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

Standard (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** |  |
| **Standard name [[2]](#footnote-2)**  |  |  |  |
| **Batch [[3]](#footnote-3)**  |  |  |  |
| **Quantity** |  |  |  |
| **Submitted for triplicate examination** |  **Yes** |  **No** |  |
| **Shelf life** |  |  |  |
| **Storage conditions [[4]](#footnote-4)**  |  |  |  |
| **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 [[5]](#footnote-5)**  |
| **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, 3rd and 4th columns of table in case you submit different standards of the same medicinal product.*** [↑](#footnote-ref-2)
3. ***It is necessary to fill in the 2nd, 3rd and 4th columns of table in case you submit different batches of the same standard for the same medicinal product.*** [↑](#footnote-ref-3)
4. ***It is necessary to mark “not complied” in the line “storage conditions” of the table in case required special storage conditions for submitted standards are not kept.*** [↑](#footnote-ref-4)
5. ***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-5)