About the general information (draft)
"How to apply the Japanese Pharmacopoeia according to the purpose"

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As we begin soliciting public comments regarding the general information (draft) "How to apply the Japanese Pharmacopoeia according to the purpose", we would like to explain the background behind the decision to list this general information.

In the JP, some tests in the monographs of drug products are specified to be performed using the relevant drug substance. In this case, it is necessary to obtain the drug substance and then to perform all tests of its monograph to confirm that the obtained material meets the requirements. However, it is sometimes difficult to test drug products at public testing institutions and in pharmaceutical education because of the difficulty in obtaining the drug substance.

Considering these situations, this general information demonstrates the following concept. When the tests in the monograph of a drug product are performed at public testing institutions, etc., if identification, purity, etc. is specified to be performed using the drug substance, the use of a reagent that have been confirmed to comply with only the necessary items in the monograph of the drug substance is allowed depending on the purpose of its use.

For example, if the use of the drug substance is specified in "system performance" of an HPLC method, the purpose of "system performance" is to confirm the resolution between the test ingredient and a target substance to be separated. Therefore, it is possible to substitute the drug substance with a reagent as far as its structure has been confirmed already. In this case, even if the substituted reagent contains an impurity, the detected impurity peak is so small to be easily distinguished from the target peak. The reagent is judged to fit for the purpose of the test by not including the impurity peak in resolution calculation.