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Application News

No. A599

Spectrophotometric Analysis

Identification Testing of Health Food Ingredients Using FTIR: Supports GMP by Using Food Additive Identification Test Program

GMP (Good Manufacturing Practice) Guidelines describe requirements that companies must observe in all processes from ingredient acceptance to packaging and shipping of finished products so as to manufacture products appropriately, safely, and with consistent quality. GMP was a legal requirement in the pharmaceuticals industry from an early date, and tests are conducted to confirm that the actual composition and contents of ingredients in pharmaceutical products conform to the product labeling, and there are no problems in terms of safety or quality [(1)].

Because health foods and nutritional supplements are mainly available in tablet and capsule form and their manufacturing processes are similar to those for pharmaceutical products, GMP has also become a legal requirement for health foods and related products in Asian countries in recent years [(2)].

Application News No. A597 introduced identification testing of L-glutamic acid by the ATR method using the Japanese Pharmacopoeia (JP) identification testing program. Here, we introduce an identification testing method by the KBr pellet method for xylitol, an ingredient in health foods, using the food additive identification test program, which is a standard feature of the LabSolutions™ IR control software of Shimadzu FTIR instruments. This program enables simple and easy identification testing in accordance with JP, ingredient acceptance inspection, and pre-shipment inspections of products.

R. Fuji

Food Additive Identification Test Program

The Japanese Pharmacopoeia is a set of standards for pharmaceutical products which is established by Japan's Minister of Health, Labour and Welfare and provides the specifications, criteria, and standard test methods necessary to properly assure the quality of pharmaceuticals in Japan. The general notices section of JP states that "Identification testing is to identify the active ingredient(s) of the drug based upon its specific property." It further states that "In identification testing that employs FTIR, the absorbance spectra of a sample and a standard are compared, and the identity of the sample and standard is verified to be the same if the same intensity of absorption at the same wavenumbers on both spectra is observed." General measurement techniques in transmission spectrometry include the potassium bromide (KBr) pellet method, potassium chloride (KCl) pellet method, solution method, paste method, and liquid film method. However, the 17th Edition of JP also allows the use of ATR method for some pharmaceuticals such as montelukast sodium and refined sodium hyaluronate eye drops [(3)].

As in the JP identification testing program, the Shimadzu food additive identification test program also has three functions in order to support diverse test methods. The first function is "peak detection," in which up to 10 peak positions can be specified as check items, the second is "spectrum output," which is used for visual comparison of spectra, and the third is "report preparation," which allows specification of as many as 10 peak positions and 4 peak intensity ratios in addition to "spectrum output."

In addition, it is also possible to use the standard spectra (including ATR spectra and transmission spectra) of the 57 components listed in "Japan's Specifications and Standards for Food Additives" (published by the Ministry of Health, Labour and Welfare), which are included in the food additives library, in the food additive identification test program.

The "report preparation" function of the Shimadzu food additive identification test program can also be applied to identification testing of health food ingredients. In "report preparation," pass/fail judgments for the peak wavenumbers and peak intensity ratios of standard spectra registered in the program library in advance can be performed easily based on the allowable values by comparison with the spectrum of the sample. In this evaluation, a maximum of 10 peak wavenumbers and a maximum of 4 peak intensity ratios among those peaks can be used. Because the allowable range of the peak wavenumbers and intensity ratios can also be set as required, testing can be conducted under the conditions required by the user, corresponding to diverse types of raw materials.

Instrument Used

An IRSpirit™ Fourier transform infrared (FTIR) spectrophotometer was used. Fig. 1 shows the external appearance of the instrument.

The IRSpirit has a small, portable body with dimensions of 390(W) × 250(D) × 210(H) mm, which is smaller than A3 size. For installation where space is limited, its unique design enables access from both sides. It features both best-in-class SN ratios and resolution and has high expandability, with the widest sample compartment in its class, which can accommodate both Shimadzu accessories and third-party accessories. Since it also has functions specifically designed for contaminant analysis, including contaminant analysis programs and contaminant libraries, it can be used in various applications, not limited to identification testing.

Fig. 1 External Appearance of IRSpirit™

Identification Testing of Xylitol

Identification testing of xylitol, which is used as a health food ingredient, was conducted by the KBr pellet method using the "report preparation" function of the food additive identification test program. Table 1 shows the measurement conditions.

Table 1 Measurement Conditions

Instrument	: IRSpirit-T (KBr window plate)
Resolution	: 4 cm^{-1}
No. of scans	: 45
Apodization	: Happ-Genzel
Detector	: DLATGS

The food additive identification test program is executed according to the program flowchart shown in Fig. 2.

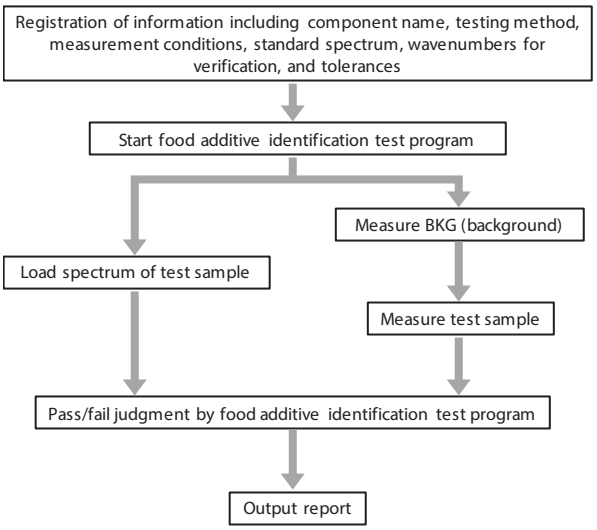

Fig. 2 Flowchart of Food Additive Identification Test Program

Information such as the component name, test method, measurement conditions, standard spectrum, wavenumbers to be verified and their tolerances must be registered in advance. Since multiple components are sometimes handled in daily routine analyses, it is possible to register a maximum of 20 components in the food additive identification test program.

After registration of the necessary items, the test is initiated by starting the program and selecting the target component. A pass/fail judgment is performed by loading a previously-measured infrared spectrum or by measuring the sample to obtain an infrared spectrum. A pass judgment is indicated by "OK" in the upper right corner of the report, and a fail judgment is indicated by "NG."

Fig. 3 shows the result of the identification test for xylitol. The result of the pass/fail judgment by comparing the spectra of the test sample and the standard was pass, as indicated in the upper right corner of Fig. 3.

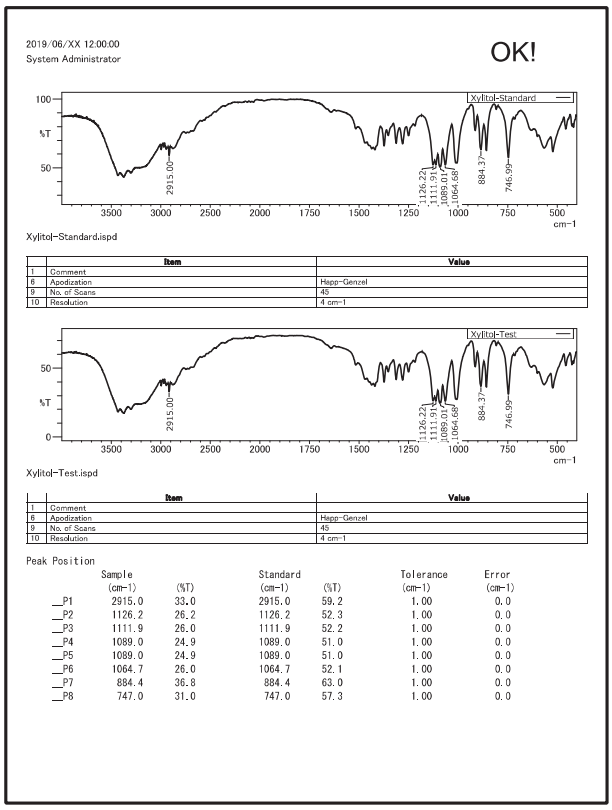

Fig. 3 Identification Testing Result

Conclusion

Simple and easy identification testing of health food ingredients was possible by using the food additive identification test program, a standard feature of the LabSolutions IR control software of Shimadzu FTIR instruments.

Efficient daily identification testing is also possible by using test conditions registered in advance.

<References>
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3) Ministry of Health, Labour and Welfare (Japan) website "Japanese Pharmacopoeia 17th Edition" https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/JP17.pdf (accessed May 9, 2019)

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