**Act on handling-acceptance of samples [[1]](#footnote-1)**

Sample(s) of the following medicinal product is (are) submitting in purpose of expertise for registration, quality related changes in specifications.

|  |  |  |  |
| --- | --- | --- | --- |
| **Trade name, pharmaceutical form, strength, presentation form of medicinal product** |  | | |
| **Name and address of manufacturer (batch releaser)** |  | | |
| **Name and address of marketing authorization holder** |  | | |
| **Sample batch [[2]](#footnote-2)** |  | |  |
| **Quantity** |  | |  |
| **Submitted for triplicate examination** | **Yes** | | **No** |
| **\* One time examination quantity is accepted,and the applicant undertakes, if necessary,to submit the required quantity of the same batch within one week:** | ***I commit \_\_\_\_\_\_\_\_\_\_\_\_\_\_***    **Yes** | | **/No** |
| **Shelf life** |  | |  |
| **Marking language** |  | |  |
| **Storage conditions [[3]](#footnote-3)** |  | |  |
| **Instruction for use (leaflet insert)** |  | |  |
| **Quality certificate** |  | |  |
| **Who handed over** | | **Who accepted** | |
| **Name of company** | | **Name of company**  “Centre of Drug and Medical Technology Expertise” SNCO | |
| **Name of department** | | **Name of department [[4]](#footnote-4)** | |
| **Name, last name** | | **Name, last name** | |
| **date, signature, seal/stamp** | | **date, signature, stamp** | |

1. ***The act shall be submitted either by marketing authorization holder or by its authorized representative in 2 copies filled, printed, signed and sealed/stamped in advance.*** [↑](#footnote-ref-1)
2. ***It is necessary to fill in the 2nd and 3rd columns of table in case you submit different batches of samples of the same medicinal product.*** [↑](#footnote-ref-2)
3. ***It is necessary to mark “not complied” in the line “storage conditions” of the table in case required special storage conditions for submitted samples are not kept.*** [↑](#footnote-ref-3)
4. ***Choose appropriate department.*** ***NOTE. Samples of narcotics or other controlled substances should be handed over to the Head of Narcotics and other controlled substances department of the Center.*** [↑](#footnote-ref-4)