

Self-inspection checklist for quality testing ver.1

March, 2026

Now, it has been decided to abolish the Checklist for document-based conformity inspection related to quality testing, and to publish the "Self-inspection checklist for quality testing" on this website, similar to non-clinical studies, as a result of consultation among the three pharmaceutical industry associations (Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA), and European Federation of Pharmaceutical Industries and Associations (EFPIA)) and the PMDA Quality Assurance Department II. Furthermore, the distinction between analytical testing (including validation) and stability testing has been removed, and they have been integrated into a single checklist.

This checklist was compiled by the PMDA Quality Assurance Department II and the pharmaceutical industry association groups following discussion of key points for verifying the reliability of the quality tests used in the approval application documents by the applicant to fulfill the applicant's responsibilities. This checklist indicates neither how PMDA conducts a document-based conformity inspection nor a list of documents to be submitted during the inspection.

Application document for a new drug must be collected and prepared in accordance with the Standards of Reliability of Application Data stipulated in Article 43 of the Regulation for Enforcement of the Pharmaceutical Affairs Law (hereinafter referred to as "the Standards"). However, there are various methods to comply with the standards. When using this checklist, please note that the purpose of this checklist is not to satisfy the check items, but to provide the materials for overall judging whether it is reliable as an application document, including scientific validity, based on the confirmation results. The checklist is continuously reviewed and revised if needed.

As of 31 March 2023, the following revisions have been made to the "Checklist for document-based conformity inspection of New Drug (Quality/Non-clinical)" published by PMDA.

- The non-clinical study (pharmacological test/pharmacokinetics study) parts have been removed from the checklist published by PMDA, and it has been revised as the "Checklist for document-based conformity inspection of New Drug (Quality)."
- Published on the Japan Pharmaceutical Manufacturers Association website as the "Self-Inspection checklist for non-clinical studies_ver.1."

Checklist		Result
Overall judgment^{*1}: YES or NO		
Is this test reliable enough to be used for approval application ?		
Check the following items as necessary and judge the overall reliability of this test.		
1 Preparation for the test	1) Contract agreement ※Only in case of contracted testing	In the contract agreement (or protocol) etc., was there a method established for the applicant to confirm the reliability of the tests conducted by the contractor? Alternatively, has the applicant confirmed and been able to guarantee the reliability of the tests conducted by the contractor?
	2) Test protocol	Was the test protocol prepared and revised if necessary?
	3) Standard operating procedures	Were the necessary standard operating procedures prepared and revised if necessary?
	4) Equipment	Was it demonstrated that the equipment has sufficient accuracy for use in the test?
	5) Samples (drug substance, drug product, reference standard etc. subject to the test)	Were the samples used as described in the test protocol etc.? Were the records of the manufacture, import, purchase, shipment/receipt, etc., of the samples appropriate?
2 Conduct of the test	1) Raw data	Were the raw data (test result records, charts, etc.) obtained in accordance with the test protocol and its revisions?
	2) Preparation records	Were there the sample preparation records?
	3) Test methods and conditions	Was the test conducted according to the test items, methods, and conditions described in the approval application documents?
	4) Correction of raw data	If the raw data of the test results was corrected, was the reason for the correction stated in the raw data and was it properly corrected?
	5) Deviation handling	If there were any changes in protocol or deviations during the test, were they properly handled?
	6) Calculation records^{*2}	If calculations were performed to derive the test results, were there the records available that clarify their contents?
	7) Temperature and humidity records, storage records ※ In case of stability tests	Were there the temperature and humidity records for the storage period of stability samples? Were there the storage records of stability samples (such as entry and exit the records of the stability test chamber)?
	8) Electromagnetic / electronic data and records	If electronic raw data and records were used, were they handled appropriately according to pre-defined agreements or procedures ^{*3} ?
	9) QC/QA process^{*4}	Was the QC/QA process for creating raw data and test reports, etc., established in the test protocol or procedures, and was the QC/QA conducted as specified?
3 Approval Application Documents	1) Approval application document data	Did the data in the approval application documents accurately reflect the raw data? Also, was the corrected data accurately reflected in the approval application documents?
	2) Approval application document figures and tables	Did the figures and tables summarizing the test results in the approval application documents accurately reflect the test results? Also, were the corrected figures and tables accurately reflected in the approval application documents?
	3) QC/QA process^{*4}	Was the necessary QC/QA conducted for the data, and the figures and tables summarizing the test results in the approval application documents?

*1: As a test to be used for approval applications, overall judgement whether the test purpose and results are objectively verified with the basis of surrounding documents, were scientifically valid, and reliability was ensured.

*2: Even if automatically calculated by the system, it is necessary to be able to present the actual calculation formulas, function programs, or records of calculation results.

*3: Including the ER/ES guidelines ("Use of Electronic Records and Electronic Signatures in Applications for Approval or Permission for Pharmaceuticals, etc." Notification No. 0401022 dated April 1, 2005) and higher-level procedural documents.

*4: The generic term "QC/QA process" is used. Because some companies or testings may rely solely on QC to assure quality, and because processes may differ between functions, it should be checked in accordance with each company's QC/QA framework and processes.