



波形データを用いたMT法による 製品同一性管理と単位空間の作成

*Product identification and unit space construction
by MT method using waveform data*

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Near-infrared spectroscopy (NIR) is a simple, quick, non-contact, non-destructive inspection method that can recognize the quality of Kampo Medicines herbal medicines. Because of its high consistency, it can be expected to find applications in the quality inspection of many such medicines. In this study, 13 539 lots of 37 commercially manufactured medicines were analyzed by NIR, and the Mahalanobis-Taguchi (MT) method was used to determine the how well NIR discriminated among the lots. Unit spaces for all 37 medicines were created by the same method, thereby avoiding such time-consuming tasks as selecting separate factors for each medicine. The resulting overall discrimination rate for these 37 medicines was 99.17 %, and we were able to create highly discriminative unit spaces for product identification and detection of abnormalities. However, it also became clear that there were misclassification problems for certain specific medicines, and remaining issues concerning the creation of the unit spaces.

Key words : near infrared spectroscopy, Kampo Medicine, equivalence, waveform, identify, Maharanobis distance, quality engineering, Taguchi methods, S/N ratio

1. はじめに

製造業では一般に多品種で大量生産が行われていることも多いが、品種が違って外見では区別が付きにくい製品を製造しているケースがある。また液

体や粉体などを扱う素材産業では、著しく性質が異なるが外見では区別がつかない製品を製造することも多く、出荷前の製品判別の検査方法には工夫が必要とされる。医薬品も同様で、本検討で取り上げる漢方製剤の外観は全て顆粒状で、色調といった外観上の差も少なく、含有成分や内容が異なっても、その外見から内容的なものを識別することは難しく、さまざまな分析機器を用いた検査方法が適用されている。しかしながら衛生上の問題もあり、可能であるならば非接触で、また非破壊試験であること

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