Validation Protocols

■ Save time and money with ready-to-use protocols

Although there are models for validating many areas of pharmaceutical manufacturing—including processes, computer systems, and new analytical methods—there are no clear guidelines for compendial methods.

To comply with Good Manufacturing Practices, the validation team must develop protocols that prove the suitability of compendial methods under actual conditions of use.

Although the validation team remains ultimately responsible for compliance, Validation Protocols from Millipore can make the job much faster and easier. Each protocol packet contains all the strategies, protocols, and worksheets, you need to prepare validation documentation for our test systems.

Complete IQ, OQ, PQ Protocols

These are not just calibration certificates or maintenance information. Each Validation Protocol packet contains comprehensive, ready-to-use installation, operation, and performance protocols—written to the same standards as the protocols used to validate pharmaceutical processes.

You get complete descriptions of all the activities necessary for both proving the suitability of the test methodology and writing SOPs for the test method, calibration, and maintenance. You also get valuable information on organizing the validation effort, including the length of time it takes to complete each activity.

Shortens Validation Times

Validation Protocols are ideal for busy QC/QA departments. They lighten your staff's workload, allowing them to focus on other projects. They also include all the necessary worksheets, so they reduce paperwork. And shortening validation times can save your company money.

Complies with International Compendia

The Validation Protocols comply with the United States, European, and Japanese Pharmacopeias.

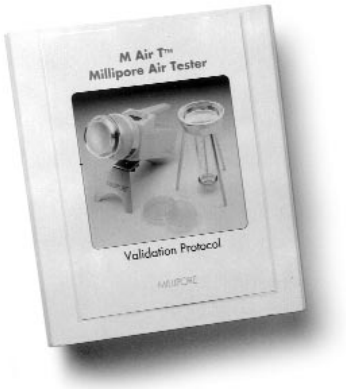
Accurate, Knowledgeable Advice

The Validation Protocols are prepared by Millipore, a company with more than 40 years history in membrane filtration and extensive experience in helping customers successfully validate microbial test methodologies.

MILLIPORE

Complete, Detailed Protocols

Each Validation Protocol includes all the information you need to organize and execute a validation protocol. You simply assemble the team, calibrate a few instruments, and purchase the media and other consumable items.



Introduction (System Qualification Overview)

Functional Specifications
How to use the instrument

Installation Qualification
Detailed procedures for all recommended activities

Operational Qualification
Detailed procedures for all recommended tests

Performance Qualification
Detailed procedures for all recommended tests

Validation Guide Final Report
Worksheets you can use to collect the validation data

Ordering Information

Protocols available as of April, 2000. Contact Millipore for the most current list.

Description	Catalogue No.
Steritest™ System Validation Protocol	TCPU0VG01
Milliflex® System Validation Protocol	MXPS0VG01
M Air T™ System Validation Protocol	ATAS0VG01

To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office:
In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**
In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**
On the Internet **http://www.millipore.com**
E-mail: **tech_service@millipore.com**

pure e-commerce

Now you can buy Millipore products online @ www.millipore.com/purecommerce

MILLIPORE

Lit. No. PF10020EN00 4/00 00-109
Printed in U.S.A.

Millipore Worldwide

AUSTRALIA
Tel. 1 800 222 111
or (02) 9888 8999
Fax (02) 9878 0788

AUSTRIA, CENTRAL EUROPE, C.I.S., AFRICA, MIDDLE EAST AND GULF
Tel. (43) 1 877-8926
Fax (43) 1 877-1654

BALTIC COUNTRIES
Tel. +358 9 804 5110
Fax +358 9 256 5660

BELGIUM AND LUXEMBOURG
Tel. (02) 726 88 40
Fax (02) 726 98 84

BRAZIL
Tel. (011) 548-7011
Fax (011) 548-7923

CANADA
Tel. 1-800-645-5476
Fax 1-800-645-5439

CHINA, PEOPLE'S REPUBLIC OF
Beijing:
Tel. (8610) 8519-1250
(8610) 8519-1058
Fax (8610) 8519-1255
Guangzhou:
Tel. (8620) 8755-4021
Fax (8620) 8755-4350
Hong Kong:
Tel. (852) 2803-9111
Fax (852) 2513-0313
Shanghai:
Tel. (8621) 5306-9100
Fax (8621) 5306-0838

CZECH REPUBLIC
Tel. 02-2051 3841
02-2051 3842
Fax 02-2051 4298

DENMARK
Tel. 70 10 00 23
Fax 70 10 13 14

FINLAND
Tel. (09) 804 5110
Fax (09) 256 5660

FRANCE
Tel. (01) 30.12.70.00
Fax (01) 30.12.71.80

GERMANY
Tel. (06196) 494-0
Fax (06196) 43901

HUNGARY
Tel. 1-205 9784
Fax 1-205 9792

INDIA
Tel. (91) 80-839 46 57
Fax (91) 80-839 63 45

ITALY
Vimodrone (Milano):
Tel. (02) 25.07.81
Fax (02) 26.50.324
Roma:
Tel. (06) 52.03.600
Fax (06) 52.95.735

JAPAN
Tel. (03) 5442-9711
Fax (03) 5442-
9736 Analytical
9737 BioProcess
9734 Lab Water

KOREA
Tel. (822) 551-0990
Fax (822) 551-0228

MALAYSIA
Tel. 603-757 1322
Fax 603-757 1711

MEXICO
Tel. (525) 576-9688
Fax (525) 576-8706

THE NETHERLANDS
Tel. 076-5022000
Fax 076-5022436

NORWAY
Tel. 22 67 82 53
Fax 22 66 04 60

POLAND
Tel. 22-669 12 25
22-663 70 31
Fax 22-663 70 33

PUERTO RICO
Tel. (787) 273-8495
Fax (787) 747-6553

SINGAPORE
Tel. (65) 842 1822
Fax (65) 842 4988

SPAIN AND PORTUGAL
Madrid:
Tel. 917 283 960
Fax 917 292 909
Barcelona:
Tel. 934 525 530
Fax 934 516 048

SWEDEN
Tel. 08-628 6960
Fax 08-628 6457

SWITZERLAND
Volketswil:
Tel. (01) 908-30-60
Fax (01) 908-30-80
Lausanne:
Tel. (021) 641 2550
Fax (021) 641 2551

TAIWAN
Taipei:
Tel. (886-2) 700-1742
Fax (886-2) 755-3267
Hsin Chu City:
Tel. (886-3) 571-0178
Fax (886-3) 572-9520

U.K. AND IRELAND
Tel. (01923) 816375
Fax (01923) 818297

U.S.A.
Tel. (781) 533-6000
Fax (781) 533-3110

IN ALL OTHER COUNTRIES
Millipore Intertech (U.S.A.)
Tel. +1 (781) 533-8622
Fax +1 (781) 533-8630