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

**DIRECTION DE L'INSPECTION**
Pôle inspection des matières premières
**Dossier suivi par Madame Aurélie DEMARCQ**
**Tél.** +33 (0)1 55 87 40 75
**E-mail** aurelie.demarcq@ansm.sante.fr
**Réf. à rappeler** 2018-MP-078Certifcat

RÉPUBLIQUE FRANÇAISE

Saint-Denis, le 25 AVR. 2019

**KOPRAN RESEARCH LABORATORIES LTD**,
Dr Mathias Sequeira, Assistant General Manager – Regulatory affairs
situé k-4/4, Additional M.I.D.C, At & Post Birwadi, Taluka Mahad, India-402 302 District Raigad, Maharashtra
**INDE**

Monsieur,

Dans le cadre du programme d'inspection de la Direction Européenne de la Qualité du Médicament et des soins de santé (DEQM), l'inspection suivante a été conduite :

- **KOPRAN RESEARCH LABORATORIES LTD**, situé k-4/4, Additional M.I.D.C, At & Post Birwadi, Taluka Mahad, India-402 302 District Raigad, Maharashtra – INDE, du 24 au 26 octobre 2018.

Je vous prie de trouver, ci-joint, **l'exemplaire original** du certificat BPF. J'attire votre attention sur le fait **qu'aucun duplicata ne sera délivré**.

Par ailleurs, je vous informe que les informations relatives aux certificats BPF délivrés par l'ANSM sont librement consultables sur la base de données communautaire EudraGMDP.

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

Dear Sir,

Within the framework of the European Directorate for the Quality of Medicines and Healthcare (EDQM) inspection programme, the inspection mentioned below was conducted :

- **KOPRAN RESEARCH LABORATORIES LTD**, located k-4/4, Additional M.I.D.C, At & Post Birwadi, Taluka Mahad, India-402 302 District Raigad, Maharashtra – INDIA, from 24th to 26th October 2018 .

Please find enclosed the **original** GMP certificate. Please note that **no duplicate will be issued**.

Furthermore, please note that the information related to a GMP certificate issued by the ANSM is freely available on the EEA database EudraGMDP.

Yours Sincerely,

**Madame Linda GALLAIS**
Cheffe du pôle inspection des matières premières
Direction de l'inspection

PJ : 1



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Agence nationale de sécurité du médicament et des produits de santé

*French National Agency for Medicines and Health Products Safety*

CERTIFICATE NUMBER: ***18MPP078HPT01***

# 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: ***Kopran Research Laboratories Limited***
Site address: ***K-4/4, Additional M.I.D.C., At & Post Birwadi,, Taluka Mahad, District. Raigad, Maharashtra, 402 302, 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 ***2018-10-26*** , 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 :

***ATENOLOL( en)***

| **3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES**<br><br>Active Substance : ATENOLOL | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>filtration |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>drying, milling<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 |

4. Other Activities - Active Substances :

***Other active substances manufactured by the site: Roxithromycin (CEP 2001-309), Azithromycin (CEP 2005-230), (Dihydrate) Amlodipine Besilate, Omeprazole, Pregabalin, Clarithromycin, lymecycline, Metoprolol Succinate, Metoprolol Tartrate. Specific types of Beta-lactam antibiotics (sterile and non-sterile) manufactured in a dedicated plant and sold only in non-regulated market: Cefditoren, Cefepime, Cefotaxime Sodium Sterile, Ceftriaxone Sodium Sterile, Meropenem Doripenem Sterile, Biapenem, Tebipenem.***

***2019-04-25***

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

Madame Linda GALLAIS
Cheffe du pôle inspection des matières premières
Direction de l'inspection

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***Linda Gallais***
***French National Agency for Medicines and Health Products Safety***
Tel:
Fax:



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