Safety - Biocompatibility of HYDROCYN aqua®

HYDROCYN® aqua has been tested for biocompatibility as per ISO 10993 and has passed following in-vivo and in vitro studies: -

Biocompatibility Test	Assessment
ISO Acute Dermal Toxicity Study	No lethal or adverse toxic effects demonstrated.
ISO In Vivo Studies; Intracutaneous Reactivity Test	No evidence of erythema or oedema was observed
ISO In Vivo Studies; Primary Skin Test	No irritation responses noted or considered negligible
ISO Genotoxicity Studies; In Vitro Micronucleus Studies	Do not induce any significant micronucleus formation & is non-clastogenic
ISO Cytotoxicity Studies Agar Diffusion Test	No cytotoxic effect shown on mammalian cell line
ISO Acute Oral Toxicity Study	Did not cause any lethal effect when administered orally
ISO Skin Sensitization Study; Guinea Pig Maximisation Test	No delayed dermal hypersensitivity reaction/ sensitization
ISO Ocular Irritation Study	No irritation shown in the treated eyes.
ISO Vaginal Irritation Study	No vaginal irritation was observed on test species
ISO Acute Inhalation Toxicity Study	Did not produce any toxicity or mortality when inhaled.

All test done under GLP conditions and reported as per international norms

HYDROCYN® aqua Order Codes

Order Code	Pip Code	Volume	Types
HW3CE700*	414-0570	100ml	Bottle Spray Mist
HW34E100*	414-0562	250ml	Bottle Cap Closure
HW35D100*	414-0554	500ml	Bottle Cap Closure

HYDROCYN® aqua is the trademark of Vigilenz Medical Devices Sdn Bhd.

VIGILENZ® is a design & development company with Class III CE marked products manufactured under ISO13485: 2016 Quality Management System. VIGILENZ® is the first Malaysian company to attain a Class III CE marked products and is FDA certified and has HALAL certification.

HYDROCYN® aqua Wound Wash, Irrigation and Debridement Solution

Powered by Neuwater™ technology

Wound Wash, Irrigation & Debridment with a Difference

No harmful Chemical Used or Added

Antimicrobial (kills bacteria <1min)
Sporicidal
Fungicidal
Antibiofilm properties
Biocompatible
Non-irritating
Non-stinging (neutral pH)
Easy to use (spray or cap bottle)

Safe, effective and easy to use

Contact

Creed Medical Ltd.
Unit 2, Hamilton Court, Oakham Business Park, Mansfield, Nottinghamshire NG18 5FB, UK
E: info@creedmed.com T: +44 (0) 1623 391578

HYDROCYN® aqua

Advanced Wound Care Solution



Anti-biofilm Properties
Bactericidal "Sporicidal 'Fungicidal

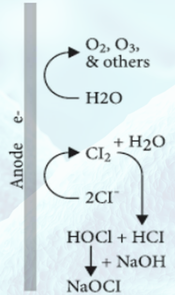
Introduction

HYDROCYN® aqua is an advanced wound wash, debridement and irrigation solution intended to support wound healing process. HYDROCYN® aqua is pH neutral, biocomptible and clinically proven to be safe and effective for various types of wounds. Advantages of HYDROCYN® aqua include following:

1) Reduces microbial load on wound
2) Removes fetid odour
3) Supports natural wound healing process
4) Non-irritant and non-cytotoxic
5) No dilution required
6) Helps removes biofilm

HYDROCYN® aqua contains hypochlorous acid (HOCl), sodium hypochlorite (NaOCl) and 99.9% acute and chronic wounds, such as stage I-IV ulcers, venous stasis and diabetic ulcerations, water. HYDROCYN® aqua is indicated as a wound wash, debridement and irrigation solution for acute and chronic wounds, such as stage I-IV ulcers, venous stasis and diabetic ulcerations, post-surgical wounds, burns and bed sores. It also helps in moistening a wound to promote debridement and controls malodour.

NEUWATER® Technology



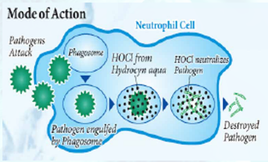
NEUWATER® Technology which is used for HYDROCYN aqua® production utilizes a unique multi chamber electrolysis cell with proprietary stabilization process.

Purified water containing trace amounts of chloride (Cl) is oxidized creating: -

~ Oxidized Water - Water (H2O) is broken down into oxygen, ozone & other oxidizing acid (HOCl)

~ Chlorine (Cl2) - Reacts with water forming Hypochlorous

Acid (HOCl) - Neutralisation with NaOH converts a portion of the HOCl to NaOCl



Antimicrobial-mode action

- **The cells of microorganism are by nature negatively charged while hypochlorous acid (HOCl) is electrically neutral.**
- **Therefore, the hypochlorous acid (HOCl) can penetrate the slime layers, cell walls and protective layer of microorganism and effectively kill them from the inside.**
- **As a result, the microorganism will either die or suffer from the reproductive failures.**

Effective - Antimicrobial Efficacy of HYDROCYN® aqua

HYDROCYN® aqua has a unique antimicrobial property against wide range of pathogen due to the presence of HOCl component. The following chart demonstrates the efficacy of HYDROCYN® aqua 's ancillary antimicrobial properties, which has been evaluated as per ASTM E2315-03 (Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure). HYDROCYN® aqua is effective against gram-positive and gram-negative bacteria (including MRSA) fungi and spores.

Bactericidal, Fungicidal and Sporocidal Activity of HYDROCYN aqua®

Classification	Microorganisms	Microbial Presence
Bactericidal	*Bacillus cereus*	ND (<1)
	Pseudomonas aeruginosa	ND (<1)
	Enterococcus feacalis	ND (<1)
	Salmonella sp.	ND (<1)
	Salmonella typhimurium	
	Staphylococcus aureus	ND (<1)
	Listeria sp.	ND (<1)
	Legionella sp.	ND (<1)
	Pseudomonas putida	ND (<1)
Fungicidal/Sporicidal	*Aspergillus niger*	ND (<1)
	Yeast & mold	ND (<1)

Antibiofilm Efficacy Test

HYDROCYN® aqua is also proven to be effective against biofilm. The in-vitro test carried out demonstrate the following: -

Microbes	Result
P. aeruginosa	HYDROCYN® aqua was tested against pseudomonas aeruginosa biofilm according to ASTM E2799-12, The result shows a log reduction of more than 5.95 from the initial biofilm concentration and is effectively reduce biofilm by 99.9%.
Methicillin-resistant *Staphylococcus aureus*	HYDROCYN® aqua was tested against according to ASTM E2799-12. The result shows a log redutction of more than 2.65 from the initial biofilm concentration and is effectively reduce biofilm by 99%.

Time-Kill Evaluations (60 sec of exposure)

The following bacteria, fungi and spores proved susceptible to HYDROCYN aqua at 60 sec exposure: -

Classification	Microorganisms	Common Diseases	% Reduction
Bactericidal	*E. feacalis*, VRE	UTI, intra-abdominal infections, pelvic and soft tissue infections, bacteremia, endocarditis,	99.99%
	MRSA	Folliculitis, skin infections	99.99%
	Mycobacterium bovis	Tuberculosis	99.99%
	Gardnerella vaginalis	Vaginosis	99.99%
	Klebsiella pneumoniae	Pneumonia, wound infection, bacteremia, septicemia, meningitis, endocarditis,	99.99%
Fungicidal	*Candida albicans*	UTI, genital yeast infections, oral thrush, mucocutaneous candidaisis,	99.99%
Sporicidal	*Bacillus subtilis*	Diarrhea, meningitis, endocarditis, osteomyelitis, bacteremia	99.99%
	Clostridium difficile	Diarrhea, botulism, gastroenteritis, gas gangrene	99.99%
	Clostridium sporogenes		98.45%
	Trichophytan mentagrophytes	Dermatophytosis	99.99%
	Sporothrix schenckii	Sphorotricosis	99.99%
	Candida auris	Bacteremia, wound and ear infections, sepsis, fever.	99.99%

Anti-biofilm Properties
Bactericidal 'Sporicidal Fungicidal'