### List of Medicinal Products, Produced at Manufacturing site of a Manufacturer or a Foreign Manufacturer Where Inspection Will Take Place

**Name and address of manufacturing site:**

<table>
<thead>
<tr>
<th>Production stage</th>
<th>Trade name of drug/ Name of pharmaceutical substance</th>
<th>INN of group (chemical) name / pharmaceutical substance</th>
<th>Dosage form, dosage (if any)</th>
<th>Registration certificate, date of issue, validity period / register entry, date of inclusion to register for substances (if any)</th>
<th>Type of product (*)/ analytical testing (**)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All stages (including release quality control)</td>
<td>—</td>
<td>—</td>
<td>—</td>
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</tr>
<tr>
<td>Manufacturing of the Finished Dosage Form</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Secondary Packaging</td>
<td></td>
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<tr>
<td>Quality Control testing</td>
<td></td>
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<tr>
<td>Market release by QA/QP (Final batch release)</td>
<td></td>
<td></td>
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<tr>
<td>Other (please indicate)</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<td>—</td>
</tr>
</tbody>
</table>

(*) , (**) – to be indicated in accordance with addendum #1 and #2.

Date of completion «__» _______ 2020

/Please insert position of authorized person/

____________________________________

Please insert name of authorized person

____________________________________

(signature) Place of stamp (printed name)

Addendum № 1

To the List of medicinal products manufactured at manufacturing site of manufacturer or foreign manufacturer in scope of inspection
The list of product types:

**Biological medicinal production:**
- blood products
- immunological products
- products based on somatic cells
- gene-therapy products
- products of tissue engineering
- biotechnological products
- products extracted from animal sources or organs (tissues) of human
- other biological medicinal products (specify type of production)

**Other biological medicinal products:**
- herbal products
- homeopathic products
- radiopharmaceutical medicinal products
- cytostatic products
- cytotoxic products
- hormones
- beta-lactam antibiotics
- products containing superpotent substance
- narcotic drug
- mind-altering drug
- other (specify type of production)

List of active substances types:
- API received by method of chemical synthesis
- API plant-based origin
- API animal-derived origin
- API of biological origin
- API of mineral origin
- API received by biotechnological synthesis.

Types of Analytical testing:

Please indicate the type of testing for manufacturing stage “quality control”:
- Microbiological testing: sterility
- Microbiological testing: non-sterility
- Chemical (physical) testing
- Biological testing