

	<b>Technical Information</b>	<b>730-180-EN</b>		<b>V03</b>
	<b>Purity of biological indicators</b>	Created	12.04.2021	UK
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The main quality characteristic of a biological indicator (BI) is its resistance to a defined sterilization procedure, which is also indicated as the  $F_{\text{Bio}}$ -value. This value can be calculated by multiplying the decimal logarithm of the population with the decimal reduction time (D-value) of the BI:

$$F_{\text{Bio}} = \lg \text{pop} \times \text{D-value}$$

This means, for example, that the population only counts logarithmically, therefore a  $10^6$  CFU indicator is only approx. 10 % more difficult to inactivate than a  $10^5$  CFU BI of the same D-value. Therefore the D-value is the main factor, which can only be determined with a resistometer according to DIN EN ISO 18472. Purity and even population are therefore much less important factors for resistance - which is also taken into account in the existing standards and pharmacopoeias:

- According to EN ISO 11138-1, either several different species or even small impurities may be present on the spore carrier of the BI if these do not have a negative effect on the function of the BI.
- In USP <1229.5> there is a requirement for purity:  
„By examination of the colonies derived from the spores on a suitable plate culture media, determine, that there is no evidence of contamination with other microorganisms“

However, signs of minor contamination can be detected using selection agar methods or sensitive proteomic MALDI-TOF (mass spectrometry) or PCR (polymerase chain reaction) amplification methods. Therefore, it is possible that very small amounts of other species <1000 CFU/BI may be found in a bioburden determination according to EN ISO 11737-1, Annex B. However, this does not play a role for the resistance of BIs and is not required.

GKE's standard biological indicators are produced aseptically as a suspension, but are not aseptically inoculated, assembled and packaged. This would increase the price 10 times without offering any advantages.

All of GKE's biological indicators (BI) comply with EN ISO 11138-1:2017 and USP NF2022.