

6-3. European Pharmaceutical Review

❖ European Pharmaceutical Review에 실린 기사 중 일부 발췌한 내용

[Revolutionizing Raman with the transmission technique]

- The drug assay and/or content uniformity of the dosage units is typically performed by a wet chemistry technique that has not significantly changed in the industry for four decades. High performance liquid chromatography (HPLC) is widely used by laboratories for that purpose. But there are drawbacks to these methods. This article explores how Transmission Raman now has the potential to revolutionize the release testing of pharmaceutical product in a QC laboratory.
- **HPLC is a slow and labor-intensive technique leading to lengthy investigations and delays in product release.**
- ❖ **HPLC 분석은 시간과 인원이 많이 필요한 방법이어서 신속한 품질검사 및 출하를 어렵게 한다.**
- **Transmission Raman spectroscopy technique eliminates sample and standard preparation time, with routine sample analysis in just minutes, and has the added benefit of eliminating environmental waste.**
- ❖ **Transmission 라만분광법은 시료의 전처리가 불필요하고 수 분내에 분석이 가능할 뿐만 아니라 환경오염을 줄이는 이점도 있다.**
- **Actavis has developed and validated replacement QC release test methods using Transmission Raman spectroscopy for the quantitation of active pharmaceutical ingredients (APIs) in intact tablets.**
- ❖ **영국의 제약회사인 Actavis는 정제 주성분의 정량을 Transmission 라만으로 하는 방법으로 변경하여 품질관리를 하고 있다.**
- **The Transmission Raman methods have received regulatory approval by the UK Medicines and Healthcare Products Regulatory Agency as alternative methods for the release of commercial product to the market.**
- ❖ **Transmission 라만분광법은 제품 출하의 대체 시험법으로 영국의 MHRA-Medicines and Healthcare Products Regulatory Agency의 승인을 받았다.**
- In Transmission Raman spectroscopy, the laser light illuminates a wide area on the whole intact sample.
- The Raman signal is made up of the contribution from throughout the sample, and is representative of the whole tablet.
- The Raman method was developed and validated on Cobalt Light Systems' Transmission Raman System TRS100.
- The validation of the Raman method therefore followed the general ICH guidelines for method validation, as well as the guidelines specific to NIRS applications.
- No sample damage was observed at the TRS100's maximum power.
- **The results obtained demonstrated that Transmission Raman was a very accurate technique, equivalent to HPLC, for QC release testing.**
- ❖ **Transmission 라만분광법은 HPLC, GC 처럼 매우 정확한 기술인 것이 밝혀졌다**
- **The development and regulatory approval of Transmission Raman methods for the routine QC testing will revolutionize how samples are analyzed for assay, content uniformity and identification.**
- ❖ **Transmission 라만분광법이 허가기관에서 승인됨으로써 함량분석, 함량균일성시험 및 확인시험에 획기적인 시험 방법으로 사용될 것이다**
- **These non-destructive Raman test methods require no sample preparation, standards, solvents, glassware, or consumable for routine QC analysis, making them very fast and simple alternatives to traditional liquid chromatography.**
- ❖ **Transmission 라만분광법은 시료전처리, 표준품, 용매, 초자기구 및 소모품이 필요 없는 신속하고 간편한 QC 시험법으로 기존의 HPLC법을 대체하고 있다**
- Actavis UK Ltd is actively developing further Transmission Raman methods for different solid dose products with the aim of reducing the laboratory costs and the time for release of products to the market.