

BluScientific Test Data

Test Report. EN 14476:2005. Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/step 1).

Test Laboratory

BluScientific Test Data

School of Life Sciences
Glasgow Caledonian University
GLASGOW
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Identification of sample

Name of the product
Manufacturer

ASPERTICO
UNICO LIMITED, NORT MAIN STREET, CARRONSHORE,
FALKIRK, SCOTLAND FK2 BHT.

Date of Delivery
Storage conditions
Product diluent
Active substances

21.6.2006
4°C and darkness
Hard Water
Not known.

Test Method and its validation

Method

Agent was diluted and 0.8 ml mixed with 0.2 ml virus suspension (DMEM + 5% FBS);

Dilution-neutralization.
Neutralizer

Dilution in Dulbecco's modified Eagles medium + 5% v/v foetal bovine serum.

Experimental Conditions

Period of analysis
Product diluent used
Product test concentrations

25TH MAY to AUGUST 2006
Sterile Hard Water
100 ppm V/V; 1000 ppm V/V; 5000 ppm V/V.

Contact times
Test temperature
Interfering substance
Stability of mixture
Temperature of incubation
Identification of virus

60 minutes \pm 10s;
20 °C \pm 1 °C
0.6 g/l foetal bovine serum + 0.3g/l bovine serum albumin.
Precipitate absent throughout the test
37 °C \pm 1 °C + 5% CO₂
Poliovirus 1 (ATCC VR-1562)/HeLa cells.
Adenovirus 5 (ATCC VR-5)/HeLa cells

Test Result (See table 1)

Conclusion.

According to EN 14476: 2005, ASPERTICO has effective virucidal activity at 60 minutes contact at 20°C, at 10% V/V of the working concentration as tested, under clean conditions (0,6 g/L protein as foetal bovine serum and 0.3 g/l as bovine serum albumin) for suspensions of Poliovirus 1 (Chat Strain) ATCC VR-1562 and Adenovirus 5 ATCC VR-5.

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Result of ASPERTICO against Adenovirus 5 under clean conditions

Product	Dilution	Level of cytotoxicity	lg TCID ₅₀		>4 lg reduction after.. min
			0 min	60 min	
ASPERTICO	10% (v/v)	3.50	7.67	3.50	60
	20% (v/v)	3.50	7.67	3.50	60
	80% (v/v)	4.50	7.67	4.50	60
Formaldehyde	0.7% (w/v)	3.50	7.67	4.50	>60
virus control	n.a.	n.a.	7.67	7.17	n.a.

Result of ASPERTICO against Poliovirus 1 under clean conditions

Product	Dilution	Level of cytotoxicity	lg TCID ₅₀		>4 lg reduction after.. min
			0 min	60 min	
ASPERTICO	10% (v/v)	3.50	8.26	3.50	60
	20% (v/v)	3.50	8.26	3.50	60
	80% (v/v)	4.50	8.26	4.50	60
Formaldehyde	0.7% (w/v)	4.50	8.26	6.17	>60
virus control	n.a.	n.a.	8.17	8.33	n.a.

VIRUCIDAL ACTIVITY IS BASED ON A REDUCTION IN VIRUS VIABILITY OF A MINIMUM OF 4 LOG₁₀ IN 60 MINUTES.

Signed



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12TH JUNE 2007. Glasgow, UK.

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