

Application News

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Spectrophotometric Analysis

Identification Testing of Health Food Ingredients Using FTIR: Support for GMP

The Good Manufacturing Practice (GMP) guidelines describe the requirements that companies must observe across all processes from ingredient acceptance to packaging and shipping of products in order to guarantee that products are produced appropriately, safely, and with consistent quality. The pharmaceutical industry is already under obligation to comply with GMP and carries out testing to confirm that products contain pharmaceutical components and content as labeled and have no safety and quality issues ¹⁾.

Health foods and nutrition supplements are mainly available in tablet and capsule form and share similarities with pharmaceuticals in terms of these manufacturing processes. Recently in Asian countries, GMP is now imposed by law even on health foods ²⁾.

This article introduces an identification of L-glutamic acid, an ingredient in health foods, using the LabSolutions™ software which controls Shimadzu's FTIR instruments. The IR software includes the JP identification test program as standard to enable identification testing in accordance with the Japanese Pharmacopoeia (JP). In addition to the pharmaceuticals described in the JP, this program can also be used for acceptance inspections of raw materials and pre-shipment inspections of products by specifying distinctive peaks.

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■ JP Identification Test Program

The Japanese Pharmacopoeia (JP) is an official document that defines the specifications, criteria, and standard test methods necessary to properly assure the quality of pharmaceuticals in Japan. The general notices section of this document states that "Identification is the test to identify the active ingredient(s) of the drug based upon its specific property". 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. Although common measurement techniques of transmission spectroscopy include the potassium bromide (KBr) pellet method, potassium chloride (KCl) pellet method, solution method, paste method, and liquid film method, the 17th edition of the JP also allows the use of ATR spectroscopy with respect to some pharmaceuticals, such as montelukast sodium and refined sodium hyaluronate eye drops ³⁾.

Since the testing method for each component is stated in the official monographs of the JP, the JP identification test program has three functions for handling the wide variety of testing methods. The first function is "peak detection," in which up to 10 peak positions can be specified for checking. The second function is "spectrum output," which is used to visually compare spectra. The third function is "report creation," which allows specification of 10 peak positions and up to four points for peak intensity comparison in addition to "spectrum output".

The "report creation" function of the JP identification test program can be applied to the identification testing of health food ingredients. In the "report creation" function, pass/fail judgment can be performed easily from threshold values as well as sample spectrum comparison with respect to peak wavenumbers and peak intensity ratios of a standard spectrum registered in advance. A maximum of 10 peak wavenumbers and peak intensity ratios of up to four corresponding points can be used in this evaluation. Since the allowable range of peak wavenumbers and intensity ratios can also be set as required, testing of various materials can be performed using the conditions deemed necessary by users.

■ Instrument Used

The instrument used for analysis was the IRSpirit™ Fourier transform infrared spectrophotometer with the QATR-S single-reflection ATR accessory, which is integrated into the sample compartment of the IRSpirit. Fig. 1 shows the external appearance of the instrument.

The IRSpirit features a small and portable body and the main unit is under A3 size with dimensions of 390 (W) × 250 (D) × 210 (H) mm. Furthermore, its unique design allows access from both sides to enable installation even in narrow spaces. Providing best-in-class SN ratios and resolution, the IRSpirit also features high expandability with the widest sample compartment in its class, which can accommodate both Shimadzu and third party accessories. The instrument can be used for more than just identification testing since functions specific to contaminant analysis, such as contaminant analysis programs and contaminant libraries, are also provided.



Fig. 1 External Appearance of IRSpirit™ + QATR™-S

■ Identification Testing of L-Glutamic Acid

Identification testing of L-glutamic acid, which is used as a health food ingredient, was performed using the "report creation" function in the JP identification test program. Table 1 lists the measurement conditions.

Table 1 Measurement Conditions

Instrument	: IRSpirit-T (KBr window) QATR™-S (wide-band diamond prism)
Resolution	: 4 cm ⁻¹
Accumulation	: 20
Apodization function	: Happ-Genzel
Detector	: DLATGS

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

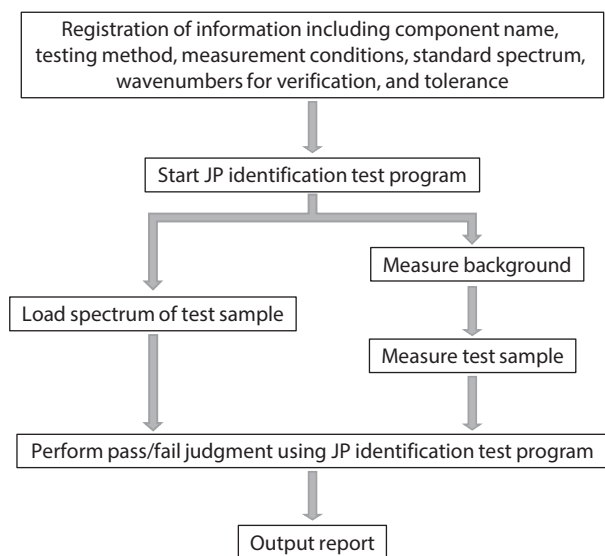


Fig. 2 Flowchart of JP Identification Test Program

Information including component name, testing method, measurement conditions, and standard spectrum in addition to wavenumbers for verification and tolerance must be registered in advance. Since several components may also be handled in daily routine analyses, up to 20 kinds of components can be registered to the JP identification test program.

After registering the required information, testing is initiated by starting the program and selecting the target component. Pass/fail judgment is performed by loading an infrared spectrum measured previously or by measuring the test sample to obtain an infrared spectrum. A pass judgment result is indicated by "OK" at the upper right of the report and a fail judgment result is indicated by "NG".

Fig. 3 shows the identification testing result for L-glutamic acid. The result of pass/fail judgment by comparing the spectra of a standard and the test sample was determined to be a pass, as indicated at the upper right of Fig. 3.

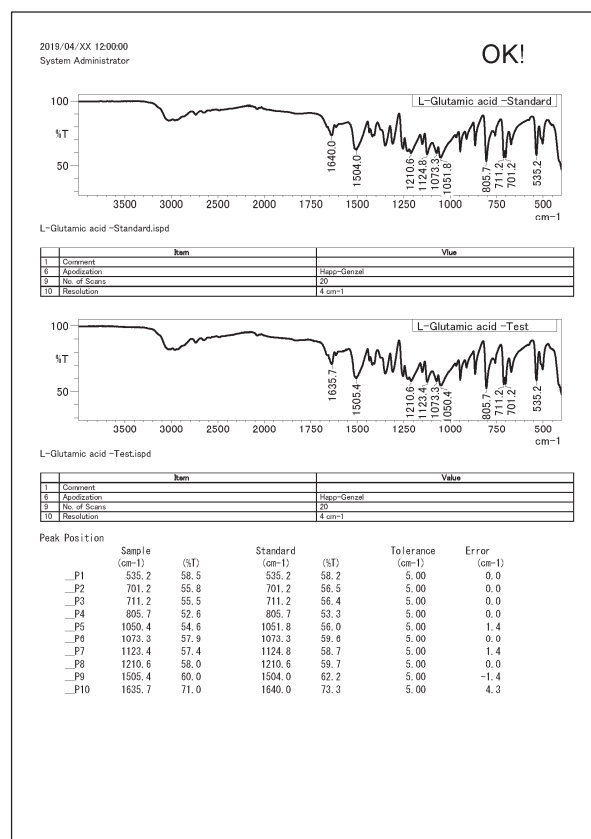


Fig. 3 Identification Testing Result

■ Conclusion

By using the JP identification test program included as standard in the LabSolutions IR software, which controls Shimadzu's FTIR instruments, we were able to easily perform identification testing of a health food ingredient. The software enables daily identification testing to be performed efficiently through the use of testing conditions registered in advance.

<References>

- 1) Ministry of Health, Labour and Welfare (Japan) website "Measures for Securing the Safety of Health Foods" <https://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/hokenkinou/dl/26.pdf> (9th May, 2019)
- 2) The Japanese Institute for Health Food Standards website <http://www.jihfs.jp/gmpn01.html> (9th May, 2019)
- 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> (9th May, 2019)

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