

3.7 Undue toxicity

The test is used to determine the absence of undue toxicity of antibiotics intended for parenteral administration.

Recommended procedure

Use healthy mice of a single strain that have not previously been used for any test. Select 5 mice, each weighing between 18 g and 22 g. Prepare the solution of the test substance as specified in the monograph. Inject a test dose of 0.5 mL intravenously into a tail vein at a uniform rate, the injection occupying 5 seconds. Keep the mice under observation for 48 hours after the injection. The product meets the requirements for freedom from undue toxicity if no animal dies within 48 hours.

If 1 or 2 mice die within the observation period, repeat the procedure once, using respectively 5 or 15 mice, healthy and not previously used for any test, each weighing between 19.5 g and 20.5 g. The product under test meets the requirements for freedom from undue toxicity if no animal dies in the repeat test within the observation period (48 hours).