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

RÉPUBLIQUE FRANÇAISE

DIRECTION DE L'INSPECTION
Pôle inspection des matières premières
Dossier suivi par Daniel ROQUE
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Réf. à rappeler 16MPP06HPT01

Saint Denis, le 20 JAN. 2017

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

Monsieur,
Dear Sir,

L'inspection réalisée par l'ANSM et achevée le 16 Septembre 2016, dans l'établissement de l'entreprise **Anuh Pharma Ltd**, E-17/3 & E-17/4 M.I.D.C. Tarapur, Taluka Palghar, District Thane, India - 401 506 Boisar, Maharashtra en Inde, a permis de constater la conformité du fonctionnement de l'établissement aux BPF. Vous voudrez bien trouver, ci-joint, le certificat de conformité aux BPF correspondant pour la substance active inspectée.

An inspection was carried out by ANSM and achieved on 16th September 2016 *for the manufacturer company* **Anuh Pharma Ltd**, E-17/3 & E-17/4 M.I.D.C. Tarapur, Taluka Palghar, District Thane, India - 401 506 Boisar, Maharashtra in India. *Please find attached the associated certificate of GMP compliance for inspected active substance.*

Je vous prie d'agréer, Monsieur, l'assurance de ma considération distinguée.
Yours faithfully.

Le chef du pôle inspection des matières premières
Direction de l'inspection

Guillaume RENAUD

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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(5) 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.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) 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.*

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Part 2

Manufacture of active substance. Names of substances subject to inspection :
ERYTHROMYCIN ETHYLSUCCINATE(en) / ÉRYTHROMYCINE (ÉTHYLSUCCINATE D')(fr)
PIRAZYNAMID(pl) / PYRAZINAMIDE(en) / PYRAZINAMIDE(fr)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : ERYTHROMYCIN ETHYLSUCCINATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Crystallization
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance : PYRAZINAMIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Crystallization
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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et des produits de santé

2016-12-16

Name and signature of the authorised person of the Competent Authority of France

Mr. Jacques Morénas
French National Agency for Medicines and Health Products Safety
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