

## USP General Tests

- Identification, <USP 191>
- Heavy Metals, <USP 231> Methods I, II and III
- Residue On Ignition, <USP 281>
- Loss On Drying, <USP 731>
- pH, <USP 791>
- Chloride and Sulfate, <USP 221>
- Arsenic, <USP 211> Methods I and II
- Iron, <USP 241>
- Melting Range, <USP 741>
- Identification, <USP 197> Methods K, U, M
- Specific Rotation, <USP 781S>
- Water, <USP 921> Methods I, II and III
- Organic Volatile Impurities, <USP 467> Methods I, II, III, IV and V

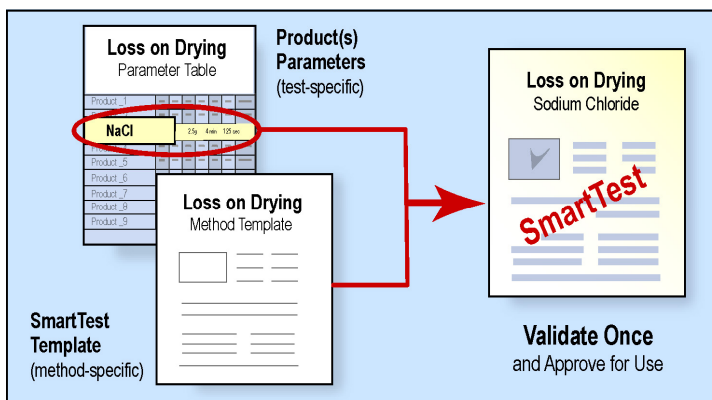
## USP Raw Materials with Full Monograph Testing

- Ibuprofen, USP
- Sodium Chloride, USP/EP
- Dextrose, USP
- Glycine, USP
- Sodium Bicarbonate, USP
- Sodium Phosphate Monobasic, USP
- Sodium Hypochlorite Solution, USP
- Tromethamine, USP
- Methotrexate, USP

The **Raw Materials Testing ApplicationPak** bundles the award winning SmartLab system with preconfigured and validated method templates for testing common raw materials used in pharmaceutical product manufacturing. Manufacturers approach the testing in various ways to ensure materials are suitable for intended use, from simple identity testing (post qualification lots) to full monograph testing for each lot of supplied materials.

Today, documentation and reporting of these test results consumes 50-75% more time and manpower than needed. By deploying the SmartLab RMT ApplicationPak, life science companies can ensure compliance and enjoy significant productivity gains in this required testing area.

When an analyst performs a raw materials test in SmartLab, the USP-based template and the specific raw material parameters are merged and presented to the analyst onscreen as a SmartTest. The analyst then executes the test, and all data captured is sent directly to the database. Any OOS values that occur are automatically flagged for review. The system automatically performs the needed calculations, and the entire process is available for on-line review, approvals and reporting. Done in this way, all of the tedious and error-prone paperwork is eliminated and regulatory compliance is assured.



## Instrument Integration

The Raw Materials ApplicationPak includes integration of up to 5 lab instruments with your SmartLab GMP ELN, along with training so you can add more at any time. Typical instruments and devices include HPLC's, balances, pH meters, GC's, and UV spectrophotometers. SmartLab verifies the compliance state (calibration, etc.) of the instruments as the analyst begins testing, and alerts the analyst when a condition is out of compliance. This assures "right first time" execution of these critical quality tests for final product release and stability testing.

## Industry Proven Technology and Extensibility to Other Applications

The Raw Materials Testing ApplicationPak includes a method template library for raw materials, XML-based parameter form, instrument integration, IOQ validation documentation, installation and training. ApplicationPaks get you started with this GMP ELN technology fast, so you can get big benefits on a small budget. You can "go-live" in as little as 45 days! At the core of each ApplicationPak is the same patented technology as a full SmartLab GMP ELN system, giving you future extensibility. You can add additional applications, instruments and users at anytime to complete a full lab automation system.



# SmartLab™ ApplicationPak Raw Materials Testing

Example: Loss on Drying for Sodium Chloride

A USP-based Loss on Drying template is chosen by the analyst.

Material specific parameters, such as temperature and drying time, are merged into the template.

Metadata and test data is captured by the system from instruments as the analyst executes the method.

Data is sent directly to the database.

Validated calculations are done automatically.

A data review dashboard shows all metadata and data at each method step.

Compliance flag columns on the left call attention to:

- Audit Trails
- Out of Limit
- Out of Date
- Source data
- Annotations
- Electronic signatures

Hyperlinks embedded in the compliance flags allow the reviewer access to raw data with a single click.

USP NF Loss On Drying \ USP\_LODR\_01 Step#: 1 PE003.01

**USP NF Physical Test**  
 <731> Loss On Drying  
 USP Page 1801  
 This test is designed to determine the amount of volatile matter of a that is driven off under the conditions specified.  
 Select the current date and material under test. Capture the physical melting point and %LOD limit for the material under test.

Prep Date: 11/13/2006 Spl Form: Material MP [degC]  
 LOD Limit [%w/w]

USP\_LODR\_01

User: Graham Janson /TS: 34 /PS: 48 Status: In Process 11/13/2006 9:16:33 AM

USP NF Loss On Drying \ USP\_LODR\_01 Step#: 2 PE003.01

**Test Conditions & Preparation**

1. Dry a clean shallow weighing bottle for 30 minutes under the test conditions given below.
2. Where drying in vacuum over a desiccant, a vacuum desiccator or a vacuum drying pistol, or other suitable vacuum drying apparatus is to be used.

Drying Chamber: Oven Test Temp [degC]: 105 Test Vacuum [mmHg]: None  
 Test Desiccant: None Drying Time [Hours]: 2 Bottle Stopper: Solid  
 Delta Temp SplMP\_Test: 696.0

USP\_LODR\_01

User: Graham Janson /TS: 34 /PS: 48 Status: In Process 11/13/2006 9:21:07 AM

Procedure Name: USP NF Loss On Drying  
 Sample ID: USP\_LODR\_01  
 Procedure ID: USP NF LODR  
 Revision: 1 Revision: 0  
 Procedure Status: In Process  
 Batch Name:  
 Hyperlink: \\vqcss01\UDA\Core\Drilldown\ACF526E-8592-4A63-802E-DFAB7F68

Sample ID	AT	OL	OD	SD	An.	App.	Att.	Rev.	Step	Field Label	Field Value	Who	Logon Id	How	Date/Time
USP_LODR_01									1	LOD Limit [%w/w]	0.5	Graham Janson	graham	FC	11/13/2006 9:19:32 AM
									1	Prep Date	11/13/2006	Graham Janson	graham	MN	11/13/2006 9:17:57 AM
									1	Material MP [degC]	801	Graham Janson	graham	FC	11/13/2006 9:19:32 AM
									1	Spl Form	Granules	Graham Janson	graham	FC	11/13/2006 9:19:32 AM
									2	Drying Time [Hours]	2	Graham Janson	graham	FC	11/13/2006 9:20:51 AM
									2	Test Temp [degC]	105	Graham Janson	graham	FC	11/13/2006 9:20:50 AM
									2	Delta Temp SplMP_T...	696.0	Graham Janson	graham	FM	11/13/2006 9:20:52 AM
									2	Test Vacuum [mmHg]	None	Graham Janson	graham	FC	11/13/2006 9:20:51 AM
									2	Test Desiccant	None	Graham Janson	graham	FC	11/13/2006 9:20:51 AM
									2	Drying Chamber	Oven	Graham Janson	graham	FC	11/13/2006 9:20:50 AM
									2	Bottle Stopper	Solid	Graham Janson	graham	FC	11/13/2006 9:20:51 AM
									10	Target Net Spl Wgt [g]	1	Graham Janson	graham	FC	11/13/2006 9:22:02 AM
									11	Bottle Wgt [g]	5.00000	Graham Janson	graham	MN	11/13/2006 9:22:25 AM
									12	Target Spl Wgt [g]	6.00000	Graham Janson	graham	FM	11/13/2006 9:22:30 AM
									12	Initial Gross Spl Wgt ...	6.00111	Graham Janson	graham	MN	11/13/2006 9:22:43 AM
									13	Initial Net Spl Weight ...	1.00111	Graham Janson	graham	FM	11/13/2006 9:22:49 AM
									16	Chamber Temp [degC]					
									16	Test Temp [degC]	105	Graham Janson	graham	FC	11/13/2006 9:20:50 AM
									17	Drying Time [Hours]	2	Graham Janson	graham	FC	11/13/2006 9:20:51 AM
								19	Loss on Drying [%w/...	0.11	Graham Janson	graham	FM	11/13/2006 9:24:13 AM	
								19	Final Gross Spl Wgt [g]	6.00000	Graham Janson	graham	MN	11/13/2006 9:24:11 AM	