

OBJECTIVE

Method equivalency between the international standard reference for challenge tests on cosmetic products (ISO 11930) and TEMPO® method for challenge tests (TEMPO® CTB and CTB). This equivalency study on cosmetic products is realized in complement to the quantification performances evaluation performed according to USP <1223>.

INTRODUCTION

bioMérieux has developed two parameters for the TEMPO® system in order to offer an innovative solution for challenge testing of cosmetic products. **This method increases CT throughput and delivers fast result, with a 50% reduction of labor savings. It allows then to manage variation of activity and to reduce the product development cycle.**

These two parameters, TEMPO® CTB and TEMPO CTF, are respectively dedicated to enumerate bacteria, yeasts and molds during challenge testing.

The aim of this study is to verify that Tempo, integrated into a cosmetic microbiological lab, can be used for challenge testing, through a comparative study between TEMPO® method and ISO 11930 method concerning these two points :

- Demonstration of the neutralization efficacy
- Demonstration of the efficacy of antimicrobial preservation of formulations

This study has been realized by ACM Pharma, a contract lab who has an ISO11930 accreditation delivered by the french accreditation committee (COFRAC) on 20 R&D formulations.

Formulations have been analyzed in parallel with the two methods, and results have been compared at two levels : enumeration values comparison and formulation acceptance comparison.

MATERIALS

Strains : ISO 11930 recommended strains has been used (Table below).

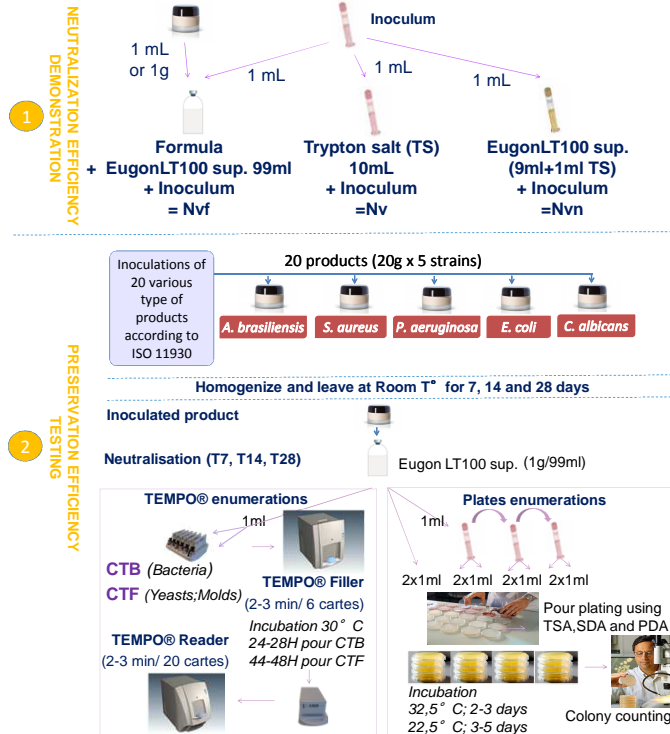
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Pseudomonas aeruginosa</i>	ATCC 9027
<i>Escherichia coli</i>	ATCC 8739
<i>Candida albicans</i>	ATCC 10231
<i>Aspergillus brasiliensis</i>	ATCC 16404

Formulations : 20 R&D formulations (unknown composition) has been selected by the contract lab with the following specifications:

- 5 formulas previously analyzed and rejected
- 5 formulas previously analyzed and accepted
- 10 formulas with no specifications

with groups of 2/3 formulas maximum coming from the same cosmetic company.

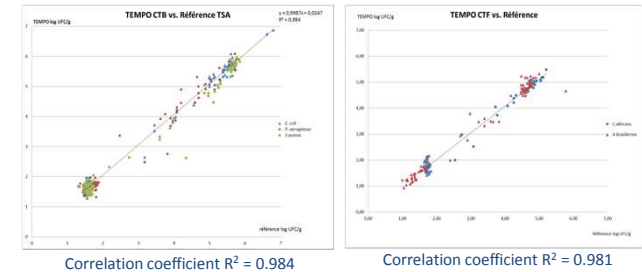
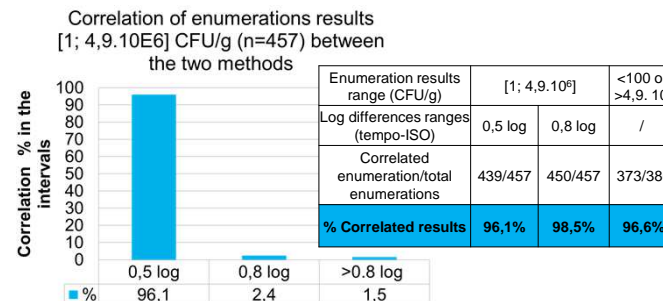
METHODS



In order to compare ISO11930 and TEMPO results on cosmetic products, 20 formulations has been inoculated separately with the ISO11930 5 standard strains, and has been enumerated in parallel with the two methods at Day 0, Day 7, Day 14 and Day 28 using the same initial neutralization dilution.

RESULTS

1- Enumerations results comparison : 457 pairs of enumerations has been compared and shows a correlation >95% between the two methods within the 0,5 log interval.



2- Formulations acceptance comparison: acceptance is obtained when log reductions requirements described in the ISO11930 standard are fulfilled. Log reductions calculations led to the same interpretations for the 20 formulas with the two methods : 14 were accepted with A criteria, 1 with B criteria and 5 were rejected (no A no B).

For each formula, the neutralization efficiency demonstration has been realized (Nv ~100 CFU; Nvn close to Nv and Nvf ≥ 0,5Nvn) to validate or adapt the dilution of the neutralized sample into the cards.

Formulas	ISO	Tempo	Non conform strains
1 Gentle Make Up cleanser	Failed	Failed	<i>E.c; P.a; C.a</i>
2 Anti-aging cream for night	Failed	Failed	<i>P.a</i>
3 Cream for sensitive/ dry skin	Failed	Failed	<i>E.c; P.a; C.a; A.b</i>
4 Anti-aging serum 1	A criteria	A criteria	
5 Honey moisturizing cream	A criteria	A criteria	
6 Anti-aging serum 2	A criteria	A criteria	
7 Cream for dry skin	A criteria	A criteria	
8 Thermal micellar water	A criteria	A criteria	
9 Sunscreen SPF 30	A criteria	A criteria	
10 Baby's cream	B criteria	B criteria	<i>A.b</i>
11 Foaming cleansing gel	A criteria	A criteria	
12 Sunscreen SPF 30 in spray	A criteria	A criteria	
13 Eye area anti-aging cream	A criteria	A criteria	
14 Thermal spray for kids	A criteria	A criteria	
15 Serum for men's	A criteria	A criteria	
16 Skin cream	A criteria	A criteria	
17 Anti aging cream	A criteria	A criteria	
18 Anti-aging cream fo night 2	A criteria	A criteria	
19 Foaming formula	Failed	Failed	<i>E.c; P.a; S.a; A.b</i>
20 Oil in water formula	Failed	Failed	<i>E.c; A.b</i>

Conclusion

Concordance of results are >95% within the 0,5 log interval.

Enumeration results showed a correlation coefficient of >0,98 between the two methods, for the two parameters CTB and CTF.

Acceptation of formulas are 100% correlated : conformity results are equivalent between the reference method and TEMPO® method on 20 formulations using the ISO11930 interpretation criteria.

Challenge tests results determined in this study with Tempo® are comparable to the ISO 11930 traditional method results.