Glutaraldehyde Disinfectant Solution 2.0% & 2.45% w/v

HOSPAL®- G & HOSPAL®- G PLUS

Disinfecting Solution for Surgical instruments

Active Ingredient:
Glutaraldehyde 2% / 2.45% w/v

Broad Spectrum Antimicrobial Activity

Usage - For effective, safe and rapid disinfection and sterilization of:

- Endoscopes
- Surgical Instruments
- Anaesthesia Equipment
- Urological Instruments
- Neonatal Care Instruments
- Dental Instruments

Precautions:

- Avoid contact with skin and eyes
- Do not immerse carbon steel objects for more than 24 hours
- Do not use the solution beyond 14 days after activation
- The use of hand gloves and face mask is recommended

Activation:
Each jar of HOSPAL-G / HOSPAL-G PLUS is provided with an activator vial. Open the seal, remove the activator vial and dissolve the entire quantity of activator in the entire solution of the jar. The green-coloured solution in now ready for use.

Pour the activated solution in a tray and immerse the instruments in such a way that they are dipped completely. Rinse the objects thoroughly before dipping in the solution. Uncleaned instruments carrying grease, smudges, fingerprints, etc. might prevent the sterilizing activity of the solution, as direct contact of the instrument with the solution may be hindered.

Duration:

- For High Level Disinfection: Immerse instruments for 45 minutes in activated HOSPAL-G /HOSPAL-G PLUS solution

Presentation:
1 Litre Can
5 Litre Can
with Liquid Activator Vial

Home

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ISO 13485 Medical Devices Certified QMS

WHO-GMP Certified

EFFICACY NOW ASSURED WITH PSK TEST STRIPS

We Protect!

HOSPAL®-G

HOSPAL®-G PLUS

PROVIDED FREE WITH EVERY 5L CAN OF HOSPAL®-G & HOSPAL® G-PLUS:

- 16 Glutaraldehyde Test Strips for verifiying 1.5% MEC
- 16 pH Test Strips for verifying Alkaline pH
- Log Sheet for recording solution compliance

Why should you test your Glutaraldehyde Solution?

- Glutaraldehyde solution effectively disinfects instruments only at concentrations greater than 1.5%, and at alkaline pH
- Since Glutaraldehyde solutions are re-used for up to 14 days, with instruments being dipped repeatedly, the solution tends to get diluted and its pH varies over this re-use period
- Therefore, to ensure that your Glutaraldehyde Disinfectant Solution efficiently destroys microorganisms during every day of re-use, the minimum effective concentration (MEC) of 1.5% Glutaraldehyde and alkaline pH required for high-level disinfection should be confirmed with appropriate Test Strips every day.

Why should you maintain a Log Sheet?

- To ensure and to document that the efficacy of your Glutaraldehyde instrument disinfectant solution is being correctly monitored every day over the course of it's re-use.

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, state that:
"Glutaraldehyde...has gained wide acceptance as a high-level disinfectant and chemical sterilant. Aqueous solutions of glutaraldehyde are acidic and generally in this state are not sporicidal. ***Only when the solution is "activated" (made alkaline)...to pH 7.5–8.5 does the solution become sporicidal****. Glutaraldehyde is commonly diluted during use, and studies showed a glutaraldehyde concentration decline after a few days of use...The decline occurs because instruments are not thoroughly dried and water is carried in with the instrument, which increases the solution's volume and dilutes its effective concentration.* ***This emphasizes the need to ensure that semicritical equipment is disinfected with an acceptable concentration of glutaraldehyde****. Chemical test strips are available for determining whether an effective concentration of glutaraldehyde is present despite repeated use and dilution.* ***The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily****; used weekly, test before use; used 30 times per day, test each 10th use).* ***The results of test strip monitoring should be documented****. To ensure the presence of minimum effective concentration of the high-level disinfectant, manufacturers of some chemical test strips recommend the use of quality-control procedures to ensure the strips perform properly...The concentration should be considered unacceptable or unsafe when the test indicates a dilution below the product's minimum effective concentration (MEC) (generally to <1.0%–1.5% glutaraldehyde) by the indicator not changing color"*

MEC Test Strips

pH Test Strips

Home

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TEMPERATURE INDICATOR

FOR GLUTARALDEHYDE & ORTHO-PHTHALALDEHYDE DISINFECTANT SOLUTIONS

Why should you monitor the temperature of your Glutaraldehyde / ortho-Phthalaldehyde (OPA) Solution?

"Liquid chemical sterilants reliably produce sterility only if... proper guidelines are followed regarding concentration, contact time, ***temperature,*** *& pH"*

"The rate of kill (of Glutaraldehyde) was directly proportional to the ***temperature****"*

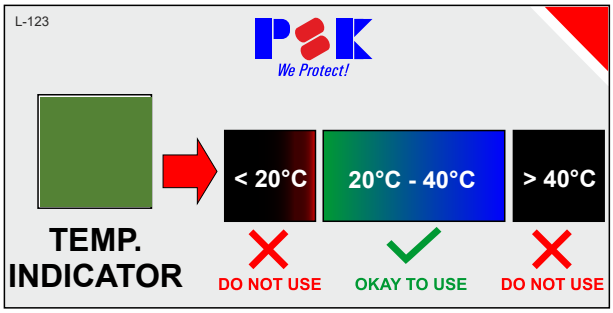
- CDC Disinfection Guidelines

"Glutaraldehyde is greatly affected by temperature. It is one of the most temperature dependent disinfectants…(its) use is ***not recommended at low temperatures below 20°C****"*

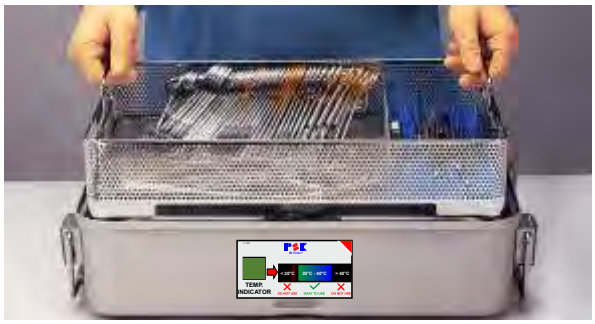
- "Effect of Temperature and Contact Time on the Activity of Eight Disinfectants - A Classification" P. GELINAS, J. GOULET, G. M. TASTAYRE, G. PICARD

Temperature Variations:

- Due to climatic variations or air-conditioning parameters, temperature of the solution can dip below 20°C, greatly reducing the activity during the use cycle
- Therefore, to ensure your Disinfectant Solution efficiently destroys microorganisms during every cycle of use, the minimum temperature of 20°C should be confirmed with the temperature indicator sticker provided



Temperature Indicator Sticker



Sticker to be simply pasted on the outside of disinfectant tray

It is now easy to monitor the disinfectant temperature using PSK's Temperature Indicator Stickers:

- One sticker provided **FREE** with every 5 Litre can of **Hospal®-G Plus** & **Hospal®-OPA**
- Sticker to be simply pasted on the outside of disinfectant tray
- Check the indicator tab & ensure **green** / **blue** colour:
  - Just before immersing instruments
  - At the end of the disinfection cycle
- If indicator tab colour is **black**:
  - Adjust the room temperature & repeat the disinfection cycle

Home

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PSK Pharma Private Limited

Manufacturers of Surgical Disinfectants & Antiseptics

HOSPAL® - G / HOSPAL® - G PLUS SOLUTION LOG SHEET

WARNING: DO NOT USE **HOSPAL® - G / HOSPAL® - G PLUS** SOLUTION & TEST STRIPS BEYOND STATED USE & REUSE LIFE
EACH CAN OF **HOSPAL® - G / HOSPAL® - G PLUS** SOLUTION IS PROVIDED WITH TWO VIALS ONE VIAL CONTAINING 16 NOS. MEC TEST STRIPS & ONE VIAL CONTAINING 16 NOS. pH TEST STRIPS (2 NOS. FROM EACH VIAL FOR QC TESTING & 14 NOS. FOR USE WITH CAN)

Name of Hospital: _____ Location / Dept.: _____

Batch No. of **HOSPAL® - G / HOSPAL® - G PLUS** solution: _____ Lot No. of Test Strips: _____

Expiry Date of **HOSPAL® - G / HOSPAL® - G PLUS** solution : _____ Expiry Date of Test Strips: _____

Date Can & Strips Opened: _____

MEC Test Strips QC Test Date: _____ MEC Strips QC Test Results: PASS / FAIL Tested By: _____

pH Test Strips QC Test Date: _____ pH Strips QC Test Results: PASS / FAIL Tested By: _____

Day of Use	Date of Testing	Time of Testing	MEC Test Results (circle one)	pH Test Results (circle one)	Tested By (initials)	Temp. °C	Comments
Day 1			PASS FAIL	PASS FAIL			
Day 2			PASS FAIL	PASS FAIL			
Day 3			PASS FAIL	PASS FAIL			
Day 4			PASS FAIL	PASS FAIL			
Day 5			PASS FAIL	PASS FAIL			
Day 6			PASS FAIL	PASS FAIL			
Day 7			PASS FAIL	PASS FAIL			
Day 8			PASS FAIL	PASS FAIL			
Day 9			PASS FAIL	PASS FAIL			
Day 10			PASS FAIL	PASS FAIL			
Day 11			PASS FAIL	PASS FAIL			
Day 12			PASS FAIL	PASS FAIL			
Day 13			PASS FAIL	PASS FAIL			
Day 14			PASS FAIL	PASS FAIL			

Test Strips Quality Control Procedure:

1. Preparation of Control Solutions for Glutaraldehyde MEC: Use undiluted **HOSPAL® - G / HOSPAL® - G PLUS** solution from the can as Positive Control Solution. To prepare a Negative Control Solution, dilute one part of **HOSPAL® - G / HOSPAL® - G PLUS** solution with two parts of water. Label each control solution carefully and clearly.
2. Preparation of Control Solutions for pH: Use undiluted, activated **HOSPAL® - G / HOSPAL® - G PLUS** solution as Positive Control Solution. Use undiluted, unactivated **HOSPAL® - G / HOSPAL® - G PLUS** solution from the can as Negative Control Solution. Label each control solution carefully and clearly.
3. QC Testing Procedure: Following the directions for use, dip one Glutaraldehyde MEC test strip each in each of the above freshly prepared Glutaraldehyde MEC control solutions and remove immediately. Observe the test strips after 3 minutes - the test strip dipped in the undiluted positive control solution should exhibit a clear PASS result as per the colour chart. The test strip dipped in the diluted negative control should exhibit a clear FAIL result.
   Similarly, dip one pH test strip each in each of the above freshly prepared pH control solutions and remove immediately. Observe the test strips after 30 seconds - the test strip dipped in the undiluted positive control solution should exhibit a clear PASS result as per the colour chart. The test strip dipped in the diluted negative control should exhibit a clear FAIL result.
4. QC Testing Frequency: It is recommended that the testing of positive and negative controls be performed on each newly opened test strip vial and can of **HOSPAL® - G / HOSPAL® - G PLUS** Solution.
5. Unsatisfactory QC Test Performance: If the results obtained from using the positive and negative controls indicate the test strips are not functioning properly, contact **PSK Pharma** for assistance.

* ***Note:*** *Ensure that solution temperature is not below 25°C to ensure effective disinfection*

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