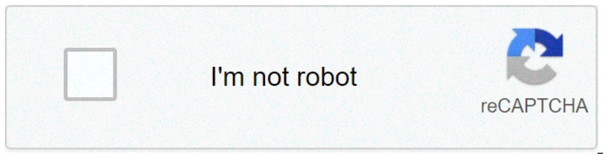

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Analytical method validation report. pdf

Validation of the analytical method according to the WHO Technical Report Series, n. 937 General Principle Pharmaceutical Methods Non Pharmacopoeic Methods Characteristics of analytical procedures Principle This appendix provides some information on the characteristics that should be considered during validation of analytical methods. Approaches other than those specified in this appendix may be followed and may be acceptable. Manufacturers should choose the validation protocol and the best procedures to test their product. The manufacturer must demonstrate (through validation) that the analytical procedure is suitable for its intended purpose. Analytical methods, which indicate stability, must be validated. The analytical method should be validated by research and development before being transferred to the quality control unit when necessary. There should be specific for both, materials and products. Tests must be described in the documentation on standard test methods. Specifications and standard testing methods in pharmacy ("macocapoeial method"), or appropriately developed specific or test methods ("non-pharmaceutical methods") as approved by the national drug regulation authority may be used. The well-characterised reference materials must be used in the validation study. Common analytical procedures include identification tests, drug murderand pharmaceutical products, quantitative tests for impurity content and limit test for impurities. Other analytical procedures include dissolution testing and particle size determination. The results of analytical procedures should be reliable, accurate and reproducible. The characteristics that should be considered during validation of analytical methods. Verification or revaluation must be performed when relevant, for example, when there are changes in the process of synthesis of the pharmacological substance, changes in the composition of the finished product, changes in the analytical procedure; when analytical methods are transferred from one laboratory to another; or when large pieces of equipment tools change. Verification or revaluation depend on the nature of changes. There should be evidence that analysts, responsible for certain tests, are adequately qualified to carry out such analyses ("analyst competence"). Pharmaceutical methods When pharmacopoeic methods are used, the tests must be available to demonstrate that such methods are suitable for routine use in the laboratory (verification). The pharmacopoeic methods used for the determination of contents or impurities in pharmaceutical products should also be demonstrated in particular with regard to the substance in question (without placebo interference). Non pharmacopoeic methods Non pharmacopoeic methods must be properly validated. MethodValidation must be performed in accordance with the validation protocol. The protocol should include procedures and acceptance criteria for all features. Results must be documented in the validation report. Justification must be provided when non-pharmapoeic methods are used if pharmacopoeic methods are available. Justifi cation should include data such as comparisons with pharmacpoeial or other methods. Standard test methods should be described in detail and should provide sufficient information to allow properly trained analysts to perform the analysis reliably. At least, the description should include chromatographic conditions (in case of chromatographic tests,) necessary reagents, reference standards, formulas for calculation of results and system fitness tests. Features of analytical procedures Features that should be considered during validation of analytical methods include: — specificity — linearity — range — accuracy — detection limit — quantification limit — robustness. Accuracy is the degree of agreement of test results with true value, or the closeness of the results obtained from the procedure to true value. It is normally established on samples of the material to be examined that they were prepared for quantitative accuracy. Accuracy must be established throughout the specified range of the analytical procedure. Note: it is acceptable to use aplacebo where a known quantity or a concentration of a reference material is used. Accuracy is the degree of agreement between the individual results. The complete procedure must be applied repeatedly to separate and identical samples taken from the same homogeneous batch of material. It should be measured by the dispersion of individual results from the average (good grouping) and expressed as the relative standard deviation (RSD). The repeatability should be evaluated using a minimum of nine determinations covering the specific range and for the procedure, for example three concentrations/three replicates each, or a minimum of six 100% determinations of the test concentration. Intermediate precision expresses laboratory variations (usually in different days, different analysts and different equipment). If reproducibility is evaluated, an intermediate precision measurement is not required. Reproducibility expresses precision among laboratories. Robustness (or robustness) is the ability of the procedure to provide analytical results of acceptable accuracy in a variety of conditions. The results of separate samples are influenced by changes in operating or environmental conditions. Robustness must be considered during the development phase and must show the reliability of an analysis when deliberate variations are carried out in method parameters Factors that may have an effect on robustness during the execution of chromatographic analysis include:standard samples and solutions. — reagents (e.g. different suppliers). — different columns (e.g. different batches and/or suppliers). — extraction time. — pH variations of a mobile phase. — changes in the composition of the mobile phases. — temperature and — rate of progress. Linearity indicates the ability to produce results directly proportional to the concentration of the analyte in the samples. A series of samples must be prepared where analytical concentrations embrace the required range of the procedure. If there is a linear relationship, the test results must be evaluated by appropriate statistical methods. A minimum of five concentrations should be used. The range is an expression of the lower and higher levels of analytical that have been proven decisive for the product. The specified range is normally derived from linearity studies. The specificity (selectivity) is the ability to measure unequivocally the desired analogy in the presence of components such as excipients and impurities that can also be foreseen to be present. A specificity survey should be conducted during validation of identification tests, determination of impurities and testing. The detection limit (relevance limit) is the smallest amount of an analytical that can be detected, and not necessarily determined, quantitatively. Approaches may include instrumental or non instrumental procedures and may include those based on: — visual assessment.— standard deviation of response and slope. — standard deviation of vacuum; and — calibration curve. the quantity limit (quantity limit) is the lowest concentration of an analytical in a sample that can be determined with acceptable accuracy and accuracy. approaches may include instrumental or non-structural procedures and may include those based on: — visual assessment. — signal and noise ratio. — standard deviation of response and slope. — standard deviation of vacuum; and — calibration curve. characteristics (including tests) which must be considered when using different types of analytical procedures are summarized in Table 1. system fitness test system fitness test is an integral part of many analytical procedures. tests are based on the concept that the equipment, electronics, analytical operations and samples to be analyzed constitute an integral system that can be evaluated as such. the parameters of fitness test of the system that must be established for a particular procedure depend on the type of procedure that is evaluated, for example, a resolution test for a hplc procedure. for further pharma updates visit – reference: who technical report series, n. 937. shiv kumar is the author and founder of the pharmaceutical guide, is a pharmaceutical professional of the indiau rich experience in more than 14 years during hisworks in quality assurance department with multinational company i.e. Zydus Cadila Ltd, Unichem Laboratories Ltd, Indoco remedies Ltd, Panacea Biotec Ltd, Nectar life Science Ltd. 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