

## 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:

| Production stage   | Trade name of drug/<br>Name of pharmaceutical substance | INN of group (chemical) name / pharmaceutical substance | Dosage form, dosage (if any) | Registration certificate, date of issue, validity period / register entry, date of inclusion to register for substances (if any) | Type of product (*)/<br>analytical testing (**) |
|--|---|---|------------------------------|--|---|
| All stages (including release quality control)                     | —   | —   | —                            | —  | —   |
| Manufacturing of the Finished Dosage Form                          | —   | —   | —                            | —  | —   |
| Secondary Packaging  |   |   |                              |  |   |
| Quality Control testing  |   |   |                              |  |   |
| Market release by QA/QP (Final batch release)                      |   |   |                              |  |   |
| Other (please indicate)  | —   | —   | —                            | —  | —   |
| (*), (**) – to be indicated in accordance with addendum #1 and #2. |   |   |                              |  |   |

Date of completion «    »            2020

|  |   |                |
|--|---|----------------|
| /Please insert position of authorized person/<br><br>_____ | 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