### 5.8 Test validation

The results of a test shall be accepted for further evaluation if they conform to the following criteria, otherwise the test shall be repeated.

Requirements for acceptance of test results are :

a) All results from at least 12 subjects shall be available.

b) The overall mean of the log prevalues for reference and test procedure(s) shall be at least 5,00.

c) In each procedure, R and P, not more than three individual log reduction factors fewer than 3,00 shall occur.

### 5.9 Evaluation of P

If the quality of the data has been found acceptable (see 5.8), they shall be used for the evaluation of the antimicrobial efficacy of the product(s) under test by applying the following pass criterion :

– For any product, the mean log reduction factor obtained shall not be significantly smaller than that obtained for the reference propan-2-ol ;

– If the mean log reduction factor of a test product is smaller than that of the reference propan-2-ol, the difference shall be tested for statistical significance (see 5.10) ;

– If the mean log reduction factor is significantly smaller than that obtained with the reference propan-2-ol, the test product does not conform to this standard.

### 5.10 Significance testing

NOTE : Examples of significance testing are given in tables C.1 to C.5.

For testing the mean log RF of P against that of R, the Wilcoxon matched-pairs signed-ranks test shall be used (see tables C.4 and C.5).

For testing the data obtained in a Latin-square design experiment, the (k-1) sign test by Rhyne and Steel [5] shall be used, comparing means of more than one test procedure with that of the reference in a pairwise manner.

Because of the confirmative nature of the test in this application, the level of significance is set at p = 0,1. The test is to be used one-sided. The discrimination efficiency of the test procedure described has been set to detect a difference between the two mean log reduction factors of approximately 0,6 log at a power of 95 %.