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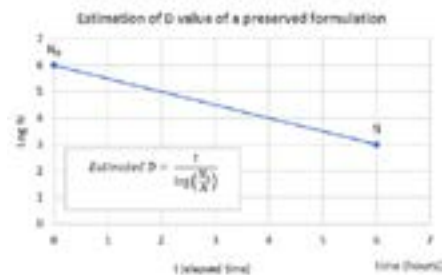
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Preservation in medicines, a QbD approach to optimize microbiological quality of pharmaceutical formulations

Preservatives have long been used in the formulation of liquid and semisolid medicines to ensure microbial quality during their shelf life and use. However, preservatives may cause undesirable effects both topically and systemically and even contribute to antibiotic resistance of microorganisms. Therefore, they should be either avoided or minimized. Within the present regulatory framework of Quality by Design recommended by ICH guidelines, a decision-tree approach is proposed to either avoid or minimize the use of preservatives. An optimization procedure to find the optimal concentration of preservative is described, on the basis of the works of Orth DS. It consists of criteria for the selection and estimated concentration ranges of preservatives for a certain formulation coupled with a procedure to estimate D values for different microorganisms. D value is a

quantitative measure of preservative efficacy of the formulation, allowing the use of regression analysis to optimize preservative concentration and other formulation parameters, thus accelerating and improving the process of formulation development.



Biography

Vega Julio Cesar has graduated in chemistry at the University of Buenos Aires. He holds a degree as master of industrial business administration from Escuela de Organización Industrial de Madrid and a postgraduate degree in Industrial Business Administration from Universidad Católica Argentina. He is R&D Manager at Laboratorio Pablo Cassara S.R.L., a pharmaceutical company in Argentina. He is author and co-author of patents related with pharmaceutical formulations and pharmaceutical primary packaging materials. He is co-author of an article on melanoma cells cryopreservation.

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