

VAC_16 - Establishment 5 doses presentation of the triple viral vaccine without albumin to reduce loss during administration

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Introduction: The World Health Organization recommends not using components of human origin in the manufacture of immunobiologicals in order to deliver safer products. The National Immunization Program, on the other hand, seeks to supply vaccines in smaller presentations, aiming to reduce losses that occur in the field during its administration. The maintenance of the stability of products without such components and the guarantee of industrial effectiveness and economic-financial sustainability in the production of smaller presentations, are the great challenges for their manufacturers.

Objective: Establish 5 doses presentation of the MMR vaccine without albumin, ensuring less waste in the field and maintaining its productive capacity and meeting demand.

Methodology: Evaluation of subsidiary approaches for strategic decision-making processes of the product portfolio linked to the evaluation of the impact on production capacity. Characterization of thermophysical properties by different analytical methods (DSC, FDM, SRE) combined with screening of processing conditions (two types of vials and four levels of filling volumes), production of experimental batches and the respective quality assessment of the finished product.

Results: Based on the processing conditions of the current vaccine, to establish a 5-dose presentation, reducing the filling volume by 50% and maintaining the vial model, the loss in production capacity is around 50%. Thus, in addition to reducing the volume, it was proposed to replace the vial model. Preliminary results showed unsatisfactory values in terms of aspect and residual moisture of the finished product. Therefore, it was proposed to reduce the filling volume by 67%, requiring the recalculation of the concentrations of the components introduced in the vaccine formulation. For a 2-dose presentation, reducing the filling volume by 83%, replacing the vial model, the loss is on the order of 60%. For a single-dose presentation, reducing the current filling volume of the vaccine by 93%, replacing the vial model, the loss is on the order of 80%. In all these conditions, the quality parameters presented values in accordance with the established approval limits.

Conclusion: The results demonstrate that only the 5-dose presentation, with a 67% reduction in filling volume, replacement of the current vial model and recalculation of vaccine component concentrations, maintains the productive capacity with the number of doses per batch produced, in the same time and lyophilization cycle currently used.

Keywords: MMR vaccine; Productive capacity; Vaccine waste