Prequalification Team Inspection services  
WHO PUBLIC INSPECTION REPORT  
(WHOPIR)  
Desk Assessment of Quality Control Laboratory (QCL)

<table>
<thead>
<tr>
<th>Part 1</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory information</td>
<td></td>
</tr>
<tr>
<td>Name and address of QCL</td>
<td>Gimopharm</td>
</tr>
<tr>
<td></td>
<td>1, chemin de Saulxier</td>
</tr>
<tr>
<td></td>
<td>91160 Longjumeau</td>
</tr>
<tr>
<td></td>
<td>France</td>
</tr>
</tbody>
</table>

Desk assessment details

<table>
<thead>
<tr>
<th>Start and end dates of review</th>
<th>24 January 2019</th>
</tr>
</thead>
</table>

Tests covered by this desk assessment

<table>
<thead>
<tr>
<th>Type of Analysis</th>
<th>Finished Products</th>
<th>Active pharmaceutical ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical/Chemical analysis</td>
<td>pH, density, refractive index, optical rotation, osmolality, water content, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, viscosity, uniformity of dosage units (mass, content), viscosity, particle size (laser,) DSC, DRX</td>
<td>Refractive index, optical rotation, water content, residual solvents, particle size, Differential scanning calorimetry, DRX, COT, viscosity, heavy metals, Ash, sulfuric ash</td>
</tr>
<tr>
<td>Identification tests</td>
<td>HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry, MS, MS-MS</td>
<td>HPLC (UV-VIS, DAD, fluorescence detection), TLC, GC, UV-VIS spectrophotometry, IR, AAS, fluorimetry</td>
</tr>
</tbody>
</table>
| Assay, impurities and related substances | GC-TCD/FID/ MS-MS  
HPLC-UV/PDA/MS-MS/ MS/Fluo/ RI | GC-TCD/FID/ MS-MS  
HPLC-UV/PDA/MS-MS/ MS/Fluo/ RI |
### Specific studies on medicinal plants:
- Heavy metals
- Pesticides
- Quality of vegetable oils
- Identification and assay of active substances

### Microbiological analysis
- Microbial limit tests, disinfectant efficacy, biocharge, preservatives efficacy test
- Biocharge, microbial identification

### Bacterial endotoxin testing (BET)
- Bacterial endotoxins test (LAL)

### Stability testing
- 25°C/40% H.R.
- 25°C/60% H.R.
- 30°C/35% H.R.
- 30°C/65% H.R.
- 30°C/75% H.R.
- 40°C/25% H.R.
- 40°C/75% H.R.
- Plus other on demand

### List of documents submitted
- Laboratory Information file ((LIF1608-1) – Containing general information on the laboratory, quality management system, document control, personnel, premises, equipment, materials, type of subcontracting and contact details, handling of samples, validation of analytical procedures, OOS process, stability and Microbiological testing.
- Scope of manufacture and import authorisation issued by Agence nationale de sécurité du médicament et des produits de santé (ANSM) against Directives 2001/83/EC and 2001/20/EC (15 November 2016).
- GMP certification issued by Agence nationale de sécurité du médicament et des produits de santé (ANSM) (certificate number HPF/FR/237/2015, valid until 6 March 2017)
- Certificate of Registration issued by U.S. Food and Drug Administration (expiry 31 December 2017)
- Appendix 1 Interlaboratory comparison protocol 2016-12-09 and Appendix 2 Interlaboratory comparison protocol 2 (2016-12-22)
- 171PP089_GIMOPHARM_Longjumeau_C3 and 171PP089_GIMOPHARM_Longjumeau_Ic3 – Final inspection report ANSM 23-24 May 2017 (provided in French)
### Part 2  Summary of SRA/NRA inspection evidence considered (from most recent to last)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Dates of inspection</th>
<th>Type of inspection</th>
<th>Unit/Division inspected</th>
<th>Tests covered</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANSM</strong></td>
<td>23-24 May 2017</td>
<td>Routine</td>
<td>Manufacturing, importation and other</td>
<td>The inspection that had been conducted was detailed. The report provided did not individually identify the tests that were reviewed. All areas inspected were found satisfactory.</td>
</tr>
<tr>
<td><strong>USFDA</strong></td>
<td>5-6 June 2014</td>
<td>Initial</td>
<td>Not listed in the report.</td>
<td>The establishment inspection report was provided. There have been no subsequent FDA inspections of the facility.</td>
</tr>
</tbody>
</table>

### Part 3  Summary of the last WHO inspection

**Date and conclusion of most recent WHO inspection**

The site has not been previously inspected by WHO.

**Brief summary of activities**

Not Applicable

**General information about the QCL**

GIMOPHRM was established in 1999 as a spin off company to Novartis (physicochemical analysis laboratory). GIMOPHARM is integrated in the group NOVOVITAE SAS.

GIMOPHARM employees 11 laboratory staff, including detailed job descriptions and staff qualifications

Subcontracted activities include

- Particles counts are subcontracted at Eurofins 16, rue Clément Ader, 68127 Sainte-Croix-en-Plaine, France. Eurofins is an inspected pharmaceutical company (GMP) by French Authority.
• Pesticides analysis are performed chez Phytocontrole (180, rue Philippe Maupas, 30035 Nîmes, France).

<table>
<thead>
<tr>
<th>Focus of the last WHO inspection</th>
<th>Abbreviations</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>API</td>
<td>Active pharmaceutical ingredient</td>
</tr>
<tr>
<td></td>
<td>CAPA</td>
<td>Corrective and preventive action</td>
</tr>
<tr>
<td></td>
<td>FPP</td>
<td>Finished pharmaceutical product</td>
</tr>
<tr>
<td></td>
<td>FTIR</td>
<td>Fourier transform infrared spectrophotometer</td>
</tr>
<tr>
<td></td>
<td>GC</td>
<td>Gas chromatograph or gas chromatography</td>
</tr>
<tr>
<td></td>
<td>GLP</td>
<td>Good laboratory practices</td>
</tr>
<tr>
<td></td>
<td>GPPQCL</td>
<td>Good practices for pharmaceutical quality control laboratories</td>
</tr>
<tr>
<td></td>
<td>HPLC</td>
<td>High performance liquid chromatograph</td>
</tr>
<tr>
<td></td>
<td>QA</td>
<td>Quality assurance</td>
</tr>
<tr>
<td></td>
<td>QCL</td>
<td>Quality control laboratory</td>
</tr>
<tr>
<td></td>
<td>SOP</td>
<td>Standard operating procedure</td>
</tr>
</tbody>
</table>

Part 4 | Summary of the assessment of additional supporting documentation

a) Authorization granted by the local authority (if any) or ISO 17025 certificate:
GIMOPHARM is a company providing analytical chemistry and quality control services as a GMP pharmaceutical facility certified by French national authority ANSM: Annexes 1 and 2: Authorization to perform pharmaceutical activities n° M15/120 May 15, 2015; certified GMP HPR/FR/237/2015, 28 October 2015.

Certificat De Conformité aux BPF d’un Fabricant issued by ANSM, certificate number HPF/FR/237/2015.

b) Laboratory information file (LIF):
The Laboratory Information file ((LIF1608-1) was provided. This document was set out in accordance with WHO requirements. It contained general information on the laboratory, quality management system, document control, personnel, premises, equipment, materials, type of subcontracting and contact details, handling of samples, validation of analytical procedures, OOS process, stability and Microbiological testing.

c) List of all regulatory inspections performed in the last 3 years and their outcomes:

<table>
<thead>
<tr>
<th>Name of Inspecting agency</th>
<th>Dates of last inspection</th>
<th>Type of inspection</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSM</td>
<td>23 – 24 May 2017</td>
<td>Re-inspection</td>
<td>Acceptable</td>
</tr>
<tr>
<td>ANSM</td>
<td>28 October 2015</td>
<td>Not available</td>
<td>Acceptable</td>
</tr>
<tr>
<td>USFAD</td>
<td>5-6 June 2014</td>
<td>Not available</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
d) Qualification, validation and calibration status of equipment:
An established process was available for the qualification, validation and calibration of equipment.

e) Confirmation by the quality manager that a full self-inspection dedicated to the tests submitted for prequalification has been performed and all matters dealt with:
The laboratory performs three types of internal audits per year in the following areas
- Equipment – equipment lists, labelling, qualification and follow-up book.
- Premises – security, cleanliness
- Quality system – revision and update of procedures, implementation of corrective and preventive actions and complaints.

Part 5  Conclusion – Desk assessment outcome

Based on the GPPQCL evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **Gimopharm, 1 chemin de Saulxier, 91160, Longjumeau, France** is considered to be operating at an acceptable level of compliance with WHO GPPQCL guidelines.

This WHOPIR will remain valid for 3 years from the date of the last ANSM inspection or when another inspection is conducted by an agency against whose report the approval was based, provided that the outcome of any inspection conducted during this period is positive.

Part 6  List of guidelines referenced in this inspection report

   *Short name: WHO GPPQCL Guidelines or TRS No. 957, Annex 1*

   *Short name: WHO TRS 1010, Annex 9*
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en

http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en

http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en

http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

http://www.who.int/medicines/publications/44threport/en

http://www.who.int/medicines/publications/44threport/en

**Short name:** WHO TRS No. 961, Annex 6

[http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)


**Short name:** WHO TRS No. 961, Annex 7

[http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)


**Short name:** WHO TRS No. 961, Annex 9

[http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)


[http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1)


**Short name:** WHO TRS No. 961, Annex 2

[http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)


**Short name:** WHO TRS No. 981, Annex 2


http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1


http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf
