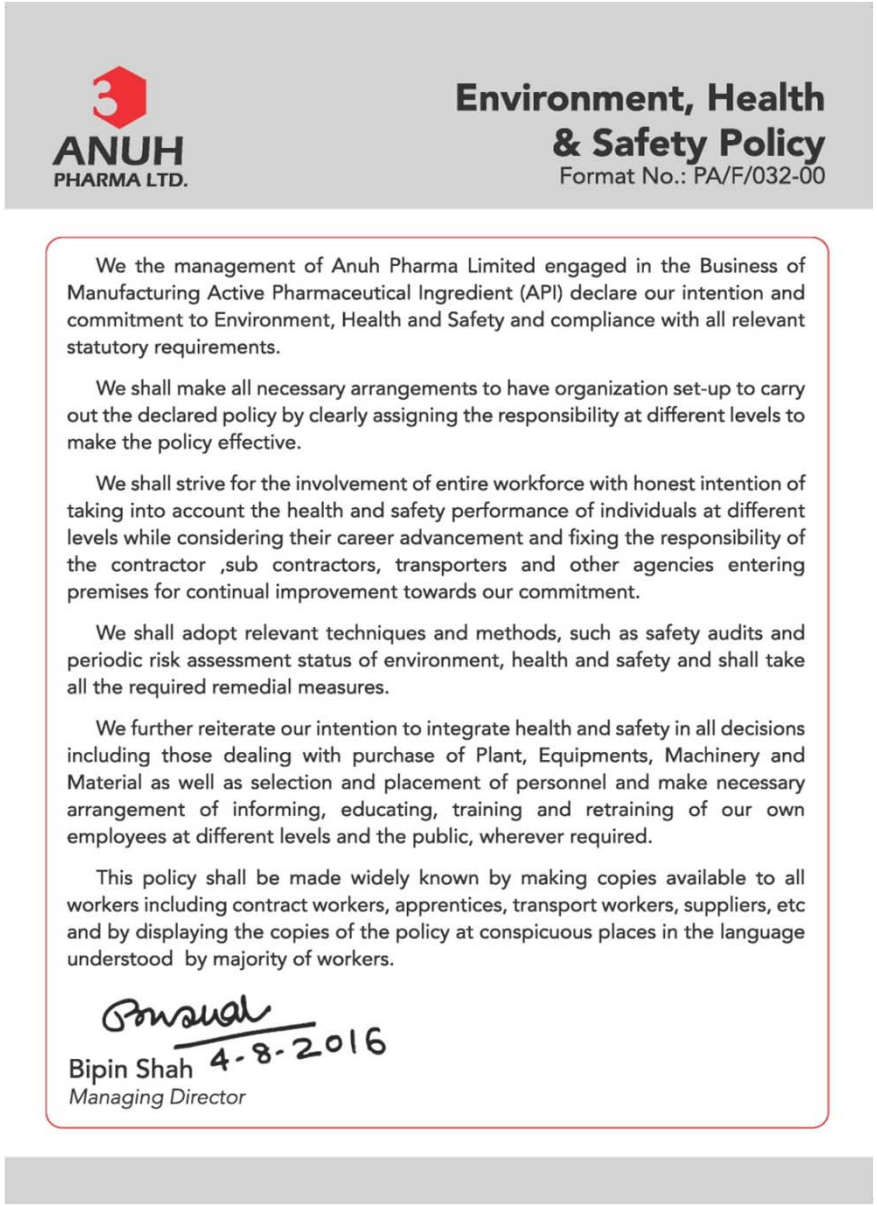
To achieve this objective, a Quality Assurance System has been developed and installed to which Management will give their full support.

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.

Bipin Shah
Managing Director
25-8-2016

EHS POLICY

- Commitment to Environment, Health and Safety.
- Safety audits and periodic risk assessments shall be conducted.
- Integrating, Environment, Health and Safety in all decision making.



ANUH PHARMA LTD.

Environment, Health & Safety Policy

Format No.: PA/F/032-00

We the management of Anuh Pharma Limited engaged in the Business of Manufacturing Active Pharmaceutical Ingredient (API) declare our intention and commitment to Environment, Health and Safety and compliance with all relevant statutory requirements.

We shall make all necessary arrangements to have organization set-up to carry out the declared policy by clearly assigning the responsibility at different levels to make the policy effective.

We shall strive for the involvement of entire workforce with honest intention of taking into account the health and safety performance of individuals at different levels while considering their career advancement and fixing the responsibility of the contractor ,sub contractors, transporters and other agencies entering premises for continual improvement towards our commitment.

We shall adopt relevant techniques and methods, such as safety audits and periodic risk assessment status of environment, health and safety and shall take all the required remedial measures.

We further reiterate our intention to integrate health and safety in all decisions including those dealing with purchase of Plant, Equipments, Machinery and Material as well as selection and placement of personnel and make necessary arrangement of informing, educating, training and retraining of our own employees at different levels and the public, wherever required.

This policy shall be made widely known by making copies available to all workers including contract workers, apprentices, transport workers, suppliers, etc and by displaying the copies of the policy at conspicuous places in the language understood by majority of workers.

Bipin Shah 4-8-2016

Managing Director

CERTIFICATIONS

Eu-GMP

ansm
Agence nationale de sécurité du médicament et des produits de santé

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: *16MPP064HPT01*

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

Part 1

Issued following an inspection in accordance with :
Art. 111(3) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:
The manufacturer: *ANUH PHARMA LTD*
Site address: *E-17/3 & E17/4 M.I.D.C. Tarapur, Taluka Palghar, District Thane, BOISAR, Maharashtra, 401 506, India*

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2016-09-16* , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

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.

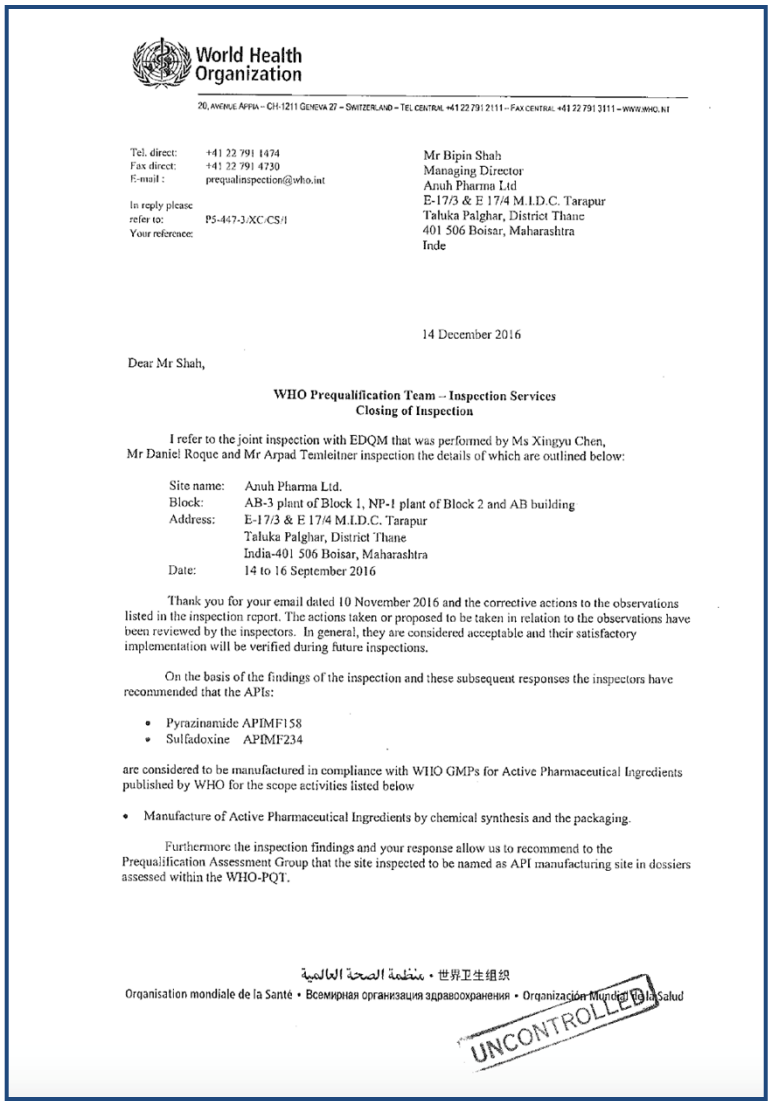
[1] *The certificate referred to in paragraph 111(3) of Directive 2001/83/EC and 80(3) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*
[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*
[3] *These requirements fulfil the GMP recommendations of WHO.*

Online EudraGMDP. Ref key: 39113 Issuance Date: 2016-12-15 Signatory: Mr. Jacques Moréras Page 1 of 3

143/147 boulevard Anatole France - F-93285 Saint-Denis Cedex - Tél.: +33(0)1 55 87 30 00 - www.ansm.sante.fr

UNCONTROLLED

WHO – PQ



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/I
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

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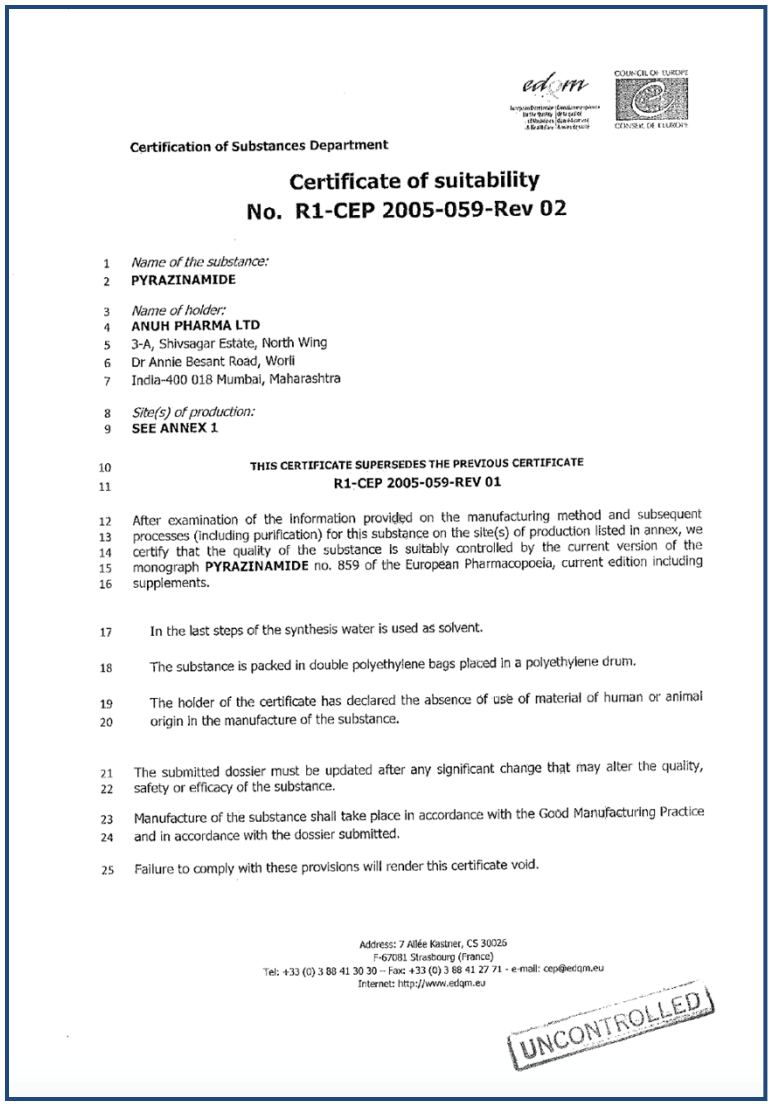
ANUH PHARMA LTD.

CERTIFICATIONS

CEP - PYRAZINAMIDE



Certification of Substances Department

Certificate of suitability
No. R1-CEP 2005-059-Rev 02

Name of the substance:
PYRAZINAMIDE

Name of holder:
ANUH PHARMA LTD
3-A, Shivsagar Estate, North Wing
Dr Annie Besant Road, Worli
India-400 018 Mumbai, Maharashtra

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2005-059-REV 01

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **PYRAZINAMIDE** no. 859 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis water is used as solvent.

The substance is packed in double polyethylene bags placed in a polyethylene drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

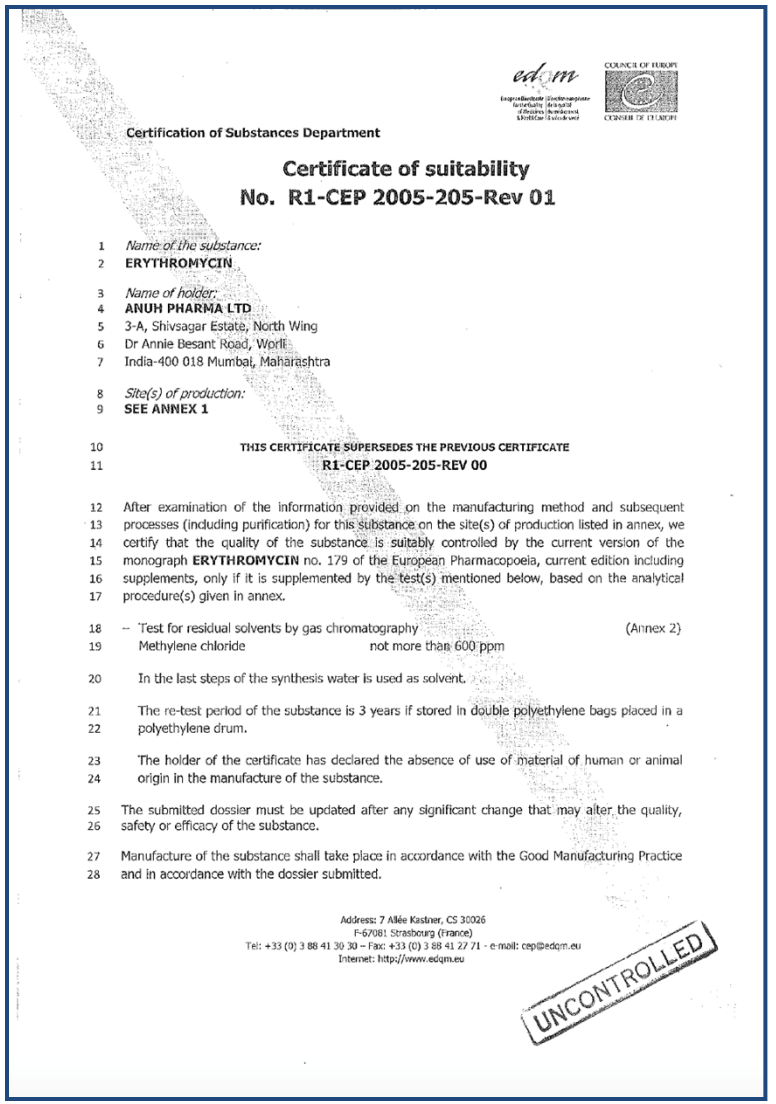
Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

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

UNCONTROLLED

CEP - ERYTHROMYCIN



Certification of Substances Department

Certificate of suitability
No. R1-CEP 2005-205-Rev 01

Name of the substance:
ERYTHROMYCIN

Name of holder:
ANUH PHARMA LTD
3-A, Shivsagar Estate, North Wing
Dr Annie Besant Road, Worli
India-400 018 Mumbai, Maharashtra

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2005-205-REV 00

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **ERYTHROMYCIN** no. 179 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

– Test for residual solvents by gas chromatography (Annex 2)
Methylene chloride not more than 600 ppm

In the last steps of the synthesis water is used as solvent.

The re-test period of the substance is 3 years if stored in double polyethylene bags placed in a polyethylene drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

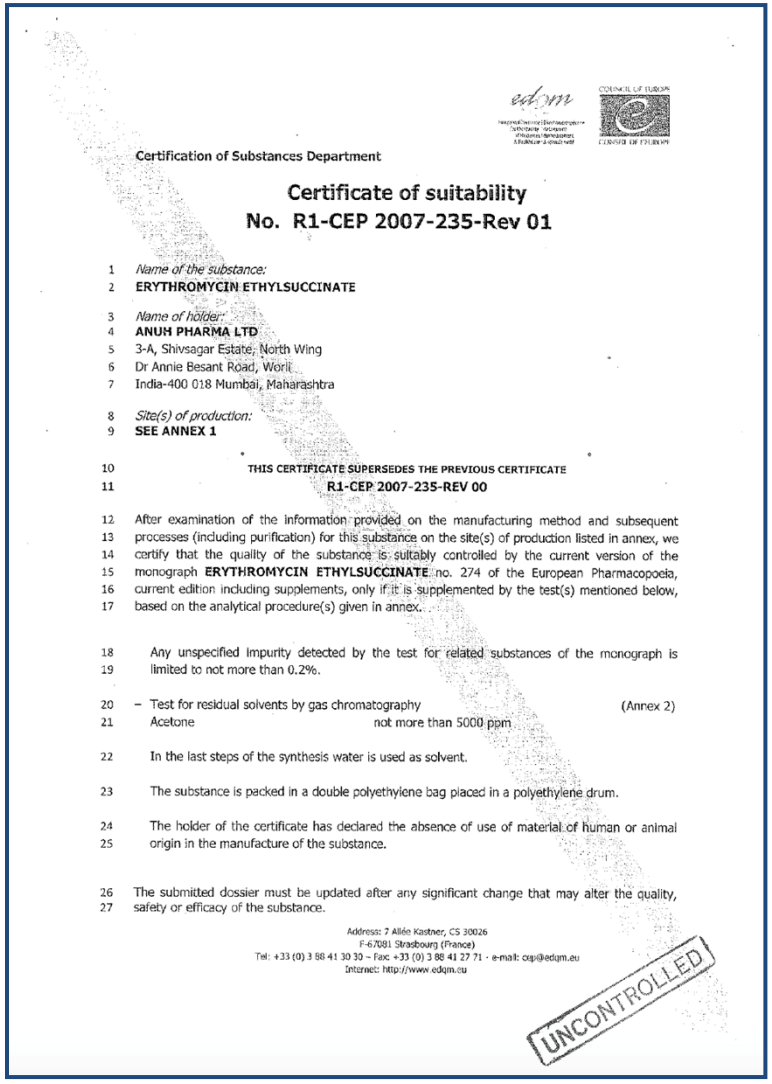
Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

UNCONTROLLED

ANUH PHARMA LTD.

CERTIFICATIONS

CEP – ERYTHROMYCIN ETHYL SUCCINATE



Certification of Substances Department

Certificate of suitability
No. R1-CEP 2007-235-Rev 01

Name of the substance:
ERYTHROMYCIN ETHYLSUCCINATE

Name of holder:
ANUH PHARMA LTD
3-A, Shivsagar Estate, North Wing
Dr Annie Besant Road, Worli
India-400 018 Mumbai, Maharashtra

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2007-235-REV 00

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **ERYTHROMYCIN ETHYLSUCCINATE** no. 274 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.2%.

– Test for residual solvents by gas chromatography (Annex 2)
Acetone not more than 5000 ppm

In the last steps of the synthesis water is used as solvent.

The substance is packed in a double polyethylene bag placed in a polyethylene drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

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

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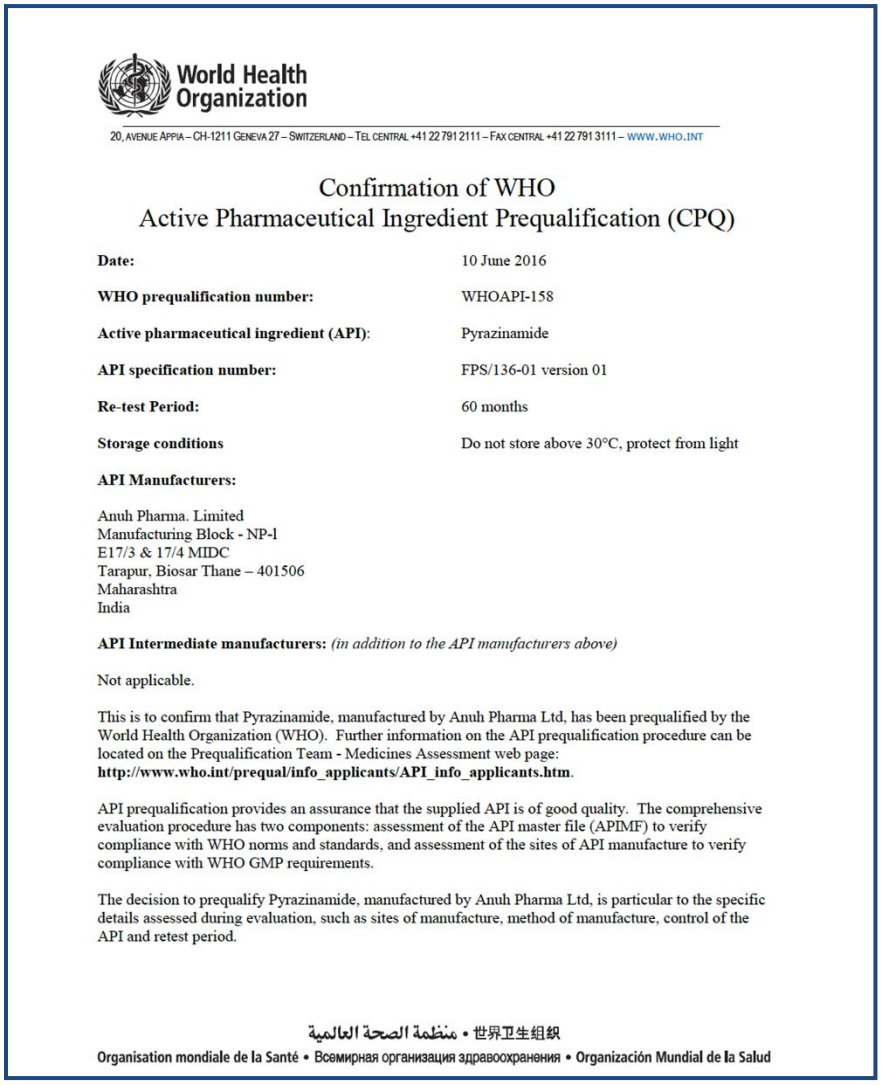
CPQ - PYRAZINAMIDE



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

Confirmation of WHO
Active Pharmaceutical Ingredient Prequalification (CPQ)

Date:	10 June 2016
WHO prequalification number:	WHOAPI-158
Active pharmaceutical ingredient (API):	Pyrazinamide
API specification number:	FPS/136-01 version 01
Re-test Period:	60 months
Storage conditions	Do not store above 30°C, protect from light

API Manufacturers:

Anuh Pharma. Limited
Manufacturing Block - NP-I
E17/3 & 17/4 MIDC
Tarapur, Biosar Thane – 401506
Maharashtra
India

API Intermediate manufacturers: *(in addition to the API manufacturers above)*

Not applicable.

This is to confirm that Pyrazinamide, manufactured by Anuh Pharma Ltd, has been prequalified by the World Health Organization (WHO). Further information on the API prequalification procedure can be located on the Prequalification Team - Medicines Assessment web page: **http://www.who.int/prequal/info_applicants/API_info_applicants.htm**.

API prequalification provides an assurance that the supplied API is of good quality. The comprehensive evaluation procedure has two components: assessment of the API master file (APIMF) to verify compliance with WHO norms and standards, and assessment of the sites of API manufacture to verify compliance with WHO GMP requirements.

The decision to prequalify Pyrazinamide, manufactured by Anuh Pharma Ltd, is particular to the specific details assessed during evaluation, such as sites of manufacture, method of manufacture, control of the API and retest period.

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ANUH PHARMA LTD.

CERTIFICATIONS

CPQ - SULFADOXINE

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

Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

Date:	12 July 2017
WHO prequalification number:	WHOAPI-234
Active pharmaceutical ingredient (API):	Sulfadoxine
API specification number:	FPS/130-03, Version 03
Re-test Period:	36 months
Storage conditions	Do not store above 30°C, protect from moisture, protect from light

API Manufacturers:

Anuh Pharma Ltd
Manufacturing Block AB–3
E-17/3&E17/4 M.I.D.C, Boisar
Tarapur, Taluka –Palghar, Dist: Thane-401 506
Maharashtra state
India

API Intermediate manufacturers: *(in addition to the API manufacturers above)*

Not applicable.

This is to confirm that Sulfadoxine, manufactured by Anuh Pharma Ltd, has been prequalified by the World Health Organization (WHO). Further information on the API prequalification procedure can be located on the Prequalification Team - Medicines Assessment web page: **http://www.who.int/prequal/info_applicants/API_info_applicants.htm**.

API prequalification provides an assurance that the supplied API is of good quality. The comprehensive evaluation procedure has two components: assessment of the API master file (APIMF) to verify compliance with WHO norms and standards, and assessment of the sites of API manufacture to verify compliance with WHO GMP requirements.

The decision to prequalify Sulfadoxine, manufactured by Anuh Pharma Ltd, is particular to the specific details assessed during evaluation, such as sites of manufacture, method of manufacture, control of the API and retest period.

.../...

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Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud

WRITTEN CONFIRMATION

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, Opp. Brij Ice factory,
M.I.D.C., Tarapur, Boisar, Dist- Thane,
Maharashtra- 401 506

List of APIs:

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

ITEM(S) NINE (09) ONLY

The Written Confirmation remains valid until: 03 years from the date of issue.

Signature

Stamp of the authority and date

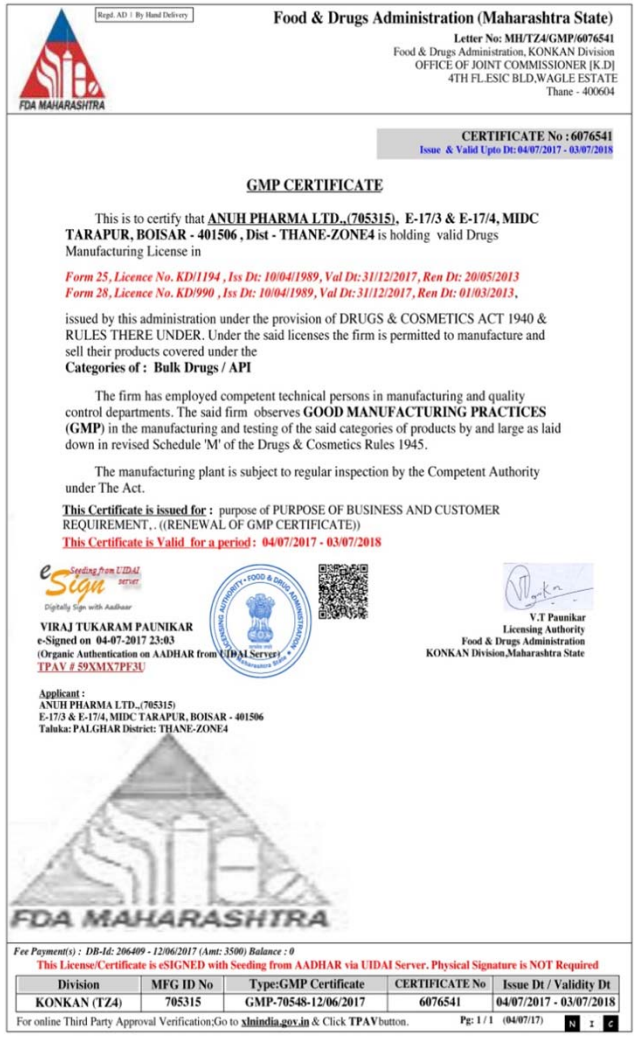
01 MAR 2017

UNCONTROLLED

ANUH PHARMA LTD.

CERTIFICATIONS

LOCAL - GMP



Regd. AD / By Hand Delivery

FDA MAHARASHTRA

Food & Drugs Administration (Maharashtra State)

Letter No: MH/TZ4/GMP/6076541
Food & Drugs Administration, KONKAN Division
OFFICE OF JOINT COMMISSIONER [K.D]
4TH FL.ESIC BLD,WAGLE ESTATE
Thane - 400604

CERTIFICATE No : 6076541
Issue & Valid Upto Dt: 04/07/2017 - 03/07/2018

GMP CERTIFICATE

This is to certify that **ANUH PHARMA LTD.,(705315), E-17/3 & E-17/4, MIDC TARAPUR, BOISAR - 401506 , Dist - THANE-ZONE4** is holding valid Drugs Manufacturing License in

Form 25, Licence No. KD/1194 , Iss Dt: 10/04/1989, Val Dt: 31/12/2017, Ren Dt: 20/05/2013
Form 28, Licence No. KD/990 , Iss Dt: 10/04/1989, Val Dt: 31/12/2017, Ren Dt: 01/03/2013,

issued by this administration under the provision of DRUGS & COSMETICS ACT 1940 & RULES THERE UNDER. Under the said licenses the firm is permitted to manufacture and sell their products covered under the
Categories of : Bulk Drugs / API

The firm has employed competent technical persons in manufacturing and quality control departments. The said firm observes **GOOD MANUFACTURING PRACTICES (GMP)** in the manufacturing and testing of the said categories of products by and large as laid down in revised Schedule 'M' of the Drugs & Cosmetics Rules 1945.

The manufacturing plant is subject to regular inspection by the Competent Authority under The Act.

This Certificate is issued for : purpose of PURPOSE OF BUSINESS AND CUSTOMER REQUIREMENT,. ((RENEWAL OF GMP CERTIFICATE))
This Certificate is Valid for a period : 04/07/2017 - 03/07/2018

eSign Seeding from UIDAI Server
Digitally Sign with Aadhaar

VIRAJ TUKARAM PAUNIKAR
e-Signed on 04-07-2017 23:03
(Organic Authentication on AADHAR from UIDAI Server)
TPAV # 59XMX7PF3U

V.T Paunikar
Licensing Authority
Food & Drugs Administration
KONKAN Division,Maharashtra State

Applicant :
ANUH PHARMA LTD.,(705315)
E-17/3 & E-17/4, MIDC TARAPUR, BOISAR - 401506
Taluka: PALGHAR District: THANE-ZONE4

FDA MAHARASHTRA

Fee Payment(s) : DB-Id: 206409 - 12/06/2017 (Amt: 3500) Balance : 0
This License/Certificate is eSIGNED with Seeding from AADHAR via UIDAI Server. Physical Signature is NOT Required

Division	MFG ID No	Type:GMP Certificate	CERTIFICATE No	Issue Dt / Validity Dt
KONKAN (TZ4)	705315	GMP-70548-12/06/2017	6076541	04/07/2017 - 03/07/2018

For online Third Party Approval Verification;Go to **xlnindia.gov.in** & Click **TPAV**button. Pg: 1 / 1 (04/07/17)

ANUH PHARMA LTD.

R&D DIVISION

- State of the art facility spread across 10,000 Sq. Ft in Navi Mumbai.
- The Chemical Synthesis Lab conducts lab scale reactions to develop processes and products.
- The Analytical Development Lab consists of equipment and utilities to facilitate activities that lead to characterization and profiling of products.
- "Research & Experience" these two values form 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.

Chemical Synthesis Lab

Analytical Development Lab

Kilo Lab

ANUH PHARMA LTD.

CSR

Anuh Pharma Ltd. takes corporate sustainability and social responsibility as a voluntary commitment rather than an obligation. We engage in social activities encompassing education, healthcare, sanitation, vocational skill building, rural development & natural conservation.

Our purpose is to improve the quality of people's lives, this we attain by closely monitoring the progress of each initiative. This trait has been inherited from the SK Group philosophy of executing charitable activities and also highlighted in our CSR Policy. CSR activities are implemented directly or via the SK Trust.

SK School of Business Management

SK Balmandir

SK Blood Bank

ANUH PHARMA LTD.

CSR

Donated Ambulance to Salwad Grampanchayat

Construction of Adiwasi High School

Construction of Digital Classrooms for Vocational Courses in HSE.

Donated Bubble CPAP with Humidifier to Byl Nair Hospital

ANUH PHARMA LTD.

AWARDS

Best Exporter's Award
By Vice President of India

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

Big 10 Pharma CEO Award - 2017

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

ANUH
PHARMA LTD.

AWARDS

Outstanding Exporters Award
2011 - 2012 - Pharmexcil

Outstanding Exporters Award
2008 - 2009 - Pharmexcil

The Second Annual Inc.
Top 500 Awards

ANUH
PHARMA LTD.

ANUH PHARMA LTD.

THANK YOU.