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Draft Guidance on Vamorolone

May 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

Active Ingredient: Vamorolone

Dosage Form: Suspension

Route: Oral

Strength: 40 mg/mL

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 40 mg/mL at the dose of 200 mg (5 mL)
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with latent tuberculosis. Subjects should be informed not to use live attenuated or live vaccines at least 4 to 6 weeks prior to or during the study.

Analyte to measure: Vamorolone in plasma

Bioequivalence based on (90% CI): Vamorolone

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Additional information:

Device:
The RLD is supplied as 100 mL in 125 mL glass bottle packaged with one bottle adapter and two 5 mL oral syringes. The oral syringes are the device constituent parts. For further information regarding the bottle adapter, see the most recent version of the FDA guidance for Industry on *Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products Guidance for Industry*. [a]

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

- Calibrated volume markings
- Number of co-packaged oral syringes

User interface assessment:
An ANDA 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*.[a]

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Unique Agency Identifier: PSG_215239

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

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*