TBXzyme Reference Manual

Huons Medicare

CONTENTS

I. INTRODUTION

As the incidence of secondary infections in medical facilities continues to increase, countries around the world are preparing and managing the need for disinfection of medical devices and the disinfectants they use. In the early 1960s, Spaulding in the United States has been used as a classification standard until now, by classifying medical devices into high-risk, semi-risk and non-risk devices depending on the degree of risk of infection. The US Environmental Protection Agency (EPA) and KGMP specify sterilant and high-level disinfectants that can kill all microorganisms, including spores. In addition, efforts are being made to kill internal infections by limiting the use of each disinfectant. [Table 1]

Because disinfectants have their own unique antimicrobial spectrum, corrosiveness and toxicity, appropriate cleaning or disinfection methods should be applied to the intended use or residue conditions of medical devices. Recently, there has been an increasing need for proper disinfectant selection for disinfection by increasing the use of automated medical devices, increasing interest in environmental pollution, and improving users 'and patients' perceptions. In particular, there is a growing interest in moderate disinfectants containing a clarifying agent or quaternary ammonium salt, which is applicable to a wide range of applications, from all medical environments to cleaning and disinfection of instruments, and because of the safety of the human body.

The amphoteric surfactant alkyldiaminoethylglycine hydrochloride, which is registered as a raw material drug by the Korean Food and Drug Administration, is the most commonly used ingredient together with benzalkonium chloride (quaternary ammonium salt) and chlorhexidine. Alkyldiaminoethylglycine hydrochloride is more stable against contaminants than other disinfectants and has germicidal power against Mycobacterium tuberculosis.

TBXzyme is an alkyldiaminoethylglycine hydrochloride whose active ingredient is a multi-purpose cleaning, Sterilization disinfectant which can be used as an intermediate disinfectant, environmental disinfectant, and enzyme detergent. In this "Reference manual", general characteristics of TBXzyme, bactericidal activity against bacteria, multidrug-resistant bacteria and fungi in Korea Testing & Research Institute (KTR), and bactericidal activity against tuberculosis in Hoseo University were shown. It also includes stimuli, toxicity, and stability to the human body.

II. PRODUCT INFORMANTION

1. GENERAL INFIRMATION OF TBXzyme

(1) Composition

■ Active ingredient	: Alkyldiaminoethylglycine hydrochloride	10%
■ Inert ingredients	: Ethanol	A proper quantity
	Protease	A proper quantity
	Lipase	A proper quantity

(2) Physical properties

- ■ Description : Clear, light yellow color liquid
- ■ pH : 8.0~10.0

2. EFFICACY OF TBXzyme

Chlorhexidine and benzalkonium chloride, which are commonly used disinfectants, have no or low effectiveness against Mycobacteria tuberculsis. In the presence of organic substances such as blood, hard water, etc., the sterilizing power decreases. In addition, when chlorhexidine is used in the mucous membrane, side effects such as shocks are observed, and precipitation phenomenon occurs when diluted with hard water. In the case of benzalkonium chloride, the effect is reduced when it is used in combination with an anionic detergent. [2)-14)]

TBXzyme, on the other hand, is an amphoteric surfactant with both detergency by anionic surfactant and disinfection by cationic surfactant. It shows disinfection ability to Mycobacteria tuberculsis and does not decrease the disinfection power even in the presence of organic substances including blood, protein and hard water. [15)-19)] The data reported on the antimicrobial action of chlorhexidine, balsalonium chloride and alkyldiaminoethylglycine hydrochloride, which is the main component of TBXzyme, are shown in [Table 2]. [2) ,24), 25)]

[Table 1] Antimicrobial action of disinfectant

Microorganism / Disinfectant	Bacteria		Fungi		Mycobacteria	Virus		Spore
	Gram(+) bacteria	Gram(-) bacteria	yeast	Mode		Enveloped virus	Non-Enveloped virus	
Chlorhexidine	○	○	○	△	X	△	X	X
Benzalkonium chloride	○	○	○	△	△	△	X	X
Alkyldiaminoethylglycine hydrochloride	○	○	○	△	○	△	X	X

○ : Efficacy △ : There is an efficacy but there are cases where sufficient efficacy can't be obtained. X : No efficacy

(1) Efficacy test

[Table 2] In-vitro testing

Institute	Test organism	Concentration	Contact time
Korea Testing & Research Institute (KTR)	Bacteria		
	Staphylococcus aureus ATCC 6538	0.5%	5 min
	Escherichia coli ATCC 25922	0.5%	5 min
	Salmonella typhimurium ATCC 13311	0.5%	5 min
	Multidrug-Resistant Organism		
	MRSA ATCC 33591	0.5%	5 min
	VRE ATCC 51299	0.5%	5 min
	Fungi		
	Candida albicans ATCC 10231	0.5%	5 min
Korea research institute of chemical technology (KRICT)	Virus		
	Feline coronavirus	0.5%	1 min
Hoseo University bio Research Institute	Mycobacteria		
	Mycobacterium bovis ATCC 35737	0.5%	5 min

We evaluated the bactericidal activity of TBXzyme against bacteria Gram (-) bacteria, Gram (+) bacteria, multidrug-resistant organism and fungi in KTR, and evaluated the bactericidal activity against Mycobacterium tuberculosis at Hoseo University and obtained valid results. According to the results of the study, it can be seen that the TBXzyme is effective at least a decimal log (lg) reduction of 5.

(2) Bactericidal efficacy

- Comparison of bactericidal activities of various disinfectants against MRSA and MSSA.[21)]

  Six strains of MRSA and MSSA isolated from hospital were used for the test. 0.05% and 0.1% alkyldiaminoethylglycine hydrochloride killed all the bacteria in 20 seconds.

  * MRSA: Methicillin-resistant staphylococcus aureus / MSSA: Methicillin-sensitive staphylococcus aureus

- Comparison of Bactericidal Effects of Commonly Used Antiseptics against Pathogens Causing Nosocomial Infections.[22)]

  10 strains of X.maltophilia and 10 strains of S.marcescens were used in the test. All strains of X.maltophilia were killed in 0.02% alkyldiaminoethylglycine hydrochloride in 20 seconds and all strains of S were killed in 0.05% of alkyldiaminoethylglycine hydrochloride in 60 seconds.

(3) Cleaning effect of TBXzyme

The TBXzyme cleaning effect test was performed using a sample contaminated with protein (EMPA-111). By complying with the usage method, the purified water, TBXzyme and other products were compared with each other and the following results were confirmed.

[Table 3] Cleaning effect test results

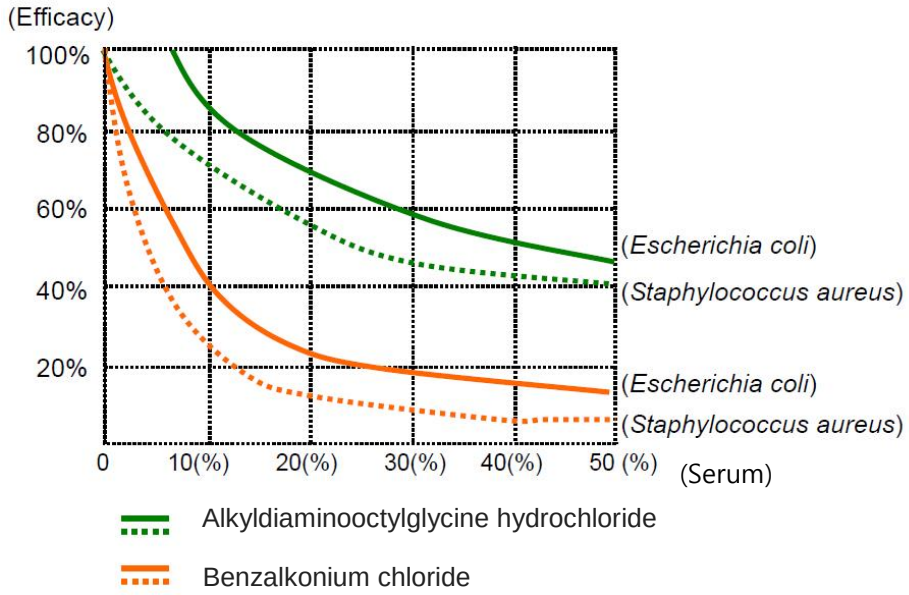
Before	Purified water	TBXzyme	A
			

The results showed that the cleansing power of TBXzyme showed a clear difference when compared with purified water, and that it had a cleaning effect equal to or higher than that of the "A" product, which is a similar component.

(4) Disinfection power of alkyldiaminoethylglycine hydrochloride

The alkyldiaminoethylglycine hydrochloride does not form a precipitate at all in the presence of protein, but does not decrease the effect, even if it is mixed under the weakest conditions. As shown in [Fig. 1], the disinfection power of alkyldiaminoethylglycine hydrochloride was more than twice as high as that of antimicrobial benzalkonium when serum was present. .[20)]

[Figure 1] Comparison of disinfecting power between alkyldiaminoethylglycine hydrochloride and benzalkonium chloride in the presence of serum



3. STABILITY TEST OF TBXzyme

(1) Toxicity evaluation

The acute oral toxicity of alkyldiaminoethylglycine Hydrochloride to rats showed an LD_{50} of more than 2,000 mg / kg.

[Table 4] Toxicity results of Alkyldiaminoethylglycine Hydrochloride solution[23)]

Item	Concentration	Animal	Result	
Acute oral toxicity	Alkyldiaminoethylglycine Hydrochloride	Rat	LD_{50}> 2,000mg/kg	Low toxicity

* LD_{50} : Lethal Dose 50%

(2) Material compatibility

Alkyldiaminoethylglycine hydrochloride is known to be suitable for a variety of materials such as metals, plastics, rubbers, and polyethylene. Therefore, the corrosiveness to copper, which is generally known to be highly corrosive to disinfectants, has been examined.

[Table 5] Material compatibility of disinfectants[24)]

Disinfectant	Metal	Porous, adsorptive synthetic rubber	Synthetic resin products
Chlorhexidine	corrosive	Unavailable (There is a possibility of alteration).	Unavailable (There is a possibility of alteration).
Benzalkonium chloride	corrosive	Unavailable	Unavailable
TBXzyme	Less corrosive	Silicone rubber has no effect (Other causes coloring)	Pigmentation by object

4. DIRECTIONS FOR USE

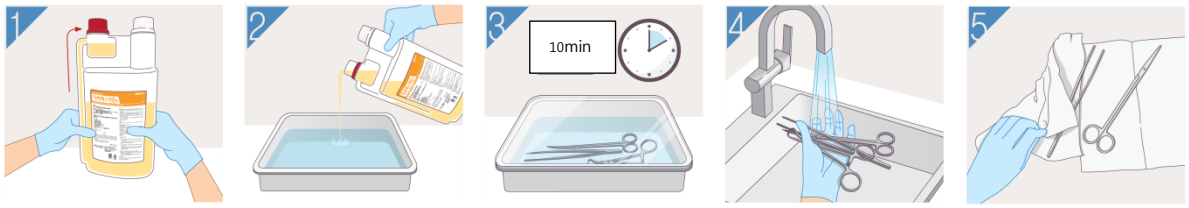
(1) Usage and Capacity

Alkyldiaminoethylglycine hydrochloride is diluted to the following concentrations depending on the application.

[Table 6] Usage and Capacity

Application	TBXzyme
Disinfection of hands and skin	Rinse with 0.0.5 ~ 0.2 % solution for about 5 minutes and wipe clean with sterile gauze or cloth.
Disinfection of the skin at the surgical site	Wash the skin to be treated with 0.1 % solution for about 5 minutes and then apply 0.2 % aqueous solution.
Mucosal disinfection of the surgical site Disinfection of wound area of skin mucosa	0.01 ~ 0.05 % solution
Disinfection of medical instruments	Immerse in 0.01 to 0.2 % solution for 10 to 15 minutes. However, 0.2 ~ 0.5 % aqueous solution should be used for disinfection related to tuberculosis patients.
Operating Room Furniture Disinfection of instrument articles	0.05 ~ 0.2 % solution. However, 0.2 ~ 0.5% solution should be used for disinfection related to tuberculosis patients.

(2) How to use



1. Open the lid of TBXzyme and force the vessel to transfer the solution to the measuring cup at the dilution rate.
2. Prepare a 0.5% (200 times) solution by adding the stock solution to the prepared water.
3. Immerse the instrument in dilute solution thoroughly and immerse for 10 minutes.
4. After immersion, clean the instruments with clean water thoroughly
5. Remove water and dry.

※ Dilution ratio table

Total solution volume	1L	5L	10L	15L	20L	25L	30L	40L
Undiluted TBXzyme	5ml	25ml	50ml	75ml	100ml	125ml	150ml	200ml

Volume of pumping (Once) : 25ml

5. STORAGE AND PRECAUTION

(1) Side effect

Occasional rashes, itching and other symptoms of irritation may occur, and in such cases, stop using.

(2) Interaction

Do not mix with other disinfectants.

(3) Influence on clinical examination

Urinary urine collected by catheter rinsed with this drug may have false positives in the urine protein test by sulfosalicylic acid method.

(4) Treatment during overdose

- Eye contact : Wash thoroughly the eyelids and eyelids. If the eyes have been washed in clean water for more than 15 minutes, treat them well.
- If you accidentally drink this medicine, rinse your mouth with water, drink water or milk and take appropriate measures. (Do not try to induce vomiting forcibly.)

(5) Precautions

1) Use only for external use.

2) Preparation

- When used in areas susceptible to irritation or irritation, it is preferable to lower the concentration at the normal site.
- If you use it in the wound or eye area you wish to use, use diluted liquid for injection and sterile purified water. Do not use tap water or purified water.

3) In use

- Be careful not to get any undiluted solution or concentrated liquid in the eyes. If it gets into the eyes, clean it with water.
- If concentrated solution is used, be careful because irritation symptoms may appear on skin mucosa.

- It is not used for a long time or widely in the mucosa, the upper surface of the wound and the inflammation site. (It is possible to work by the whole body absorption.)

(6) Etc

- Soap is weak enough to sterilize this medicine, wash it thoroughly and use it.
- If it is necessary to immerse the iron appliance for a long time, dissolve sodium nitrite to prevent corrosion. (There is no effect on sterilization action). Copper appliances are not immersed for a long time because they can't prevent corrosion by adding sodium nitrite.

(7) Storage Precautions

There may be differences in the hue of the hue, and in the cold, it may cause some turbidity but it does not affect the sterilization. It is dissolved when the turbidity is raised.

(8) Packing and shelf-life

- Packing unit : 1L/bottle (1L x 12bottle/Box), 5L/bottle (5L x 2bottle/Box)
- Shelf - life : 24 months

III. CONCLUTION

The raw material of TBXzyme is a general purpose, versatile cleaning, sterilant·disinfectant which is mainly composed of alkyldiaminoethylglycine hydrochloride registered as general medicine, and also serves as enzyme detergent as well as disinfection at the middle level including protease and lipase.

TBXzyme can be used in the skin area of trauma, medical equipment and medical facilities, cleaning and disinfection related to tuberculosis patients, and other medical environments. In addition, TBXzyme has stronger disinfecting power than chlorhexidine and benzalkonium chloride, and has relatively strong disinfecting power even in organic matter. It can be used by diluting up to 200 times depending on the use environment.

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