

Are RSA vials approved by the FDA for use in clinical testing - FAQ

The FDA does not “Approve or Disapprove” of vials for use in analytical testing.

Therefore any vial may be used for this purpose to be compliant with FDA regulations including the RSA™ vials. However, if vials are used for human clinical testing or packaging of pharmaceuticals or diagnostics, you might need to validate and get FDA certified. Please check with your regulatory department.

The RSA vials are designed for analytical testing and while this application would be outside the scope of the products' intended use, since RSA vials are not coated and are TYPE-33 borosilicate glass, they do not fall into a problem category such as with a coating and are simpler to get validated.



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