# Prequalification Unit Inspection services

**WHO PUBLIC INSPECTION REPORT**  
(WHOPIR)

## Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

<table>
<thead>
<tr>
<th>Part 1</th>
<th>General information</th>
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<tbody>
<tr>
<td><strong>Company information</strong></td>
<td></td>
</tr>
<tr>
<td>Name of Manufacturer</td>
<td>PolyPeptide Laboratories France SAS</td>
</tr>
<tr>
<td>Corporate address of manufacturer</td>
<td>PolyPeptide Laboratories France SAS, 7 rue de Boulogne, Strasbourg, 67100, France</td>
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<table>
<thead>
<tr>
<th>Inspected site</th>
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<tbody>
<tr>
<td>Name &amp; address of manufacturing site</td>
<td>PolyPeptide Laboratories France SAS, 7 rue de Boulogne, Strasbourg, 67100, France</td>
</tr>
<tr>
<td>DUNS 634883672</td>
<td></td>
</tr>
<tr>
<td>Synthetic Unit/Block/Workshop</td>
<td>B2 and B3</td>
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<table>
<thead>
<tr>
<th>Desk assessment details</th>
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<tbody>
<tr>
<td>Start and end dates of review</td>
<td>08 September 2022</td>
</tr>
<tr>
<td>APIs covered by this desk assessment</td>
<td>RH095: Carbetocin API for use in Carbetocin Solution for injection 100 mcg/ml</td>
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<table>
<thead>
<tr>
<th>List of documents submitted</th>
<th>Documents requested:</th>
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<tbody>
<tr>
<td>a) A list of all regulatory inspections performed in the last 5 years and their outcomes, including inspections that resulted in “non-compliant” outcomes;</td>
<td></td>
</tr>
<tr>
<td>b) Current full inspection report(s), including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past three years with a certified translated copy where this is not in English;</td>
<td></td>
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<tr>
<td>c) Proof of CAPA implementation and final decision by the competent stringent regulatory authority related to observations or deficiencies noted in the latest inspection report or to any warning letter or equivalent regulatory action (production-line specific);</td>
<td></td>
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<tr>
<td>d) A copy of the manufacturing authorization and GMP certificate granted by the local national authority together with a certified translation, where this is not in English;</td>
<td></td>
</tr>
<tr>
<td>e) A site master file whose approval date was not more than one year</td>
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ago, and any forecast modifications, together with legible colour
printouts of water treatment and air-handling systems, including
pipeline and instrumentation drawings in A3 or A2 format;

f) The list of all the products and dosage forms manufactured on-
site. The list should include proprietary names and International
Nonproprietary Names (INN), including all types of chemicals and
products (e.g., pesticides, herbal medicines, chemicals or veterinary
products, etc.);

g) The most recent product quality review(s) (PQR)(s) of the
concerned product(s); PQR(s) or equivalent documentation
covering all required subsections and trend results, including
statistical evaluation;

h) The completed batch manufacturing and packaging record(s),
including the analytical part, for the most recently released batch of
relevant product(s);

i) The list of any recalls in the past three years related to any product
manufactured on site with quality defects;

j) A confirmation by the senior quality assurance representative that
a full self-inspection or external audit dedicated to the product(s)
has been performed and all matters dealt with;

k) Master batch manufacturing and packaging record(s) of the WHO
product(s) of interest;

l) Copy of any warning letter, or equivalent regulatory action, issued
by any authority to which the site provides or has applied to provide
the product;

m) Description of any recent or foreseen out-of-stock situations;

n) A list of notifications of upcoming inspections by competent
national regulatory authorities in the next 6 months;

o) A table to specify which parts of the manufacturing process for the
concerned product(s) were covered by the inspection of the
competent SRA authorities performed in the last 5 years

<table>
<thead>
<tr>
<th>Part 2</th>
<th>Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments</th>
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<tbody>
<tr>
<td>ANSM France</td>
<td>Dates of inspection: 8 to 10 December 2020</td>
</tr>
<tr>
<td></td>
<td>Type of inspection: GMP</td>
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<tr>
<td></td>
<td>Block/Unit/Workshop: B2 and B3</td>
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<tr>
<td></td>
<td>Type of APIs covered: Chemically synthesized peptides Peptides for clinical trials</td>
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<tr>
<td>FDA</td>
<td>Dates of inspection: 9 to 12 September 2019</td>
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<tr>
<td></td>
<td>Type of inspection: Pre-announced abbreviated GMP inspection for APIs</td>
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<tr>
<td></td>
<td>Block/Unit/Workshop: Not mentioned</td>
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</table>
**Type of APIs covered:** Synthetic growth hormone

### Part 3

**Summary of the last WHO inspection**

- Date and conclusion of most recent WHO inspection: There was no previous WHO PQ inspection on site

### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>BMR</td>
<td>Batch manufacturing record</td>
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<td>BPR</td>
<td>Batch production record</td>
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<tr>
<td>CAPA</td>
<td>Corrective and preventive action</td>
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<tr>
<td>CC</td>
<td>Change control</td>
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<tr>
<td>GMP</td>
<td>Good manufacturing practices</td>
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<tr>
<td>NC</td>
<td>Non conformity</td>
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<td>NRA</td>
<td>National regulatory agency</td>
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<td>POR</td>
<td>Product quality review</td>
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<td>PQS</td>
<td>Pharmaceutical quality system</td>
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<td>QA</td>
<td>Quality assurance</td>
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<td>QC</td>
<td>Quality control</td>
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<td>QCL</td>
<td>Quality control laboratory</td>
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<td>QMS</td>
<td>Quality management system</td>
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<td>QRM</td>
<td>Quality risk management</td>
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<td>RA</td>
<td>Risk assessment</td>
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<td>RCA</td>
<td>Root cause analysis</td>
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<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
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### Part 4

**Summary of the assessment of supporting documentation**

a) **Manufacturing authorization and GMP certificate granted by the local authority:**

- Registration number issued by ANSM: 2021 – 00710 (Dated 22 March 2022).
- GMP certificate was issued 20MPP075HFR01.

b) **Site master file (SMF):**

- The SMF including annexes, dated 5 November 202, was provided, reviewed, and found acceptable.

c) **List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:**

- Gonadorelin-(6-D-Phe) acetate
- Macimorelin acetate
- Avizafone
- Carbetocin
- Lecirelin
- Difelikefelin
- Peptides for clinical trials
d) List of all regulatory inspections performed in the last 3 years and their outcomes:
ANSM, France 2020. Compliant.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
Carbetocin Drug substance: Period April 2021 to March 2022. Three batches were produced during the review period (2021) - (batch CP 22, 24, 28).
One OOS was reported. There were no rejected batches, no complaint and no recalls. There was no reprocessing or reworking of batches.
Stability study data were reviewed. Changes and deviations were reviewed. Data were subjected to statistical calculations.
The process was considered under control.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant API(s):
The BMR and results for testing (analytical report, BR QC: 227 pages) for Carbetocin; batch 23-22-0011-01, were submitted. No significant observations were made.

g) Master batch manufacturing and packaging record(s) of the API(s) of interest:
Master Batch documentation Assembly and cleavage (Version 3), purification (version 22), purification version 23 were submitted. No significant observations were made.

h) Recalls in the past three years related to APIs with quality defects:
The company had no recalls in the last three years

i) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the API(s) has been performed and all matters dealt with:
The company declared that self-inspections were done in accordance with procedures.

j) copy of any warning letter, or equivalent regulatory action, issued by any authority for their market, to which the site provides or has applied to provide the API(s):
The company declared that no warning letter or equivalent regulatory action had been issued.

k) Out-of-stock situations:
The company declared that it did not foresee any out-of-stock situation

l) Additional documents submitted:
N/A
Part 5  Conclusion – Desk assessment outcome

Based on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **PolyPeptide Laboratories**, located at **France SAS, 7 rue de Boulogne, Strasbourg, 67100, France**, is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6  List of guidelines referenced in this inspection report

   [untitled (digicollections.net)]

   [https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf]

   [https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf]

   [9789240020900-eng.pdf (who.int)]

   [https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf]


   https://digicollections.net/medicinedocs/#d/s21438en


   https://digicollections.net/medicinedocs/#d/s20177en/

   https://digicollections.net/medicinedocs/#d/s20175en/

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


Essential Medicines and Health Products Information Portal (digicollections.net)


9789240020900-eng.pdf (who.int)


Short name: WHO TRS No. 992, Annex 6


9789240020900-eng.pdf (who.int)

[Short name: WHO TRS No. 1025, Annex 6 9789240001824-eng.pdf (who.int)](9789240001824-eng.pdf (who.int))