Items to be included in the validation report of purity and other test methods
(Recovery tests)

1 Title (including the name of the target substance and test items. Example: Validation report of the xxx test method for yyy)

2 Date of report

3 Author

4 Testing institution (e.g., institution name, address, phone number, email address)

Note: Describe the contents of (1) to (4) below for each item specified in the draft specifications.

(1) Test method

Describe the test method to be included in the draft specifications.

- When using a test method in the General Tests of Japan's Specifications and Standards for Food Additives (JSFA), state the name of the test (e.g., JSFA General Test, No. 36 Arsenic Limit Test Method 1) and the conditions specified in each Article (e.g., weight of sample, standard solution volume).
- When setting up a test method other than those in the General Tests of JSFA (including when you are using a test method that has been partly changed from the original), include the following items so that the test can be performed by using only the information you supply:

(a) Procedure
– Include methods of preparation of test solutions and standard solutions
– Operating conditions: Describe the operating conditions (including equipment conditions) used in the test.
(b) Reagent chemicals and reagent solutions: Describe the reagent chemicals and reagent solutions used in the test (e.g., specifications, purity, manufacturer's name).
(c) Equipment: Describe the equipment used in the test (e.g., model, manufacturer)
(d) Operating conditions
(e) Specification values, judgment method
(f) Flowchart of the test method
(g) Cite and attach any references used in tests other than JSFA
Example of the description of a reference: author name, article title, journal name, year of publication, volume (issue), page numbers

(2) Procedure of recovery tests

(a) Information about the samples used in the test, showing the origin of the sample (e.g., the name, manufacturer, date of production, and lot number)
(b) Concentration of added analyte and rationale for setting this value
(c) Concentration and method of preparation of the standard solution to be added
(d) Method of addition of standard solution and amount added
(e) Number of trials: for samples to which the analyte was added, at least three trials; for control samples, at least two trials

(3) Test results

Even in limit tests, such as those for arsenic, please show numerical data such as absorbance measured in the solutions. Include the data so that the test progress is evident, bearing in mind the following points:

(a) For samples to which the analyte was added or control samples, indicate the weight of the sample and the found values (e.g., absorbance, peak area) in table form.
(b) Provide a calibration curve if necessary.
(c)Calculate and show the concentrations of the analyte in the test solutions and the samples.
(d) If HPLC or GC is used, attach the chromatograms of the reference standard and the sample.
(e) Indicate the recovery rate and the relative standard deviation.

(4) Considerations

Describe your thoughts regarding the recovery tests.

Example of a report description

Validation report of Purity Tests for yyy

Date of report: MM/DD/YYYY
Author: xxx
Testing institution: xxx

Report on validation of the xxx test method for yyy

1. Test method
   (1) Procedure
   (2) Reagent chemicals and reagent solutions
   (3) Equipment
   (4) Quantitative calculation (formulae)
   (5) Specification values, judgment method
   (6) Flowchart of the test method
   (7) Cite and attach any references used in tests other than JSFA

2. Procedure of recovery tests
   (1) Information about samples used in the recovery test
   (2) Concentration of added analyte and rationale for setting this value
   (3) Concentration and method of preparation of the standard solution to be added
   (4) Method of addition of standard solution and amount added
   (5) Number of trials

3. Test results

4. Considerations

Note: This is an example of the report. Your report does not necessarily have to be consistent with this if there are more appropriate ways of describing your results. Items to be included in the test method should be changed as appropriate to suit your test method.