

## Micronova Manufacturing Inc. Certificate of Analysis

Product: Lot #: Date of Manufacture: Product expiration date:	AquaHol – IC-220 5315SWE1 August, 2015 July, 2018	
Test	Specification	Result
Description	IPA 70% v/v in water for injection, passed through a 0.1 micron filter: double bagged and irradiated. Provides sterile alcohol upon opening.	Positive
Appearance/Odor	Clear, colorless liquid with a characteristic spirituous odor	Positive
Acidity	Not more than 1.0 ml of 0.02N Sodium Hydroxide	0.5 mL
Specific Gravity	0.872 – 0.883 at 20°C	0.877
Alcohol Content	68 – 72% v/v	70.00%
Non-volatile residue	Not more than 0.01% w/v	Complies
Irradiation Dose	Not less than 25.0 kGy	Complies
Sterility	Passes the USP test for sterility	Complies

This batch was manufactured in and assembled in accordance with the requirements of  $\ensuremath{\mathsf{GMP}}$ 

Authorization: Dip a Comp

Phillip LeCompte Director of Design & Development

Micronova Manufacturing Inc. 3431 West Lomita Boulevard, Torrance, CA 90505 (310) 784 6990 Fax: (310) 784 6980



## Micronova Manufacturing Inc. Certificate of Sterility

Product:	<u>AquaHol – IC-220</u>	
Lot #:	5315SWE1	
Date of Manufacture:	August, 2015	
Product expiration date:	July, 2018	
Product Description:	70% v/v IPA blended with WFI, 500ml	
Irradiation Certificate No:	UK33S11442590-2-1	
Sterility Test No:	150825-2	
Test Performed to:	Sterility test methods as per current USP test	
Test Result:	Samples comply with the above testing requirement.	

Authorization:

Pailip & Comp

Date: October 6, 2015

Phillip LeCompte Director of Design & Development

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## Micronova Manufacturing Inc. Certificate of Irradiation

Product:	<u>AquaHol - IC-220</u>
Lot #:	5315SWE1
Date of Manufacture:	August, 2015
Product expiration date:	July, 2018
Product Description:	70% v/v IPA blended with WFI, 500ml
Irradiation Certificate No:	UK33S11442590-2-1
Certificate of Analysis No:	1509304960007CA
Irradiation dosage received	figure (kGy): Min = 29.2 Max
	Max = 35.5

This is to certify that the notified goods have undergone irradiation by exposure to  $\gamma$  (Gamma) Irradiation with an exposure of not less than 25kGy.

Irradiation treatment applied was in accordance with:

- EN ISO 13485:2012 Quality Systems Medical Devices
- EN ISO 9001:2000 Quality Management Systems
- ISO 11137-1:2015 Sterilization of Healthcare Products

Authorization:

Pailip & Comp

Date: October 6, 2015

Phillip LeCompte Director of Design & Development

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