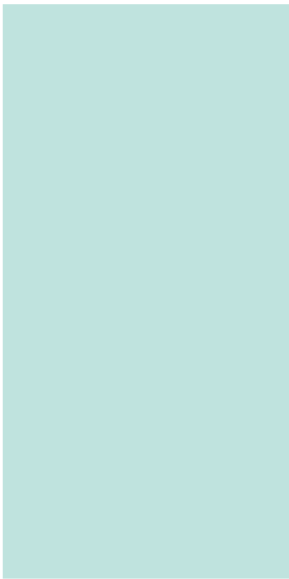


Q7

1

2

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products under practical conditions. However, the method-









some contradictory data are available on this topic [46]. Therefore, the consensus group considers that in most of cases, the evaluation of the sterility of the final product is not generally required in the stability studies. However, the evaluation of long-term preservation of sterility is mandatory for preparations expected to be stored for a long-term such as batches preparation, drug diluted in dextrose or infusions with components considered as promoters of bacterial growth such as proteins. In these cases, any ‘‘microbiological stability’’ study should be designed taking in account the specificity of the final product.



