

PHARMACEUTICAL / API TEST REQUISITION FORM

Company:

Contact:

FINAL REPORT WILL BE SENT TO THE ADDRESS PROVIDED BELOW.

Address:

Phone:

E-mail:

ENTER ADDRESS IF DIFFERENT THAN COMPANY ADDRESS

Billing Address:

Quote #:

P.O.#

Study Request

Compliance	Study Name	Protocol Number (if applicable)
Select <input style="width: 50px; height: 15px;" type="text"/>	<input style="width: 310px; height: 15px;" type="text"/>	<input style="width: 240px; height: 15px;" type="text"/>
Select <input style="width: 50px; height: 15px;" type="text"/>	<input style="width: 310px; height: 15px;" type="text"/>	<input style="width: 240px; height: 15px;" type="text"/>
Select <input style="width: 50px; height: 15px;" type="text"/>	<input style="width: 310px; height: 15px;" type="text"/>	<input style="width: 240px; height: 15px;" type="text"/>
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Test Materials Information (Exact wording will be used in the final report)

Description		
Test article identification:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Lot /Batch Number:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
CAS Number:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Physical Description:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Color:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Expiration Date:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Storage Requirement:	<input style="width: 230px; height: 15px;" type="text"/> If Other, specify: <input style="width: 70px; height: 15px;" type="text"/>	<input style="width: 110px; height: 15px;" type="text"/> If Other, specify: <input style="width: 70px; height: 15px;" type="text"/>
Special storage or handling requirements:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Formulation instructions*:	<input style="width: 410px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>
Disposition: <small>Will the unused test article and any Sponsor-supplied controls and vehicles be returned to Sponsor?*</small>	<input style="width: 230px; height: 15px;" type="text"/>	<input style="width: 260px; height: 15px;" type="text"/>

Safety Data Sheet (SDS) and Certificate of Analysis (COA) must be provided. OSHA, Town of Bedford, and other regulatory agencies require this information, we will not be able to proceed with testing without the safety data for handling and disposal.

*Attach additional sheets if necessary for each Test of Control Material.
**The Sponsor is responsible for all shipping, returns, and associated costs.

Initials: _____

Date: _____

Test Article Characterization

Toxikon Corporation requires characterization of the test article to include, but not limited to, identity, purity, strength, classification, and composition. This ensures the integrity of dosing solutions as well as the safety of those handling the test article. A copy of this characterization will be included as an appendix to the study report and will be archived within the study file.

1. Has the test article been characterized?

Select

2. Is stability data readily available for test article?

Select

Test Article Preparation/Formulation

Dose preparation, concentration verification, and stability of dosing solutions are integral part of any study.

1. Will test article be utilized as prepared by Sponsor? Does the Sponsor assume all dose preparation and analytical confirmation?

Select

2. Does the Sponsor request formulation of dosing solutions by Toxikon? If so, is a vehicle and protocol for such a preparation available?

Select

3. Is stability of test article in specified vehicle known?

Select

4. Does the Sponsor request analytical confirmation of dosing solutions by Toxikon?

Select

5. If yes, has an analytical method been provided to Toxikon?

Select

6. Has a certificate of analysis been provided?

Select

To be in compliance with GLP regulations, the test article(s) and control article(s) must be characterized in regard to stability and identity, strength, purity, composition, or other characteristics to define the test and control articles. In addition, test and control article preparations must be analyzed to determine their stability and uniformity (as applicable) or concentration. Toxikon will not perform any of these services on test article or dosing preparation unless specifically contracted to do so. The negative, positive, and predicate control articles that may be utilized as part of the study design are characterized per Certificate(s) of Analysis on file with Toxikon from the manufacturer or vendor, or provided by the Sponsor.

If the Sponsor has not performed the above characterizations on the test article and/or dose preparation verification, these items will be listed as exceptions on the GLP Compliance Statement on the report. To facilitate proper incorporation and reporting of this data wherever required, Toxikon should be provided the analytical data or should be contracted to conduct these analyses for the Sponsor. **FAILURE TO PROVIDE TEST ARTICLE CHARACTERIZATION MAY DELAY THE SCHEDULED LABORATORY START DATE. IT MAY ALSO AFFECT REGULATORY COMPLIANCE OF THE STUDY SINCE STUDY DIRECTOR WILL HAVE TO DRAW STUDY SUMMARY CONCLUSIONS IN THE ABSENCE OF THIS DATA.**

PLEASE EMAIL SCANNED VERSION OF COMPLETED AND SIGNED REQUEST FORM TO LOG-IN@TOXIKON.COM OR FAX TO 781-271-1138, SUBMIT SAMPLES TO TOXICOLOGY LOGIN AT 15 WIGGINS AVENUE, BEDFORD, MA 01730

TO BE COMPLETED BY SPONSOR REPRESENTATIVE

By submitting to Toxikon Corporation a completed copy of this form and a signed copy of the protocol(s) and all ancillary records, it is understood that the Sponsor assumes responsibility for completeness and advisability of the study contract documentation. The services to be provided shall be in all respects subject to and governed by the Terms and Conditions of Toxikon's contract documents previously agreed to by the undersigned. Your dated signature below attests to the completeness and accuracy of information that you have provided.

Sponsor signature:

Date:

Print Name:

FOR TOXIKON USE ONLY

Project number:

Initials:

Special instructions:

Date:

TO BE COMPLETED BY TOXIKON REPRESENTATIVE

My dated signature below attests to a review of the information that has been provided by the Sponsor.

Study Director signature:

Date:

Print Name:

Initials: _____

Date: _____