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FUNDAMENTALS OF THE ACCEPTANCE CRITERIA DEVELOPMENT FOR TRANSFER OF ANALYTICAL PROCEDURES

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Transfer of analytical procedures (TAP) between facilities or laboratories is a necessary part of pharmaceutical development and commercialization. It constitutes the documented process that qualifies a laboratory (the receiving unit) to exercise an analytical test procedure that originated in another one (the sending unit), thus ensuring that the procedural knowledge and ability of the receiving unit are sufficient to perform the transferred analytical procedure as intended. To secure the same reliable results in the receiving unit, the validated state of validated analytical procedures should be maintained when they are transferred between laboratories and sites. The successful TAP should be based on well-founded acceptance criteria.

Ukraine has been a member of PIS/C since 2011, so all GMP rules, in particular, the requirement to perform TAP, have to be strictly observed by Ukrainian manufacturers.

The problem is that there are no metrologically-based acceptance criteria for TAP in existing regulatory and recommendation documents (*USP <1224> Transfer of analytical procedures*, *WHO guideline on transfer of technology, ISPE Good Practice Guide: Technology Transfer*). It results in baseless recommendations for TAP ─ at present, all of them are based only on the comparison of means and variability of results omitting the purpose of procedure application (the maximum permissible uncertainty, also referred to as target uncertainty). It means that the goal of procedure (for assays ─ content limits) and requirements to measurement results are not differentiated for various applications of the transfer.

As the methodology for TAP is not defined, regulatory documents may require the receiving unit to confirm technology of manufacturing processes (to conduct analyses of samples obtained from different technological batches), which is not, in fact, the goal of transfer.

The absence of the scientifically proven concept for TAP leads to the fact that the experiment size of TAP becomes equal or greater than that of validation studies. In turns, use of the concept of the maximum permissible uncertainty of measurement results described in the State Pharmacopeia of Ukraine enables analysts to evaluate the transfer properly and reduce the experiment size.

Therefore, the development of a system of TAP to conduct the main pharmaceutical tests based on the concept of the maximum permissible uncertainty is an issue of great importance for manufacturers of pharmaceuticals.

In this connection, the objective of our work is to establish scientifically grounded acceptance criteria for TAP by using the concept of the maximum permissible uncertainty.

The pharmaceuticals containing an active ingredient of desloratadine will be used as test samples. The TAP for tests *Assay*, *Uniformity of Dosage Units, Dissolution, Water, Impurity* and *Organic Solvents* will be conducted. The suitability of elaborated criteria will be verified with the use of following analytical appliances: UV-visible spectrophotometers, liquid and gas chromatographs, automatic titrators.

The expected practical significance of results of this work is that the acceptance criteria established in accordance with the metrological concept of the State Pharmacopoeia of Ukraine will make it feasible to successfully endure the strictest requirements of regulatory and recommendation guides to TAP, reduce the experiment size, and harmonize criteria to validation procedures, equipment qualification and requirements to personnel.