

Test Report: Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension. Hepatitis C virus (Bovine Viral Diarrhoea Virus surrogate)

Test Laboratory

BluTest Laboratories Ltd

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Identification of sample

Name of the product
Project Code
Manufacturer
Date of Delivery
Storage conditions
Active substances

DUOMAX DR-1

BT-DUO-04

DUO TECH LTD, 11-12 QUEENS SQUARE, BRISTOL, BS1 4NT
7 January 2010
Room temperature
Not Known

Test Method and its validation

Method

Sample was diluted and 0.8 ml mixed with 0.1 ml virus suspension (DMEM + 5% FBS) and 0.1 ml 0.3% W/V bovine serum albumin

Dilution-neutralization
Neutralizer

Dulbecco's modified Eagles medium + 5% v/v foetal bovine serum at 4°C.

Experimental Conditions

Period of analysis
Product diluent used
Product test concentrations
Contact times
Test temperature
Interfering substance
Stability of mixture
Temperature of incubation
Identification of virus

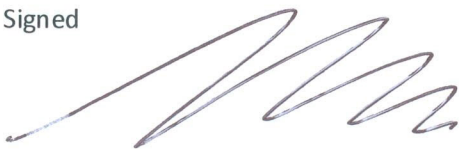
April 2010
Sterile Hard Water
1.0 % V/V; 2.5 % V/V; 4.0% V/V
5 minutes $\pm$ 10s
20°C $\pm$ 1°C
0.6 g/l foetal bovine serum
Precipitate absent throughout the test
37°C $\pm$ 1°C + 5% CO₂
Bovine Viral Diarrhoea Virus surrogate ATCC VR – 1422

Conclusion

According to a modified EN 14476 protocol **DUOMAX DR-1 (concentrate)** at 1.0 % V/V retains effective virucidal activity of $> 2.83 \log_{10}$ * reduction) at 5 minutes contact at 20°C under CLEAN conditions (0.6 g/l protein as foetal bovine serum + 0.3g/l bovine serum albumin) for suspensions of Hepatitis C virus (Bovine Viral Diarrhoea Virus surrogate ATCC VR – 1422).

* Limited by the maximal achievable titre of virus from duplicate tests.

Signed



Dr Chris Woodall
Director
BluTest Laboratories Ltd
Glasgow, UK, June 2010

Suspension test results for the efficacy of of DUOMAX DR-1 from DuoTech Ltd against Bovine Viral Diarrhoea Virus (BVDV) as a surrogate for Hepatitis C Virus under CLEAN conditions

Exposure Time	Virus Recovery (0 min)		Virus Recovery (5 min)		Cytotoxicity		Disinfectant Suppression		4.0% (v/v)		2.5% (v/v)		1.0% (v/v)	
	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml
t = 5	3.50	1.00E+05 1.00E+05	3.83	2.14E+05 2.14E+05	2.00	3.16E+03 3.16E+03	2.00	3.16E+03 3.16E+03	1.00	3.16E+02 3.16E+02	1.00	3.16E+02 3.16E+02	1.00	3.16E+02 3.16E+02
log		5.00		5.33		3.50		3.50		2.50		2.50		2.50
log difference								1.83		>2.83		>2.83		>2.83

Stock Virus (TCID₅₀)

Raw data: 5.00

TCID₅₀/ml: 3.16E+06

Formaldehyde reference inactivation control

Exposure time	Virus Recovery (0 min)		Virus Recovery (t min)		Cytotoxicity		Formaldehyde (0.7%)	
	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml
t = 5	3.50	1.00E+05 1.00E+05	3.83	2.14E+05 2.14E+05	1.00	3.16E+02 3.16E+02	1.83	2.14E+03 2.14E+03
log		5.00		5.33		2.50		3.33
log difference								2.00

Table of results of virucidal activity of DUOMAX DR-1 from DuoTech Ltd against Bovine Viral Diarrhoea Virus (BVDV) as a surrogate for Hepatitis C Virus under CLEAN conditions

Product	Interfering substance	Test Product Concentration	Level of cytotoxicity	lg TCID50	
				0 min	5 min
DUOMAX DR-1	0.3g/l BSA	4.0% (v/v)	3.50	5.00	2.50
		2.5% (v/v)	3.50	5.00	2.50
		1.0% (v/v)	3.50	5.00	2.50
Formaldehyde		0.7% (w/v)	2.50	5.00	3.33
Virus Control		n.a.	n.a.	5.00	5.33

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