

# CERTIFICATE OF COMPLIANCE

# MICROVAL



HEREBY DECLARES THAT THE CERTIFICATION ASSESSMENT BY  
**LLOYD'S REGISTER QUALITY ASSURANCE**  
HAS DEMONSTRATED THAT THE PRODUCT

## COMPACT DRY TC

Manufactured by:  
Nissui Pharmaceutical Co.Ltd.  
3-23-9 Ueno,  
Taito-Ku, Tokyo, 110-8736  
JAPAN

Supplied by:  
HyServe GmbH & Co. KG  
Hechenrainer Strasse 24  
82449 Uffing  
GERMANY

### COMPLIES WITH

The MicroVal Rules and Certification Scheme version 5  
The validation has been performed in accordance with EN ISO 16140: 2003

As demonstrated by Report number MB/REP/INT/940621/1

Certificate no.: MV0703-001LR

Validation date: 20 March 2007  
Surveillance date: 20 March 2007  
Expiry date: 19 March 2011

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ISSUED BY: Lloyd's Register Nederland B.V.  
Rotterdam, The Netherlands

## PRINCIPLE OF THE METHOD

Compact Dry (Nissui Pharmaceutical Co. Ltd.; supplied by Hyserve GmbH & Co. KG) are ready-to-use dry media sheets comprising culture media and a cold soluble gelling agent, rehydrated by inoculating 1 ml diluted sample into the centre of the self-diffusible medium. The Compact Dry TC (Total Count) method contains the redox indicator tetrazolium salt and is an alternative method to the standard plate count, enabling determination of aerobic colony counts in foods after 48 hour incubation.

## SCOPE

All human food products

## RESTRICTION OF USE

None

## REFERENCE METHOD

BS EN ISO4833: 2003 Microbiology of foods and animal feeding stuffs. Horizontal method for the enumeration of microorganisms. Colony count techniques at 30°C

## LINEARITY and RELATIVE ACCURACY

Comparison of performances of the alternative method and the reference method.

## LINEARITY STUDY

The tests were performed in 2006 on five food product/strain, of which 110 were naturally contaminated, of which 5 contained organisms at levels below the limit of detection of the test (< 10 cfu/g), and 15 were artificially contaminated, belonging to the following principle food product categories; meat products, poultry products, fish and seafood products, dairy products and fruit and vegetable based products.

The samples were analyzed in duplicate with each of the two methods, at the five naturally contamination levels within the ranges: 10 to 100, 100 to 1000, 1000 to 10,000, 10,000 to 100,000, 100,000 to 1,000,000 and 1,000,000 to 10,000,000 and artificially contaminated levels: 100 to 1000, 1000 to 10,000 and 10,000 to 100,000 CFU/g.

### Table of results:

Food category	Food product/strain pair	Regression line
Meat products	Raw ground beef	$y = -0.370 + 1.03 x$
Poultry products	Cooked chicken	$y = -0.067 + 0.980 x$
Fish and seafood products	Frozen fish	$y = 0.225 + 0.875 x$
Fruit and vegetable based products	Lettuce	$y = 0.039 + 0.914 x$
Dairy products	Milk powder	$y = -0.371 + 1.09 x$

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## ACCURACY STUDY:

The tests were performed in 2006 on five food product/strain, of which 110 were naturally contaminated, of which 5 contained organisms at levels below the limit of detection of the test (< 10 cfu/g), and 15 were artificially contaminated, belonging to the following principle food product categories; meat products, poultry products, fish and seafood products, dairy products and fruit and vegetable based products.

The samples were analyzed in duplicate with each of the two methods, at the five naturally contamination levels within the ranges: 10 to 100, 100 to 1000, 1000 to 10,000, 10,000 to 100,000, 100,000 to 1000,000 and 1000,000 to 10,000,000 and artificially contaminated levels: 100 to 1000, 1000 to 10,000 and 10,000 to 100,000 CFU/g.

Food category	Contamination range (in log CFU/g)
Meat products	3.4 to 7.9
Poultry products	LOD (<1) to 6.2
Fish and seafood products	2.9 to 7.0
Fruit and vegetable based products	2.5 to 7.5
Dairy products	LOD (<1) to 5.7

LOD (limit of detection)

The equation of the regression line between the alternative method and the reference method, for all categories combined, is as follows:

$$y = -0.270 + 0.955 x$$

$$R^2 = 0.977$$

$$y = \log(N \text{ alternative method})$$

$$x = \log(N \text{ reference method})$$

r of alternative method and reference method

Conclusion: *for the linearity and relative accuracy:* The results of the method comparison study clearly showed the 48h Compact Dry TC method to be equivalent to the reference method ISO 4833 (2003) for a range of foods.

## Selectivity (INCLUSIVITY/EXCLUSIVITY)

Not relevant as this method was for total viable microorganisms

## PRACTICABILITY

Overall, the comments about the test from the laboratories were positive. Some laboratories reported faint or slight loss of colour associated with colonies. Plates containing high numbers of colonies were easy to read from the reverse but a clearly defined grid system for counting colonies could improve counting, especially when colony numbers are high. Spreading/merging of colonies was observed with some plates at high and low concentrations.

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## INTERLABORATORY STUDY

Indicate details as date of conduction, number participating collaborative laboratories, details about the samples, the levels of the samples:

- level, etc.

Obtained results

Contamination level	Number of samples taken into account	Reference method		Alternative method		
		Repeatability r	Reproducibility R	Repeatability r	Reproducibility R	Bias
Low ( $10^2$ )	26	0.144	0.213	0.083	0.317	-0.104
Medium ( $10^3$ )	26	0.116	0.283	0.121	0.301	-0.089
High ( $10^4$ )	26	0.210	0.357	0.108	0.263	-0.050

## Conclusion

No substantial differences were found between the Compact Dry TC plate method and the reference method (ISO 4833; 2003) for the enumeration of total viable microorganisms at 30°C. There was statistically significant evidence for a difference in repeatability in favour of the alternative method, but this was small.

**Please send any queries concerning the performance of the validated method to Lloyd's Register Quality Assurance.**

**On request, Lloyd's Register Quality Assurance will send you a summary document on the preliminary and collaborative studies**

[www.lrqa.nl](http://www.lrqa.nl);

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