

## INFORMATION ON THE CHALLENGE TEST SERVICE FROM COSPHATEC

Cosphatec offers challenge testing according to ISO 11930 and to European Pharmacopoeia (Ph. Eur.) 5.1.3. as a service to our customers.

The challenge test method based on ISO 11930 is widely used and recognised as a standard test for checking the microbial stability of a cosmetic product. The challenge test method based on the Ph. Eur. 5.1.3 was designed primarily for non-sterile pharmaceutical products but can also be applied to cosmetic products.

Although both are recognized methods and similar with respect to many test parameters, they differ in the inoculation of yeasts and moulds, testing time points and acceptance criteria. The inoculation method according to Ph. Eur. provides  $10^5$ - $10^6$  cfu/g, whereas ISO 11930 describes a slightly lower inoculation of yeasts and moulds of  $10^4$ - $10^5$  cfu/g. We have summarized the differences in the testing time points and acceptance criteria in the following table.

REQUIRED LOGARITHMIC REDUCTION VALUES					
		Ph. Eur. 5.1.3.		ISO 11930 <sup>a</sup>	
Germ	Day	A rating	B rating	A rating	B rating
Bacteria	2	≥ 2	-	-	-
	7	≥ 3	-	≥ 3	-
	14	-	≥ 3	≥ 3 and NI <sup>b</sup>	≥ 3
	28	≥ 3 and NI <sup>b</sup>	≥ 3 and NI <sup>b</sup>	≥ 3 and NI <sup>b</sup>	≥ 3 and NI <sup>b</sup>
Yeasts	7	-	-	≥ 1	-
	14	≥ 2	≥ 1	≥ 1 and NI <sup>b</sup>	≥ 1
	28	≥ 2 and NI <sup>b</sup>	≥ 1 and NI <sup>b</sup>	≥ 1 and NI <sup>b</sup>	≥ 1 and NI <sup>b</sup>
Moulds	14	≥ 2	≥ 1	≥ 0 <sup>c</sup>	≥ 0 <sup>c</sup>
	28	≥ 2 NI <sup>b</sup>	≥ 1 and NI <sup>b</sup>	≥ 1 and NI <sup>b</sup>	≥ 0 and NI <sup>b</sup>

a: acceptable range of deviation of 0.5 log is accepted

b: NI: no increase in the count from the previous contact time

c: No increase from the initial count

The choice of test method depends on individual factors. Depending on the customer's requirements, a challenge test method is selected and commissioned by us.

## PROCEDURE



1. Cosphatec requires the following information from the customer for placing the order:

- Selected challenge test method
- Preservation system (concentration and name of antimicrobials used)
- Formulation pH value
- Formulation type (O/W, W/O, surfactant-based, water-based)



2. For the challenge tests, 300 grams per sample are needed. Please send your samples in sufficiently labelled containers with a wide opening to the following address:

Johanna Wientapper  
Cosphatec GmbH  
Hopfenmarkt 33  
Germany



3. As soon as the challenge tests are commissioned, the responsible sales manager will send you the first interim results after approx. 2-3 weeks. The final report can be expected after approx. 6-7 weeks.

If you have any further questions about the challenge test methods or our service, please feel free to contact us.