Annex 13
to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during Validity Period of Registration Certificate
(item 4 of section IV)

Criteria
for referring the medicinal product for laboratory tests

1. The laboratory tests of medicinal products, which are submitted for registration (to confirm the reproducibility of methods of quality control proposed by the applicant), may be conducted for both all specification parameters and certain parameters.

2. The laboratory tests shall be conducted in the authorized laboratory having appropriate accreditation after the Center referral based on the contract between the Center and the applicant.

3. The laboratory tests confirming the reproducibility of control methods shall be conducted as per methods of quality control, submitted in the materials of registration dossier. If the methods of quality control, submitted in the materials of registration dossier, are not reproduced in the authorized laboratory, the arbitration laboratory tests and/or repeated laboratory control shall be conducted on the applicant’s request in another authorized laboratory.

4. The laboratory tests confirming the reproducibility of control methods shall not be conducted in the following cases:

When additional (to already registered) dose of medicinal product is registered, provided the composition of dose is similar in ratio, the medicinal product is manufactured with the same equipment as per conditions of license to manufacture this medicinal product;

When several doses of medicinal product are registered at the same time, the laboratory test shall be conducted only for one dose in the same pharmaceutical form provided the composition of dose is similar in ratio, the medicinal product is manufactured with the same equipment as per the conditions of license to manufacture this medicinal product;

The medicinal product is of high cost (equivalent of 200 EUR and more) or the total cost of laboratory control is 200 EUR and more;

There is no necessary equipment for laboratory test on reproducibility of methods for particular quality parameters in the authorized laboratory;

The medicinal product is the product of limited use (orphan product);

When the medicinal product is registered with the other name (change of product name);

When API is registered;

The production technology of medicinal product consists of the process of packaging from in bulk product, and in bulk product has been registered in due order;

It is a WHO prequalified medicinal product;

The medicinal product has been registered in country which regulatory authorities apply high quality standards complying with standards recommended by WHO, particularly of EU Member States, Switzerland, UK, USA, Canada, Japan, Australia, Iceland, Lichtenstein;

Medicinal product is produced according to the approved specification;

When the medicinal products (e.g. sodium chloride solution, antibiotics etc.) are registered, which monograph is present in SPhU or harmonized pharmacopoeias or other leading pharmacopoeias.

{Annex 13 in wording of MoH Ukraine Order №460 as of 23.07.2015}