LRQA
Business Assurance

CERTIFICATE OF APPROVAL

MICROVAL

THIS IS TO CERTIFY THAT THE FOLLOWING METHOD

COMPACT DRY TC

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

Supplied by:
Hyserve GmbH & Co.
Hechenrainer Str. 24
82449 Uffing
GERMANY

has been approved by Lloyd's Register Quality Assurance Limited in accordance with The MicroVal Rules and Certification Scheme. The validation has been performed in accordance with:

EN ISO 16140:2003

as demonstrated by report MB/REP/INT/940621/1

Certificate no.: RQA2007LR01

Validation date: 20 March 2007
Current date: 20 July 2011
Expiry date: 19 March 2015

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 1ml 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 in an alternative method to the standard plate count, enabling determination of aerobic colony counts in foods after 48 hour incubation.

HISTORY OF THE METHOD

In July 2011 the renewal of the MicroVal certification for the Compact TC has been undertaken without performing additional validation study since neither the Compact Dry TC method, nor the reference method, nor the kit insert have been changed.

SCOPE

All human food products

RESTRICTION OF USE

None

REFERENCE METHOD

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 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.

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:

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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

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 alternative method)
x = log (N 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. This was noticeable during the 72h reading of plates that had previously been read at 48h. Plates containing high numbers of colonies were easy to read from the reverse but it was remarked that a more clearly defined grid system for counting

colonies would improve counting, especially when colony numbers are high. Spreading/merging of colonies was observed with some plates at high and low concentrations.

INTERLABORATORY STUDY

The inter-laboratory study was conducted in November 2006 with 14 laboratories from 5 different EU countries. The analyses were carried out on pasteurised milk samples artificially contaminated with an Escherichia coli strain.
The laboratories tested, using each of two methods, two replicates per contamination level.

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	0.157	0.190	0.085	0.284	-0.117
Medium (10^3)	26	0.116	0.266	0.112	0.268	-0.099
High (10^4)	26	0.212	0.268	0.114	0.271	-0.049

The result of 1 laboratory have not been taken into account because of unacceptably high counts in each of the negative control samples.

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.