Cultivate

A PARASOL MEDICAL PRODUCT

USP Chapter <797> & <800> Testing Supplies

How clean are your testing supplies?

The first aseptic products built to minimize risk—
starting with the packaging itself

Smarter, Cleaner, Convenient…Cultivate™

When it comes to improving aseptic practices and quality control, our new quality assurance products deliver the total package.

Introducing **Cultivate**™, the new line of quality assurance products from Parasol Medical with a breakthrough difference: all are delivered in packaging designed to help pharmacies comply with USP 797 requirements.

Cultivate delivers products that are *superior*—

Superior packaging. Each product is delivered in customized packaging with resealable lids designed to keep products secure.

- Lint-Free. Eliminate particles in your environment with Cultivate thermal form trays. Unlike corrugated boxes, they're non-lint producing, easy to wipe down and protect test media from contamination.

- Convenient. Cultivate products are safe to store in the pharmacy or "clean room" without the need to remove or repackage the product first.

Superior products. Best in class products designed for air particle monitoring, surface testing, personal aseptic technique testing, needleless dispensing, safe handling of hazardous drugs and more.

- Variety. Product offerings for low, medium and high complexity procedures covered in USP Chapter guidelines.

- Accuracy. Strict Regulatory processes assure media is free of particulates for precise results. Lot specific Certificate of Analysis (COA) are available at Parasolmed.com

DID YOU KNOW...

More than 19,000 patients were exposed to contaminated pharmacy-prepared sterile compounds between 1990 and 2005, resulting in at least 15 deaths.[1]

USP Chapter <797> and Chapter <800> Designed.

In response to numerous and significant patient safety incidents related to sterile drug compounding, United States Pharmacopeia created guidelines to specify best practices for the storage, handling and preparation of prescription drugs in clinics, hospitals and pharmacies. Chapter <797> focuses on quality assurance activities to prevent microbial contamination, while Chapter <800> describes the requirements of personnel handling hazardous drugs, cleaning, spill control and more.

Cultivate™ packaging is designed to adhere to these standards because no detail is too small to make a difference in your QA needs. We have spared no expense producing superior products and packaging to help reduce lint in your critical environment.

DID YOU KNOW...

Between 2011and 2012, contaminated pharmacy-prepared sterile products harmed more than 244 patients nation-wide.[1]

To learn more about Cultivate or any of our medical products contact your Parasol Medical Sales representative or visit **parasolmed.com**

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Now Available!

Hazard Test 2™

Cat. No: TVA5251

Two Technique Validations – One Test

The Hazard Test 2™ Test Kit simultaneously validates both the aseptic and containment techniques of personnel compounding hazardous sterile preparations.

See reverse side for new Hazard Test 2™ Test Log Sheet

For a complete list of Cultivate products and to learn more visit www.parasolmed.com/cultivate or call 847.520.3000

PARASOL MEDICAL LLC

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HazardTest 2™ Test Log

Simultaneous Hazardous Compounding & Aseptic Technique Verification Kit

USP <800> Hazardous Drug Compounding and Handing
USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation

TVA5251™
V1.1

Evaluation Information

Employee Name: _____ Evaluation Date: _____ Evaluation Start Time: _____

Observer Name(s): _____ Additional Information: _____

Person Reading & Documenting Results: _____ _____

Media Fill-Test Type: ☐ Initial ☐ Re-Test ☐ 6 Month ☐ Other: _____ _____

Manufacturing Information

Component Description	Comp. No.	Media	Media Manufacture	Lot No.	Exp. Date
50 mL vial	T2C-V050	TSB	Parasol Medical		
50 mL vials (half fill)	T2C-V5025	TSB	Parasol Medical		
10 mL ampule	T2C-A010	TSB	Parasol Medical		

Aseptic Manipulation Evaluation

INTERVAL 1 USP <797> 20-25°C for 7 days.			INTERVAL 2 USP <797> 30-35°C for 7 days.		
1st Incubation Temp	1st Interval Start Date	Growth in 1st Interval (Yes or No)	2nd Incubation Temp	2nd Interval Start Date	Growth in 2nd Interval (Yes or No)
	_____ / _____ / _____			_____ / _____ / _____	

Hazardous Compounding Evaluation

Location	Residue Recovery check if residue was recovered	Other Location(s)	Residue Recovery check if residue was recovered
14" x 14" section of critical aseptic work surface	☐		☐
Vial septa, syringe barrels, bags and bottle exteriors and additive ports	☐		☐
Gloved hands, and gown cuffs, and sleeves of the candidate	☐		☐
Front grille and lower threshold (lip) of the BSC	☐		☐
14" x 14" section of the floor immediately adjacent to the BSC	☐		☐
Counter top or work surface where product is place following removal from the hood	☐		☐
Disposal Area/Container Exterior	☐		☐

Results

Aseptic Media Manipulation Test

Failure of aseptic manipulation test is indicated by visible turbidity or other visual manifestation of growth in the media in one or more of the container-closure unit(s) on or before 14 days.

☐ PASS or ☐ FAIL

Date growth was detected: _____

per USP <797>, if turbidity is observed the incubation can be stopped as the test failed.

Report any growth greater than action level to appropriate management

Hazardous Compounding Containment Test

Failure of the hazardous compounding containment is indicated by the presence of red dye on the inspected surfaces.

☐ PASS or ☐ FAIL

Failure demonstrates a breach of proper containment technique and indicates the need for additional training in containment manipulation.

Corrective Action / Comments:

Signoff after completion of HazardTest™

Employee Signature: _____ Date: _____

Observer / Manager Signature : _____ Date: _____

The first aseptic products built to minimize risk—starting with the packaging itself.

Meet the ever-expanding **Cultivate**™ family of products, the superior medical testing products built to comply with USP 797 requirements.

Contact™

Microbial Contamination Monitoring System for Surface Testing and Gloved Fingertip Testing

- Makes testing uneven and difficult to reach surfaces easy
- Test gloved fingertips
- Rapid growth of common bacteria, yeasts and fungi
- Available pedestal cap with hinged paddle or contact plates

PASS Kit Personal Aseptic Sampling System™

Aseptic Technique Training and Validation Aids

- Key to continuous quality improvement in IV pharmacies
- Prepackaged media avoids mixing mess and false positives
- Custom configurations available to fit any QA program

Clear Check™

Microbial Contamination Tester Using Direct Transfer Method

- Check sterility of oral inhalation drug products, and viscous aqueous-based drugs
- Convenient flip cap and needle port to prevent contamination
- Dramatically reduces testing costs

Double Check™ System

Sterile Products Microbial Contamination Tester

- Test emulsion and suspensions
- Validated with wide range of organisms
- Detect low levels of contamination
- One step transfers reduce false positives
- Stores at room temperature

TTMicro™ System

Full Filtration Systems for Testing Small Volume Sterile Drug Products

- Syringe to syringe, and syringe to sterile container transfers
- Eliminates DEA and state documentation problems

Cultivate™ Vial Adaptors

Safely Fill Syringes Without Needles

- Fits all multi-dose vials
- Use with other needleless systems

Cultivate™ Syringe Filters

High Performance Syringe Filters

- Quicker procedures with less effort
- Filter more liquid before clogging

From the Healthcare Innovator

Parasol Medical is a premier developer of specialty medical devices designed to serve the ever-changing healthcare industry. Our greatest priority is making the lives of healthcare workers easier and improving patient outcomes.

At the forefront of new and emerging technologies, Parasol Medical is rapidly expanding its footprint throughout the healthcare market to include products in our four main divisions: Patient Safety, Life Science, Diagnostic and Advanced Wound Care. Parasol Medical complies with Current Good Manufacturing Practices (cGMPs) and maintains an ISO 13485 quality system.

Manufactured by Parasol Medical, LLC

PARASOL MEDICAL

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FDA Registered Manufacturer | FDA Listed Products | ISO 13485 | CE

 [1] *Guidelines for the Safe Preparation of Sterile Compounds: Results of the ISMP Sterile Preparation Compounding Safety Summit of October 2011*, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3839457/