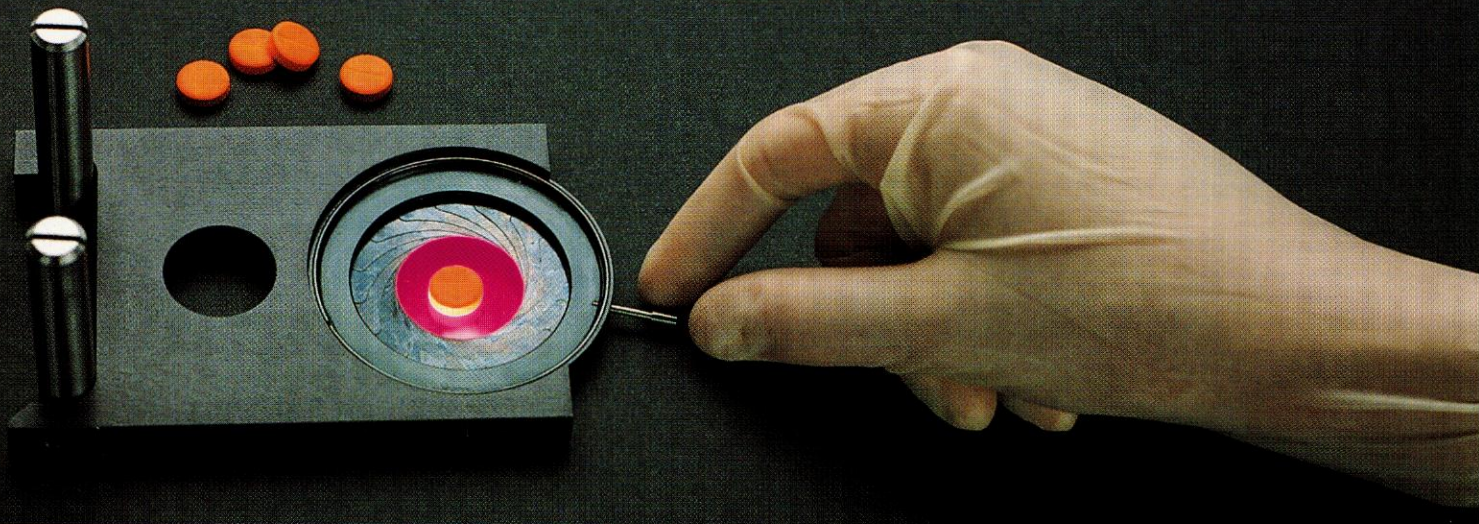


# The Rapid-Content Analyzer gives you content uniformity data on tablets in 42 seconds...



## and gives you the sample back.

**M**eet the Rapid-Content Analyzer. It's going to make your workload a lot lighter. Rapid-Content is our multi-purpose dosage form assay instrument, with a "technology platform" design to handle a wide range of sample types:

- Tablets
- Capsules
- Sealed vials of lyophilized parenterals
- I.V. bags
- Unopened reserve samples

### **SPEEDY, RELIABLE ASSAY**

It can't be simpler. Center an intact tablet or capsule on its test surface, close the cover and in forty-two seconds you will receive not only the active content uniformity value but also a GMP-conforming pass/fail quality control report.

The Rapid-Content Analyzer uses the unique properties of the Near InfraRed spectrum to penetrate deeply into dense or scattering pharmaceutical

materials. The immediate benefit is that no reagents are involved. No sample preparation is necessary, and the technique is completely non-destructive. And perhaps



best of all, measurement directly through the walls of an unopened container becomes routine.

### **GMP, NIR AND THE REGULATORS**

Two hundred or more NIRSystems Pharma analyzers are already at work in pharmaceutical manufacturing plants. The

instruments are smaller than a desktop computer and far easier to use. Assays use results from compendial methods as standards, so conformance is assured.

Approval of NIR as an alternative method is becoming commonplace. Because of its speed, simplicity and freedom from reagents or sample treatment, S.O.P.'s are also simple and easily accommodated.

### **TO LEARN MORE -**

A telephone call or mail request will bring you more detailed information. Active discussion is best, however, so

why not consider a private seminar and demonstration in your own facility? We'll be happy to oblige.

## **NIRSystems**

A Perstorp Analytical Company

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# Questions about the Rapid-Content™ Analyzer...

## 1. What principle of measurement does the Rapid-Content Analyzer use?

The analyzer couples unique near-infrared (NIR) scanning optics with a diffuse-reflectance sampler designed to accommodate a wide variety of pharmaceutical dosage forms and sealed containers. The resulting system is computer-driven and uses chemometric assessment of the spectral values obtained. The near infrared spectral region is particularly useful at penetrating container walls and dense, compacted material, such as tablets, without the need for sample preparation.

## 2. Is the Rapid-Content Analyzer widely used in the pharmaceutical industry?

The Rapid-Content Sampler is new. It is an improved version of our Direct Content Analyzer™ which, together with our raw material analyzers, are used in over 200 pharmaceutical manufacturing plants worldwide. All NIRSystems pharmaceutical analyzers share the same patented optical scanning technology and assay software.

## 3. Is the Rapid-Content Analyzer restricted to tablets only?

No. The sampler portion of the instrument is designed as a technology platform to accept sample-conforming kits for specific applications. For instance, an inexpensive positioning kit configures the instrument for use with tablets or capsules. Replacing the tablet device with another kit allows the unit to be used with I.V. bags. Still other kits are used for holding sealed vials of lyophilized injectables for moisture determination.

## 4. Is the system limited to small vials or samples?

No. The sampler chamber is fitted with hatches which accept oversized containers, tubulation or power leads for future applications.

## 5. Is the Rapid-Content Analyzer primarily designed for laboratory use?

No. It has been designed for operation at-line, although users of other NIRSystems Pharma products use the instruments in both laboratory environments or in "instrument rooms" within the quality control environment. All of the pharmaceutical analyzer products share the unique NIR scanner, which frees the specific analyzers from dependence on a protected environment.

## 6. What standards are required for use?

The chemometric approach used in this instrument depends on your current compendial methods: it constructs a statistical matrix for continual comparison of your laboratory values with the instrumental results. Once you have introduced a calibration, or learning, set, it remains useful and robust until you introduce a change in the analytical method. This conformity with compendial methods has helped acceptance of the method by regulatory agencies.

## 7. What are the chief benefits which I could expect from adoption of this instrument?

The Rapid-Content system can complete an assay of content uniformity, or of active vs. placebo identification, or even of blend-evaluation samples in forty-two seconds. The analyst is not required to add reagents, weigh anything, treat the sample or to dispose of anything. The assay sample remains intact.

Time for analysis is reduced drastically, which means that the efficiency of the manufacturing process is dramatically increased and the quality control workload is decreased.

## 8. Is operation simple?

Yes. The software, which drives the instrument and performs the chemometric analysis, uses a simple, unambiguous menu

design. In addition, method development menus and auditable data files are security protected by password access. The instrument supervisor can control the degree of user interaction with the instrument completely.

## 9. What plant support services are required to use the Rapid-Content Analyzer?

The instrument 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 support bench.

## 10. What is the best way to assess the usefulness of the Rapid-Content Analyzer in my plant?

We suggest that we present a seminar with a subsequent demonstration within your facility. The time required for this is between two and three hours. If you invite analytical services, quality assurance, manufacturing and regulatory affairs people to the seminar, you will have an opportunity to assess its utility from several different points of view.

**T**he Rapid-Content Analyzer is a highly flexible member of the NIRSystems pharmaceutical product group. For more information about Dosage Form assay instruments, Raw Material identification and qualification analyzers and Formulation testers, contact NIRSystems or your distributor through the information listed below.

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