

# Pharmaceutical Microbiology Turnkey Solutions





HuanKai® EM Series represents state-of-the-art culture media technology from both a formulation and packaging perspective.

Measuring the effectiveness of contamination control is an essential component for environmental risk management. Accurate Environmental Monitoring data is crucial when making product release decisions.

Culture media must be robust enough to withstand the rigorous conditions in today's pharmaceutical cleanrooms. Culture media needs to be both reliable and sensitive to promptly detect stressed organisms inherent to aseptic manufacturing areas.

With over 30 years of microbiology experience, HuanKai has developed a solution specifically designed for pharmaceutical environmental monitoring.





# PROVEN

Validated for use by

pharmaceutical

manufacturers

world-wide for their most

critical manufacturing

environments



#### **PHARMACEUTICAL**

Designed to meet the needs of the pharmaceutical industry for the highest quality culture media for use in clean room and isolator manufacturing areas



#### **PERFORMANCES**

Media formulations
optimized for maximum
sensitivity and
reproducibility within
the same lot from
batch to batch

uality is critical, which is why HuanKai has implemented to ensure the best media products are available for professional use:

# Vertically Integrated Production Process.....

HuanKai maintains control of the production process from peptone digestion to the finished product to consistently provide you with high quality media.



# **Robust Quality Manufacturing**

HuanKai ensures lot-to-lot consistency of the highest quality media through our ISO 9001 quality systems and 10-6 SAL manufacturing facilities.



FILLING PROCESS





PETRI DISH MOLDING



The little things matter - For over 30 years, our people have focused on the little details that add up to something big.



## Storage Flexibility

A storage temperature range of 2-25°C provides you the highest flexibility and resource utilization.



#### **Ease of Transfer**

Triple-wrapped packaging enables easy transfer and storage while maintaining sterility.



### **Resource Efficiency**

Maximize batch sizes and reduce incoming QC testing with up to 6 months shelf-life.



### **Sterility Assurance**

An SAL claim of 10-6 minimizes the risk of false positives and protects your environments from the risk of contaminants.



#### No Sweat

The impermeable packaging system of Triple-wrapped sterile plated media ensures condensation will not form inside the package or on the plates.



#### **Safe Gamma Irradiation**

An indicator placed on each box of plates confirms that the irradiation with the required doses window of 9 to 20 kGy was irradiated successfully.



# A SELECTION OF READY-TO-USE MEDIA



# **CONTACT PLATES 55MM RODAC**

Description	Packaging	PK	Art. no.
Tryptic Soy Agar	triple wrapped, irr.*	10 Plates	CP0201J
Sabouraud Dextrose Agar	triple wrapped, irr.*	10 Plates	CP0301J
Nutrient Agar	triple wrapped, irr.*	10 Plates	CP0101J
TSA+Cephalosporinase	triple wrapped, irr.*	10 Plates	CP0202J
TSA+Penicillinase	triple wrapped, irr.*	10 Plates	CP0203J
TSA+Lecithin+Tween 80	triple wrapped, irr.*	10 Plates	CP0204J
TSA + Lecithin + Tween 80+Histidine+Sodium Thiosulfate	triple wrapped, irr.*	10 Plates	CP0205J

Note: \*irradiated

#### **SETTLE PLATES 90MM**

Description	Packaging	PK	Art. no.
Tryptic Soy Agar	triple wrapped, irr.*	10 Plates	CP0201C
Sabouraud Dextrose Agar	triple wrapped, irr.*	10 Plates	CP0301C
Nutrient Agar	triple wrapped, irr.*	10 Plates	CP0101C
TSA+Cephalosporinase	triple wrapped, irr.*	10 Plates	CP0202C
TSA+Penicillinase	triple wrapped, irr.*	10 Plates	CP0203C
TSA+Lecithin+Tween 80	triple wrapped, irr.*	10 Plates	CP0204C
TSA + Lecithin + Tween 80+Histidine+Sodium Thiosulfate	triple wrapped, irr.*	10 Plates	CP0205C

Note: \*irradiated

#### **OTHER PLATES 90MM**

Description	Packaging	PK	Art. no.
R2A Agar	triple wrapped, irr.*	10 Plates	CP2029B1
Rose Bengal Agar	triple wrapped, irr.*	10 Plates	CP1011B1
Yeast Peptone Dextrose	triple wrapped, irr.*	10 Plates	CP1100B1

Note: \*irradiated

# The Industry Standard for GMP Compliant **Performance**

#### **ACTIVE AIR MONITORING**

The HKM-III Portable Microbial Air Sampler is the industry standard for use in critical environments. This compact, yet sophisticated instrument is the preferred choice for the highest demands in microbial air monitoring, providing utmost accuracy and excellent, proven collection efficiency. The low particle generation complies with the requirements of ISO 14644 for use within ISO 5 controlled environments.

HKM-III

#### Main Features



Sampling head with up to 589 impaction nozzles



Large-capacity memory,record >2000 sample data



Dual power supply mode, with built in rechargeable lithium polymer battery the working time could up to 15 hours



Retrieve recorded sampling data at any time through the sampler

# Technical Parameters

Sampling head impaction nozzle number: 589

Rechargeable lithium polymer battery: 6400 mA capacity

Sampling flow rate: 100L / min

Sampling head port flow rate: 0.38m/s

Automatic control sample volume: 10 - 6000L, minimum unit: 10L

Parameter settings records storage: 99

Sampling records storage: 2000

Applicable Petri dish: Φ 70 – 90 ×15 mm

Power Supply: AC 110 - 220V









# COMPRESSED GAS SAMPLING FOR ENVIRONMENTAL **MONITORING**

Microbial air sampling devices are widely used in Pharmaceutical and Personal care industries as well as Food, Beverage and Environmental applications. Compressed gases are used at different stages of many industrial manufacturing processes, so microbial testing of compressed gas is an important part of contamination control programs. The CG-100A from HuanKai has taken the air sampling process to a new level with clear advantages for the users.



Built-in self-cleaning system cleans the internal tubes automatically to reduce the risk of internal contamination





Sampling by volume for higher accuracy and reproducibility



Utilizes standard 90mm agar plates which are easy to find and inexpensive are easy to find and inexpensive



Full sampling traceability & LIMS connectivity

Max 8,000 pages complete data records



Rechargeable battery operated for remote sampling up to 6 Hrs <standard option>, max 24 Hrs <extra battery option>



Material: Body - stainless steel; Sampling Head - anodised aluminum

Flow rate: 100L/min

Air Flow: 10-100L/min, 0-1MPa Sampling Volume: 10-6000L

Software to PC: Yes

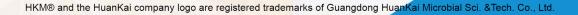
Power Supply: 100-240V 50-60Hz

Display: LCD 122×32 pixels

Battery: 12.0V 4200mAh continuously work for 24hrs

Dimension: 26.5cm×23.5cm×31.5cm

Weight: 4.5Kg / 9.9 lbs



# HuanKai® ENVIRONMENTAL MONITORING SOLUTIONS

Enhance your overall experience by exploring our range of solutions









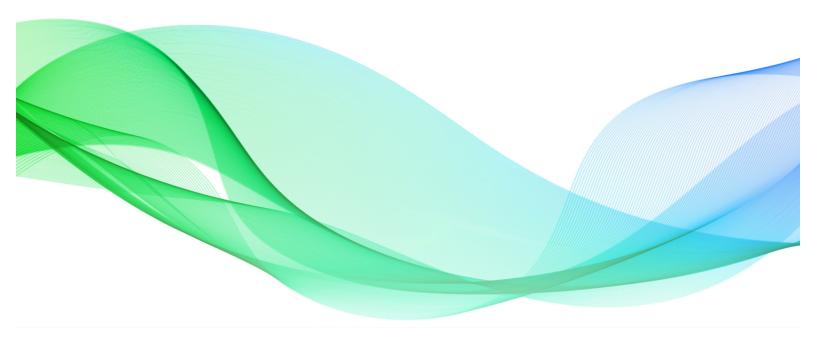
**Pharmaceutical** 

Food & Beverage

Cosmetics

Laboratory

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