

*Contains Nonbinding Recommendations*  
*Draft – Not for Implementation*  
**Draft Guidance on Air Polymer-Type A**  
**August 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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**Active Ingredient:** Air polymer-type A

**Dosage Form:** Foam

**Route:** Intrauterine

**Strength:** 10 mL

**Recommended Studies:** In vitro comparative physicochemical characterization studies

**In vitro comparative physicochemical characterization studies:**

The comparative studies should be performed on at least three exhibit batches<sup>1</sup> of the test and three batches of the reference standard (RS) products and should include:

- a. Appearance, density, viscosity and pH of the gel
- b. pH of the water
- c. Bubble size and concentration (number of bubbles/mL, for bubbles between 20 to 200 micrometers) of the reconstituted product by Coulter counter analysis
- d. Appearance and osmolality of the reconstituted product

**Additional comments:**

1. Foam preparation should follow the label instructions and should be used in the comparative studies within five minutes of reconstitution.

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<sup>1</sup> The manufacturing process for the exhibit batches should be reflective of the manufacturing process to be utilized for commercial batches.

2. If the test product is not qualitatively (Q1<sup>2</sup>) and quantitatively (Q2<sup>3</sup>) the same as the reference listed drug (RLD), an additional study or studies to identify any increased risk posed by the differing inactive ingredients or formulation differences between the test product and the RLD may be necessary.
3. Depending upon the specific study or studies recommended, e.g., safety assessment following intrauterine exposure, a test drug product that is not Q1/Q2 the same as the RLD may need to be submitted in a new drug application to the FDA.

**Additional information:**

Device:

The RLD is presented as a kit with two prefilled syringes containing different drug formulation components and a syringe-to-syringe adapter. The device constituent parts are the two pre-filled syringes and the syringe-to-syringe adapter.

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD device when designing the test device including:

- Single-use, single-dose format of the pre-filled syringes
- Syringe-to-syringe adapter

User interface assessment:

An abbreviated new drug application for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.<sup>a</sup>

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<sup>a</sup> For the most recent version of a guidance, check the FDA guidance website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>2</sup> Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the RLD.

<sup>3</sup> Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the RLD.