

Transdermal Patches:

**To make them faster,
you've got to
inspect them faster.**

Transdermal patches. Three-shift production, new plant facilities and increasing demand. But the requirement for dosage content uniformity testing is always there.

There is a way to match testing speed with production capacity. The new RapiDerm™ analyzer from NIRSystems can assay the active drug concentration in less than one minute—with little or no sample preparation and unparalleled ease of operation. RapiDerm's small footprint saves vital space, too.

And because RapiDerm uses the proven spectrometric advantages of the near-infrared, its results conform to compendial methods with excellent precision.

AT LINE

RapiDerm analyzers are already in use for rapid, at-line active assay. The RapiDerm-OL™ system performs continual, on-line assay of the moving web during coating operations.

And because it uses the same patented oscillating grating technology found in the RapiDerm, the on-line system provides 100% inspection with remarkable precision. And it's production-proven, too.

While you've been reading this message, chances are good that your patch content-uniformity testing has been backing up. Call NIRSystems today to evaluate a RapiDerm analyzer. We'll even provide a feasibility study on your materials.

ON LINE

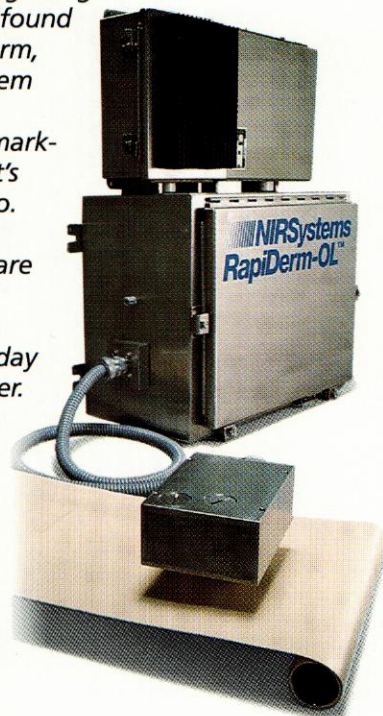
NIRSystems

A Perstorp Analytical Company

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Questions about the RapiDerm™ Transdermal Patch Analyzer...

1. Is the RapiDerm Analyzer currently being used for transdermal patch content uniformity analysis?

Yes. The RapiDerm Analyzer is being used for finished patch assay as well as for assessment of in-process material.

2. What standardization is required?

The RapiDerm uses Near-infrared (NIR) spectrophotometry coupled with chemometric statistical analysis to accomplish content-uniformity assay. Values for concentration of the active taken from your compendial methods are used to construct a training set within the software. The software automatically assesses the best of several algorithms to provide a statistically valid analysis.

3. Is this method acceptable to pharmaceutical regulatory agencies?

Yes. NIRSystems has installed more than two hundred pharmaceutical analyzers, all of which share common spectrophotometric and chemometric technology. The method is usually submitted as an ANDA. Because of its frequent submission, its direct relationship to the compendial method, widespread use, and measurement precision, conformity to accepted values is unusually close.

4. Is the method acceptable on a worldwide basis?

Yes. More than half of NIRSystems Pharma instruments are in use in Europe and Asia. In every case, adoption of the method has required compatibility with local governing regulations.

5. What reagents or sample preparation are required for the assay?

None. This is one of the overriding values of NIR spectrophotometry. The active surface of the finished patch is illuminated with NIR light. Reflectance detection and automated chemometrics complete the determination. In the case of at-line RapiDerm measurements, the operator clamps the patch, adhesive/drug side up, into a specially-designed holder, closes the access panel and starts the process. The patch rotates incrementally during exposure to the light to provide an average determination of the active content over the patch surface.

After the test is completed, the patch is removed manually. The test is non-invasive and non-destructive.

6. How fast is the assay?

The actual test is completed in forty-two seconds. With loading and unloading time, the test generally takes less than one minute.

7. Is operation simple?

Yes. The software, which drives the instrument and performs the chemometric analysis, uses a simple menu design with unambiguous choices. In addition, method development menus and auditable data files are security protected by password. The instrument supervisor can limit screen and menu access easily and positively.

8. Can the analyzers handle delivery systems with a drug reservoir as well as a patch with the active drug in the adhesive only?

Generally, yes. At the wavelengths used in the RapiDerm, the beam will penetrate thick layers of material. Assay of two-component systems is very simple. Four-component systems are calibrated differently, but the analytical method is the same.

9. Will NIRSystems Pharma assist in calibration of the method?

Yes. Our laboratories can perform feasibility studies, under confidentiality agreements, prior to adoption of the instrument by the patch manufacturer. These studies are the initial step in establishing a defined calibration. The user then accumulates data during actual operation to refine the calibration further.

The RapiDerm Analyzer is one of the NIRSystems Pharma family of Dosage Form assay instruments. For information about other analyzers — for Raw Material identification and qualification, Formulation Studies and Pharmaceutical Method Development — contact NIRSystems or your distributor through the information listed below.

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10. Is the software validatable?

Yes. NIRSystems has developed software according to the Lifecycle method which is advocated by the Pharmaceutical Manufacturers Association (the PMA). In addition to the software, NIRSystems offers a validation support kit to meet regulatory audit needs. The program is administered and tested by an external validation organization under PMA guidelines.

11. Is the RapiDerm cost effective?

Yes. The acquisition cost is commensurate with most high-technology instruments. Operating costs are very low, since the instruments are rugged, no reagents are required and the test does not require chemical disposal. The real return on investment, however, is experienced with the on-site speed of analysis, even at high duty cycles.

12. What plant support services are required to use these analyzers?

The RapiDerm has a small footprint, actually smaller than a desk-top computer. It operates on either 115 or 230 VAC nominal power at low current. No external gas or water supplies are needed. Ambient air temperature should be below 30 C. Vibration requirements are minimal, but low frequency-high amplitude devices such as shakers, compressors and the like should not be mounted on the same instrument bench.