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Homogeneity of reference material Dw 2021:B

Homogeneity is evaluated by use of some different measures, both decisive ones and other to understand the result distribution. Duplicate analyses from 10 vials have been used.

Test 1[#] is a numerical check to see if the cfu results *within the vials* are randomly distributed as expected by a Poisson distribution. The ratio between variance/mean is used as the test value for an "Index of dispersion". This value is compared with what is expected from a χ^2 distribution. If the value is higher than expected there is an over dispersion, if the value is lower than expected there is an under dispersion (**I₁**).

Test 2[#] is similar to test 1 but here the "Index of dispersion" compares the results *between vials* (**I₂**). [**Decisive**]

Test 3 is a one way analysis of variance, ANOVA (**AN**), to *check if the variance* (= the squared standard deviation) *is larger between vials than within*. If there is strong under dispersion in test 1 (unusually small variation due to chance) the variation between vials will, relatively seen, be regarded as large. This situation may result in a high F-value even when variation between vials is not unusually large. *This test is a traditional one in e.g. chemistry.*

Test 4^{##} is a separate test of reproducibility *between vials* (**T**) that has the property to be insensitive to the cfu values (in contrast to **I₂**, where high cfu results will more easily be deemed inhomogeneous than low cfu results). [**Decisive**]

The homogeneity is judged as satisfactory when the two decisive criteria, **I₂** and **T**, not simultaneously have values larger than 2.

Based on calculations of **T₁** and **T₂**, respectively, according to BCR information, Report EUR 15008 EN, 1993 (Statistical analysis of certification trials for microbiological reference material)

RIVM Report 250935001/2003. KA, Moojman, M During, NJD Nagelkerke. MICROCRM: Preparation and control of batches of microbiological reference material consisting of capsules.

Mean values and measures of homogeneity for RM Dw 2021:B¹

Analysis	Volume (ml)	Mean value		CV ² (%)	Homogeneity ⁴			
		(cfu)	$\sqrt{(cfu)}$		I ₁	AN ³	I ₂	T
Microfungi – Moulds 25 °C. 7d	10	25	4.979	11.5	1.10	NS	1.51	1.66
Microfungi – Yeasts 25 °C. 7d	10	20	4.498	11.8	0.71	NS	1.54	1.76
Actinomycetes 25 °C. 7d	5	58	7.630	5.9	1.06	NS	0.50	1.19

1 Results from 10 vials in duplicate dissolved in 500 ml diluent 16 weeks after freeze-drying. For more information, see INSTRUCTIONS.

2 Coefficient of variation (CV) is SD as per cent of the mean (square-root transformed values), where SD is the pooled standard deviation from the ANOVA with a degree of freedom of 19.

3 NS: not significant F-test; *, **, ***: F-test significant on the levels 5, 1 and 0.1%, respectively.

4 The decisive tests of homogeneity. **I₂** and **T**, together indicate homogeneity.