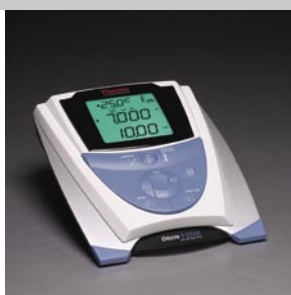


Pharmaceutical

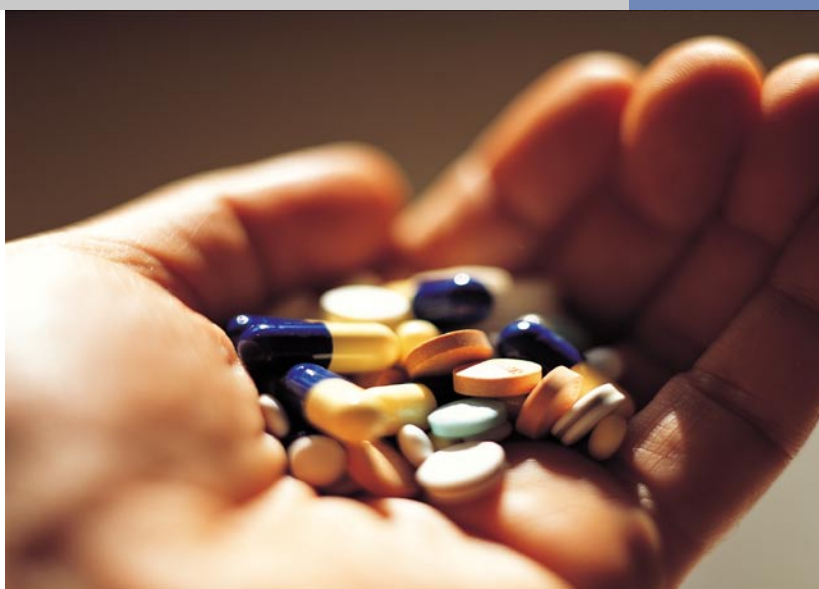
The purity of pharmaceutical products depends upon the quality of raw materials. One of the test methods utilized is the measurement of pH. The new Orion 4-Star pH/ISE meter and ROSS Ultra® combination pH electrode (Cat. No. 8102BNU) assures you of the most stable, drift-free pH measurements possible.

pH USP <791>

Orion 4-Star pH/ISE
Benchtop Meter



For instructions on pH USP measurements using Orion products, download our Star Series meter information at www.thermo.com/water.



Orion 4-Star pH/ ISE for pH USP <791>

Pharmacopoeia and formulary monographs such as the US, European and Japanese Pharmacopoeia provide standardized test methods such as USP 791 which outlines pH measurements for a multitude of pharmaceutical products. Pharmaceutical tests are performed not only to determine if the material's specifications are met but also to address anticipated regulatory concerns. These tests can be used to determine general drug compatibility, routine quality control or stability shelf life studies.

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
pH		
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
ISE		
Range / Resolution	0 to 19900 / 1,2, or 3 significant digits	Wide operating range/Increased accuracy
Relative Accuracy	± 0.2 mV or 0.05%, of mV reading 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	
Special ISE Calibration Features	Linear point to point, selectable auto-blank non-linear, low concentration range	
Temperature		
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	
Display	Custom backlit LCD, for easy viewing	Easy to read screen
Special GLP Software Features		
# 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
Power	Universal power adapter and battery power 4 x AA batteries	Data is secure
Regulatory and Safety	CE, CSA, UL, TÜV, FCC Class A limits	Meets all necessary regulations
Environmental Operating Conditions		
Ambient Operating Temperature	5 to 45 °C	
Relative Humidity	5 to 85% Non-Condensing	
IP Rating	IP54, splashproof and dustproof	
Warranty	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 USP <791> Application Package (includes items listed below)	1010153
Star Series Method Note: pH USP <791>	M-1701-E
4-Star benchtop pH/ISE meter	1115000
Orion ROSS Ultra® pH Electrode	8102BNU
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	1010007

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