Are RSA Vials Approved by the FDA for Use in Clinical Resting - FAQ

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The **FDA does not "approve" or "disapprove"** specific vials for use in analytical or clinical testing. Instead, the FDA focuses on whether the overall process and materials used in a regulated application (such as clinical trials, pharmaceutical packaging, or diagnostic testing) meet compliance standards.

✅ Use in Analytical Testing

RSA™ vials are specifically designed for analytical laboratory applications, including LCMS, HPLC, and other high-sensitivity workflows. They are made from TYPE-33 borosilicate glass and are **free of surface coatings**, which reduces the risk of chemical interference and simplifies validation for many lab environments.

⚠️ Use in Clinical or Regulated Applications

If RSA™ vials are intended for use in:

- Human clinical testing
- Pharmaceutical packaging
- Diagnostic sample collection or storage

…then *regulatory validation is required.* This may include:

- Material compatibility testing
- Leachables and extractables studies
- FDA submission and certification (if applicable)

In these cases, we strongly recommend consulting your regulatory or quality assurance department to determine what documentation or testing is needed to support FDA compliance.

🔍 Why RSA™ Vials May Be Easier to Validate

Because RSA™ vials are:

- Made from high-purity borosilicate glass
- Not coated (unlike some specialty vials)
- Manufactured for low adsorption and low extractables

…they often present fewer regulatory hurdles compared to coated or chemically treated vials.

🔗 Click **HERE** for RSA™ Glass Vial Ordering Information and Product Images

RSA™
REDUCED SURFACE ACTIVITY GLASS

MicroSolv Technology Corporation
9158 Industrial Blvd. NE, Leland, NC 28451
Tel: (732) 380-8900
Fax: (910) 769-9435
Email: customers@mtc-usa.com
Website: www.mtc-usa.com