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## pH of Tablets

Orion 4-Star pH/ISE  
Benchtop Meter

### Pharmaceutical

The pH measurement of pharmaceutical tablets is critical to the health and safety of consumers. The FDA regulates the testing of over-the-counter (OTC) drugs, such as Ibuprofen tablets to ensure the safety and effectiveness of drug products used for the prevention, diagnosis, and treatment of illness. The new Orion 4-Star pH/ISE meter and ROSS™ Sure-Flow® combination pH electrode (Cat. No. 8172BNWP) assures you of the most accurate and drift-free pH measurements possible.



### Orion 4-Star pH/ ISE for pH of Tablets

Ibuprofen tablets belong to a class of drugs called non-steroidal anti-inflammatory drugs NSAIDs that are used for the management of mild to moderate pain, fever, and inflammation. Prostaglandins are chemicals that are made by the body and are responsible for causing pain, fever and inflammation. Ibuprofen blocks the enzyme that makes prostaglandins, resulting in their lower levels. As a consequence, inflammation, pain and fever are reduced. This makes Ibuprofen an effective pain reliever, but in doing so, it also impairs the defense system in the intestine and increases the danger of damaging the mucous layer and potentially causes ulcers and gastrointestinal bleeding.

Proper digestion of foods also requires proper pH balance. In order to digest food and kill the

kinds of bacteria and viruses that come with the food, the inside of the stomach is acidic. The stomach pH is maintained near 4.0.

When ibuprofen tablets are ingested with water, the pH value inside the stomach rises resulting in the stomach wall secreting more hydrochloric acid to bring the pH value back to 4.

The Orion 4-Star pH/ISE meter has a unique feature set to improve the quality of your pH measurements. The Star Series meters include a convenient, built in Quick-Start Guide, advanced self test and diagnostics, GLP electrode verification, storage of up to 10 password-protected methods and optional 21 CFR Part 11 Software.

# Orion 4-Star pH/ISE

Thermo Electron's advanced technology offers you superior quality with the Orion 4-Star pH/ISE meter. Ensure analytical integrity with built-in

21 CFR Part 11 compliant software that includes systems validation, security, audit trails, data archiving, and retrieval.

## Orion 4-Star pH/ISE Specifications:

| Specifications                            |  | Benefit  |
|---|--|--|
| <b>pH</b>                                 |  |  |
| Readout Range / Resolution                | -2.000 to 19.999 or 0 to 14 in aqueous solutions / 0.1,0.01,0.001                | Calibration point flexibility                  |
| Relative Accuracy                         | ± 0.002  | For exceptional accuracy                       |
| SMART STABILITY™ and SMART AVERAGING™     | Resolution dependent / automatic   | Optimized accuracy, precision & response time  |
| AUTO-CAL™ and/or Manual Calibration       | 1 to 5 points; US/NIST, DIN, and custom buffers recognized                       | Protocol compliance                            |
| <b>ISE</b>                                |  |  |
| Range / Resolution                        | 0 to 19900 / 1,2, or 3 significant digits  | Wide operating range/Increased accuracy        |
| Relative Accuracy                         | ± 0.2 mV or 0.05%, whichever is greater  |  |
| SMART STABILITY™ and SMART AVERAGING™     | Resolution dependent / automatic   | Optimized accuracy, precision, & response time |
| Units                                     | M, mg/L, %, ppb, or no units   | Choice of reporting units                      |
| # ISE Cal points                          | 1 to 5   |  |
| <b>Special ISE Calibration Features</b>   | Linear point to point, selectable auto-blank non-linear, low concentration range |  |
| <b>Temperature</b>                        |  |  |
| Range / Resolution                        | -5 to 105 °C / 0.1 up to 99.9 °C, 1.0 over 99.9 °C                               | Allows for temperature variations              |
| Relative Accuracy                         | ± 0.1 °C   |  |
| Temperature Compensation                  | Auto/Manual  |  |
| <b>Display</b>                            | Custom backlit LCD, for easy viewing   | Easy to read screen                            |
| <b>Special GLP Software Features</b>      |  |  |
| # Of Data Logging Points                  | 200 points by time, stability or manual read with time/date stamp                | Expanded data storage available                |
| Calibration Log                           | Last 10 Calibrations   | Establish audit trail                          |
| User Method Storage                       | 10 Saved   | For easy retrieval of routine tests            |
| <b>Power</b>                              | Universal power adapter and battery power 4 x AA batteries                       | Data is secure                                 |
| <b>Regulatory and Safety</b>              | CE, CSA, UL, TÜV, FCC Class A limits   | Meets all necessary regulations                |
| <b>Environmental Operating Conditions</b> |  |  |
| Ambient Operating Temperature             | 5 to 45 °C   |  |
| Relative Humidity                         | 5 to 85% Non-Condensing  |  |
| IP Rating                                 | IP54, splashproof and dustproof  |  |
| <b>Warranty</b>                           | 36 months (from date of purchase)  | Reduces service cost                           |

## Equipment needed for pH/ISE measurement using the Orion 4-Star pH/ISE meter:

Above data generated under optimal/controlled circumstances.

| Description  | Orion Cat. No.         |
|--|------------------------|
| pH Application Package (includes items listed below)   | 1010154                |
| Star Series Method Note: pH in Tablets                 | M-1702-E               |
| 4-Star benchtop pH/ISE meter                           | 1115000                |
| Orion ROSS™ Sure-Flow® pH Electrode                    | 8172BNWP               |
| Star Stainless Steel ATC Probe                         | 927007MD               |
| Benchtop Stirrer                                       | 096019                 |
| Benchtop Electrode Stand                               | 1110001                |
| pH Buffers 4.01, 7.00, and 10.01, 475 mL bottles       | 910104, 910107, 910110 |
| Optional 21 CFR Part 11 Software (Not included in kit) | 1010007                |