

Draft Guidance on Aspirin

October 2025

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Active Ingredient:	Aspirin
Dosage Form:	Capsule, extended release
Route:	Oral
Strength:	162.5 mg
Recommended Studies:	Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 162.5 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 162.5 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analytes to measure: Acetylsalicylic acid and its active metabolite, salicylic acid in plasma

Provide the data for salicylic acid as supportive evidence of comparable therapeutic outcome. For salicylic acid, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C_{max}.

Bioequivalence based on (90% CI): Acetylsalicylic acid

Additional strengths: Not applicable

Dissolution test method and sampling times: For modified release drug products, applicants should develop specific discriminating dissolution methods. Alternatively, applicants may use the dissolution method set forth in any related official United States Pharmacopeia (USP) drug product monograph, or in the FDA's database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>, provided that applicants submit adequate dissolution data supporting the discriminating ability of such a method. If a new dissolution method is developed, submit the dissolution method development and validation report with the complete information/data supporting the proposed method. Conduct comparative dissolution testing on 12 dosage units for each strength of the test product and the reference list drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

In addition to the method above, submit dissolution profiles on 12 dosage units for each strength of the test product and RLD generated using USP Apparatus 1 at 100 rpm and/or Apparatus 2 at 50 rpm in at least three dissolution media (e.g., pH 1.2, 4.5, and 6.8 buffer). Agitation speeds may be increased if appropriate. It is acceptable to add a small amount of surfactant if necessary. Include early sampling times of 1, 2, and 4 hours and continue every 2 hours until at least 80% of the drug is released to provide assurance against premature release of drug (dose dumping) from the formulation.

Alcohol dose dumping studies: None

Document History: Recommended July 2017; Revised October 2025

Unique Agency Identifier: PSG_200671

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*.