

Chemistry Specifications for Chemistry Services Contractors

National Toxicology Program

Appendix 1. Report Formatting Requirements

Final

August 11, 2016

***A4.1.1. Monthly Progress Report – Content and Format*****1. Introduction**

The following sections depict the required cover page format, monthly progress report content requirements for each section, and formatting requirements for the data presented.

Contractor's Contract Number

mmddyyyy (Report Date)

STATUS REPORT – #

mmddyyyy – mmddyyyy

Chemistry Support Services for the National Toxicology Program

Contract No N01-ES-nnnnn

Approved By:

  
  

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Submitted To:

COR

National Institute of Environmental Health Sciences

111 Alexander Drive

P.O. Box 12233

Research Triangle Park, NC 27709-2233

Chemistry Support Services Monthly Status Report – #      Report Date Page

## 1. INTRODUCTION

This report describes the project activities performed under the chemistry support services contract for the NIEHS, Contract No N01-ES-{nnnnn} during {report period}. The status of current assignments in progress during the reporting period is shown in the tables that follow. The status categories used in the tables in this report are defined as follows;

Started	Work initiated during the reporting period but not completed
Continued	Work initiated during a previous reporting period but not completed
Report	Work in either of the first 2 categories for which the lab work is completed and the report is in progress
Review	Work for which a report has been issued, but not yet approved
Completed	Work for which a report has been issued and approved.

Table 1.1. Program and Funding Codes

Program/Funding Code	Description
Funding Codes	
NTP	Work done in support of NTP contract or in-house research
etc.	
Program Codes	
NTEC	Work done as part of the NTP nanotechnology initiative
etc.	

Table 1.2. Functional Activity Acronyms

Functional Activity Acronym	Functional Activity
BCM	Biochemical Measurement
CCA	Chemical Characterization
CH	Chemical Handling
etc.	

## 2. REPORTS ISSUED

{Number of reports} analytical reports and {number of interim reports} interim reports were issued during the {reporting period}.

### 2.1. BASE CONTRACT

A list of all reports issued under the Base contract and Option years is presented below.

Table 2.1. Reports Issued – Base Contract and Option Years

Functional Activity	Chemical Name	Work Description	Species/Strain	Status Code	Lab Assigned Work No.	NTP Assigned Work No.

### 2.2. OPTION X<sup>1</sup>

A list of all reports issued under Option X is presented below.

Table 2.2. Reports Issued – Option X

Functional Activity	Chemical Name	Work Description	Species/Strain	Status Code	Lab Assigned Work No.	NTP Assigned Work No.

## 3. MATERIALS HANDLING<sup>2</sup>

### 3.1. SAMPLE RECEIPT

A list of all samples received under the Base Contract and Option X is presented below.

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<sup>1</sup> This section may include multiple option tables if more than one option is exercised.

<sup>2</sup> Subsections may include multiple option tables if more than one option is exercised.

Table 3.1.1. Samples Received – Base Contract

Sample Type	Species /Strain	Sample Description	Sample Codes	Lab Assigned Work No.	NTP Assigned Work No.

Table 3.1.2. Samples Received – Option X

Sample Type	Species /Strain	Sample Description	Sample Codes	Lab Assigned Work No.	NTP Assigned Work No.

### 3.2. PROCESSING

A list of all sample aliquots prepared under the Base Contract and Option X is presented below.

Table 3.2.1. Aliquots Prepared – Base Contract and Option Years

Aliquot Type	Species /Strain	Sample Description	Sample Codes	Lab Assigned Work No.	NTP Assigned Work No.

Table 3.2.2. Aliquots Prepared – Option X

Aliquot Type	Species /Strain	Sample Description	Sample Codes	Lab Assigned Work No.	NTP Assigned Work No.

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3.3. SHIPMENT

A list of all shipments under the Base Contract and Option X is presented below.

Table 3.3.1. Shipments – Base Contract

Sample Type	Species /Strain	Sample Description	Sample Codes	Lab Assigned Work No.	NTP Assigned Work No.

Table 3.3.2. Shipments – Option X

Sample Type	Species /Strain	Sample Description	Sample Codes	Lab Assigned Work No.	NTP Assigned Work No.

4. SAFETY PROGRAM

This section describes all accidents and/or injuries, industrial hygiene, and training activities involving contract staff during the reporting period. Hazardous chemical disposal activities and costs are reported here.

4.1. Accidents/Injuries

4.2. Industrial Hygiene

4.3. Hazardous Chemicals/Waste

Table 4.3.1. Surplus Chemicals Disposed

Chemical Name	Lot No.	Supplier	Amount Disposed

Table 4.3.2. Other Hazardous Waste Disposal



Description of Hazardous Waste

4.4. Training

Table 4.4.1. Health and Safety Training

Month	Course Name	Course No.

4.5. Incident Response

4.6. Other Items

5. QUALITY ASSURANCE

A summary of the activities of the Quality Assurance Unit are described here along with a table that summarizes the work performed on individual assignments for the base contract and all exercised options during the reporting period.

Table 5 – Quality Assurance Activities

Functional Activity	NTP Assigned Work No.	Lab Assigned Work No.	Description of QA Activity	Status Code	Staff Person Responsible for Work

6. INFORMATION MANAGEMENT

This section describes activities relating to computer facilities, software, and equipment used under the Contract, including work performed on the contractors information management system and databases. Activities include routine maintenance, software and hardware upgrades, and software development projects related to the contract.

7. STATUS SUMMARY

7.1. STATUS OF ALL ACTIVE ASSIGNMENTS

The following table lists the status of all the work started, continued, reported, or completed during the reporting period.

Table 7. Active Assignment Status

NTP Assigned Work No.	Lab Assigned Work No.	Chemical Name	Functional Activity	Species/Strain (Vehicle)	Status Code*	Due Date	Date Completed

Comments for Active Status Table	
1	Include numbered comments that illustrate, clarify, or elaborate the assignment status.
2	Comment numbers shall be referenced in the status code column
3	
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.	
.	

## 8. FISCAL DATA

Monthly and cumulative summaries of total expenditures, direct costs and labor incurred on the project for {reporting period} are shown in the graphs. Sections 8.1 and 8.2 provide the monthly totals and cumulative contract costs for a rolling calendar year for the base effort and contract options. Costs are broken out for direct costs (attributable to a specific assignment) and administrative costs. Section 8.3 reports active assignment costs for all the work started, continued, reported, or completed during the reporting period sorted by funding source and program. Table 8.5 lists the estimated total cost, actual monthly cost, and cumulative cost for each active assignment.

Total project expenditures for {reporting period} were \$ nnn,nnn (including fee), of which \$ nnn,nnn was charged to specific assignments.

## 8.1. BASE CONTRACT

Table 8.1. Contract Costs – Base

Budgeted Amount for {yyyy}: \$

Month	Monthly Direct Costs	Monthly Administrative Costs	Monthly Total Costs	Cumulative Administrative Costs	Cumulative Total Costs
January					
February					
(etc.)					

Total Costs for {reporting period}: \$ {nnn,nnn}

8.2. OPTION(S) X (- Y)<sup>3</sup>

Table 8.2.1. Contract Costs – Option X

Budgeted Amount for yyyy: \$

Month	Monthly Direct Costs	Monthly Administrative Costs	Monthly Total Costs	Cumulative Administrative Costs	Cumulative Total Costs
January					
February					
(etc.)					

Total Costs for {reporting period}: \$ {nnn,nnn}

## 8.3. ACTIVE ASSIGNMENT COSTS

The following table lists all the work started, continued, reported, or completed during the reporting period for the base and each exercised option. The table is split into subtables by funding source and then by program. Total costs for each program are given after each subtable; total costs for each funding source may be found after the last subtable in each funding section.

Table 8.3.1. Active Assignment Costs

NTP ChemTask No.	Lab Assigned Work No.	Chemical Name	CSRN	Functional Activity	Estimated Cost	Period Cost	Cumulative Cost
CHEM10207							

<sup>3</sup> This section may include multiple option tables if more than one option is exercised.

(etc.)							
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Total Costs for {reporting period}: \$ {nnn,nnn}

Footnotes for Table 8.3.1

<sup>1</sup>First footnote narrative...

8.4. COST SUMMARY

This section presents invoiced costs for the current contract year for the Base contract and Option years and each exercised Option.

Table 8.4.1. Cost Summary<sup>4</sup>

Month	Base Costs	Option X Costs	Total Cost
January			
February			
(etc.)			
Total			
Budgeted			

Table 8.4.2. Cumulative Program Annual Cost Summary (Contract Year nn)

Month	AIDS Direct Costs	AIDS Admin Costs	AIDS Total Cost	Other Program or Funding e.g. HTS, DIR, etc.
January				
February				
(etc.)				
Total				

8.5 GRAPHS

This section contains plots of monthly and cumulative expenditures and labor hours for the base contract, option X, and the total contract displayed for a rolling calendar year. Plots shall be displayed such that the monthly and cumulative graphs for each contract unit are displayed on the same page. Plots shall display actual and budgeted amounts.

9. IT SECURITY PROGRAM

This section describes all IT security and training activities involving contract staff during the reporting period.

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<sup>4</sup> This table may include multiple option columns if more than one option is exercised.

- 9.1. System scans
- 9.2. Software updates
- 9.3. Security incidents and response
- 9.4. Data backups
- 9.5. Training
- 9.6. Other Items



**A4.1.3. Report Header and Cover Page Formats**

1. Rationale
  1. This section describes the information that must be included in each chemistry report submitted by the Contractor.
2. General Information
  1. To ensure that the information is presented consistently, formats for the report headers along with the information they must contain are given for each report.
  2. For 1-page reports the format for the entire report including the header section, along with the information that must be contained in the report is given.
3. Conventions Used in the Examples
  1. Words to be replaced by information from the Contractor are enclosed in curly braces (e.g., {Chemical Name} means to replace the phrase “Chemical Name” with the name of the chemical for which the report is being written).
  2. Words that supply information to the reader to clarify what is meant by a term in the header are enclosed in square brackets (e.g., Storage Conditions [@Analytical Lab] is intended to convey that the storage conditions to be entered here are those under which the chemical was stored at the analytical lab).
  3. Words enclosed in parentheses are intended to indicate that the information requested should be placed in parentheses.
  4. Words not enclosed in any type of bracket, braces, or parentheses are to be followed by the requested information (e.g., “CAS No.” should be entered into the header as CAS No. 1234-56-7). When there is a choice of words to be used as a label, they will be separated by a forward slash.
4. Report Headers

**Chemical Procurement (CP) report** (One Page)

## CHEMICAL PROCUREMENT REPORT

{CHEMICAL NAME}

{LAB ID NO.}

{REPORT DATE}

CAS No.	Amount Received
{LAB} Log No.	{LAB} Receipt Date
ChemTask No.	Lot No. (Vendor, City, State)
Program Supported	Vendor Purity [% or see attached]
Appearance	Storage Conditions
Lab Complete Date	

Prepared by: Approved by:

[Signature] [Signature]

{Preparer}

{Name}

{Title}

Principal Investigator

Submitted To:

{COR}

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**Chemical Handling (CH) report**

[Chemical Name]

CAS No.	Chemical Lot No. (Vendor, City, State, Vendor Purity)
{LAB} Chemical ID Code	Appearance
{LAB} Task/Log No.	
ChemTask No.	Vehicle(s)
Program Supported	Lot No(s). (Vendor, City, State, purity [if applicable])
Handling Date(s)	
Lab Complete Date(s)	
Draft Final Report Issued Date	

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

**Chemical Storage (CS) report** (One Page)

{LABNAME}

Chemistry Support Services for the NTP

NIH Contract No. N01-ES-{xxxxx}

{LAB} Project {nnn-nnnn-nnn}

ChemTask Number:

## CHEMICAL STORAGE REPORT

{CHEMICAL NAME}

{LAB ID NO.}

{REPORT DATE}

CAS No.	Amount Received
{LAB} Log No.	{LAB} Receipt Date
ChemTask No.	Received From
Program Supported	Lot No. (Vendor, City, State)
	Vendor or Last Analyzed Purity [date]
Appearance	Storage Conditions

{Description of work performed}

Prepared by:

Approved by:

[Signature]

[Signature]

{Preparer}

{Name}

{Title}

Principal Investigator

Submitted To:

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**Shipping (SHIP) report (One Page)**

One page report. Note: font size reduced to allow display of multiple headers.

{LABNAME}

Chemistry Support Services for the ETP

NIH Contract No. N01-ES-{xxxxx}

{LAB} Project {nnn-nnnn-nnn}

SHIPMENT REPORT

{CHEMICAL NAME}

{LAB ID NO.}

{REPORT DATE}

For Bulk Chemicals use this:

CAS No.	Chemical Lot No. (Vendor, City, State)
{LAB} Taask/Log No.	Purity (date [if applicable]) [Vendor or last analyzed purity]
ChemTask No.	Appearance
Program Supported	Shipped To: [Name and Address]
Recommended Storage Conditions	Amount Shipped
Lab Complete Date	Shipping Date

Chemical Structure	Mol. Wt.	Mol. Formula

For Multiple Chemicals or HTS Chemicals use this:

NTP CAS No. [for ChemTask]	Container Format: [Microplate ID No.] or xx-mL amber glass vial]
NTP ChemTask No.	Description: [e.g., 500 $\mu$ L, of 20 mM solutions in DMSO]
{LAB} Assignment No.	Supplier Lot No.: (see Table 1)
Program Supported:	CoA Purity: (see Table 1)

Recommended Storage Conditions:	HIPS Purity: (see Table 1) [if available]
Ship Date:	Shipped To: {Name and Address}
Lab Complete Date:	Amount Shipped: (see Table 1)

<b>Chemical Structure</b>	<b>Mol. Wt.</b>	<b>Mol. Formula</b>

Prepared by:    Approved by:

[Signature]    [Signature]

{Preparer}    {Name}

{Title}                      Principal Investigator

Submitted To:

{COR}

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For Dose Vehicles use this:

CAS No.	Vehicle Lot No. (Vendor)
{LAB} Log No.	{Result of Last Analysis} ({Date})
ChemTask No.	Shipped To: [Name and Address]
Program Supported	Amount Shipped
Recommended Storage Conditions	Shipping Date
Lab Complete Date	

For Dose Formulation Samples use this:

Test Chemical	Amount Shipped
CAS No.	Shipping Date
LAB Log No.	Chemical Lot No. (Vendor, City, State)
NTP ChemTask No.	Vehicle Lot No. (Vendor, City, State)
Program Supported	Sample Type
Shipped To:	Dose Concentrations including sample identification color codes.
(Name and Address)	
Lab Complete Date	

<b>Chemical Structure</b>	<b>Mol. Wt.</b>	<b>Mol. Formula</b>

Prepared by:    Approved by:

[Signature]

[Signature]

{Preparer}

{Name}

{Title}

Principal Investigator

Submitted To:

{COR}

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For Biological Samples use this:

Test Chemical	Lot No. (Vendor, City, State) [Test Chemical]
CAS No.	Shipped To: [Name and Address]
{LAB} Chemical ID Code	Amount Shipped
{LAB} Task No.	Shipping Date
ChemTask No.	Matrix Type [rat plasma, liver, etc.]
Program Supported	Dose Groups (by Route/Vehicle) including sample identification color codes.
Recommended Storage Conditions [on receipt]	Sample Acquisition Date
Lab Complete Date	Sample Storage Conditions [prior to shipment]

Chemical Structure	Mol. Wt.	Mol. Formula

Prepared by:    Approved by:

[Signature]    [Signature]

{Preparer}    {Name}

{Title}                      Principal Investigator

Submitted To:

{COR}

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**Protocols Development (PD) report**

{Chemical Name}

CAS No.	Physical Properties:
{LAB} Chemical ID Code	Appearance
{LAB} Task/Log No.	Melting Point [if applicable]
ChemTask No.	Boiling Point [if applicable]
Program Supported	Vapor Pressure [if applicable]
	Storage Conditions [@Analytical Lab]
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt.      Mol. Formula

{STRUCTURE}

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Executive Summary

**Chemical Characterization (CCA, LLID, CIPS, MIPS) report**

{Chemical Name}

CAS No.	Lot No.
{LAB} Chemical ID Code	Amount Received
{Lab} Task/Log No.	Receipt Date
ChemTask No.	Appearance
Program Supported	Submitter
Analysis Date(s)	Study Lab
Interim Results Date	Vendor (City, State)
Lab Complete Date	Vendor Purity
Draft Final Report Issued Date	Storage Conditions [@Analytical Lab]

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

## Chemical Reanalysis (CRA)

{Chemical Name}

CAS No.	Lot No. (Vendor, City, State)
{LAB} Chemical ID Code	Purity ({Vendor or rf. to last analyzed purity})
{LAB} Task/Log No.	Samples Received
ChemTask No.	Sample Receipt Date
Program Supported	Submitter
Nominal Dose Concentration(s)	Study Lab
Vehicle	Receipt Condition
Vehicle Lot No. (Vendor)	Formulation Appearance [clear blue sol'n]
Mix Date(s)	Shipping Container
Analysis Date(s)	Storage Conditions [@Analytical Lab, formulation]
Interim Results Date(s)	SOP [rf. to analytical SOP]
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

**Preliminary Formulation Studies (PFS) report**

[Chemical Name]

CAS No.	Chemical Lot No. (Vendor, City, State, Vendor Purity)
{LAB} Chemical ID Code	Appearance
{LAB} Task/Log No.	
ChemTask No.	Vehicle(s)
Program Supported	Lot No(s). (Vendor, City, State, purity [if applicable])
Analysis Date(s)	
Interim Results Issued Date(s)	
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

**Formulation Development, Formulation Development and Validation (FD, FDV) reports**

{Chemical Name}

CAS No.	Lot No. (Vendor, City, State, Vendor Purity)
{LAB} Chemical ID Code	Appearance [bulk chemical]
{LAB} Task/Log No.	Storage Conditions [@Analytical Lab, bulk]
ChemTask No.	Vehicle
Program Supported	Vehicle Lot No. (Vendor, City State)
Nominal Formulation Concentrations	Storage Conditions [@Analytical Lab, vehicle]
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

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**Formulation Analysis (FA, FP, FPA, FPAS) reports**

{Chemical Name}

CAS No.	Lot No. (Vendor, City, State)
{LAB} Chemical ID Code	Purity ({Vendor or rf. to last analyzed purity})
{LAB} Task/Log No.	Samples Received {sample type, e.g, post-dosing, animal room, etc.}
ChemTask No.	Sample Receipt Date
Program Supported	Sample Ship Date [FPAS only]
Nominal Dose Concentration(s)	Submitter
Vehicle	Study Lab
Vehicle Lot No. (Vendor)	Receipt Condition
Mix Date(s)	Formulation Appearance [clear blue sol'n]
Analysis Date(s) [FA, FPA, and FPAS]	Shipping Container
Interim Results Date(s) [FA, FPA, and FPAS]	Storage Conditions [@Analytical Lab, formulation]
Lab Complete Date	SOP [rf. to analytical SOP or DFD if not routine]
Draft Final Report Issued Date	

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

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**Referee Analysis (RA) reports**

{Chemical Name}

CAS No.	Lot No. (Vendor, Vendor Purity)
{LAB} Chemical ID Code	Samples Received
{LAB} Task/Log No.	Sample Receipt Date
ChemTask No.	Submitter
Program Supported	Study Lab
	Mix Date [if applicable]
Analysis Date(s)	Receipt Condition
Interim Results Date(s)	Shipping Container
Lab Complete Date	Storage Condition [@Analytical Lab]
Draft Final Report Issued Date	

Mol. Wt. Mol. Formula

{STRUCTURE}

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Executive Summary

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**Vehicle Analysis (VA) reports**

{VEHICLE NAME}

CAS No.	Vendor (City, State)
{LAB} Log No. [if applicable]	Lot No. [vehicle]
{LAB} Task No.	Method [ref SOP or see attached]
ChemTask No.	Subcontractor [if applicable]
Program Supported	Samples Received
Study Supported [name or NTP study number]	Sample Receipt Date
Analysis Date(s)	Submitter [source of vehicle sample to be analyzed]
Interim Results Date(s)	Study Lab
Results [this analysis only]	Receipt Condition
Lab Complete Date	Appearance
Draft Final Report Issued Date	

{STRUCTURE} Mol. Wt. Mol. Formula

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Executive Summary

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**Biosample Analysis (BSMD, BSA, PBSA, PCD, EXS) reports**

{Chemical Name}

CAS No.	Lot No. (Vendor, City, State)
{LAB} Chemical ID Code	Samples Received
{LAB} Task/Log No.	Sample Receipt Date
ChemTask No.	Submitter
Program Supported	Study Lab
	Sample Collection or Study Date
Analysis Date(s)	Receipt Condition
Interim Results Date	Shipping Container
Lab Complete Date	Storage Condition [@Analytical Lab]
Draft Final Report Issued Date	

Mol. Wt.      Mol. Formula

{STRUCTURE}

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Executive Summary

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**Toxicokinetic Study (PTKS, TKS) reports**

{Test Chemical Name}	Species/Strain/Sex [Male HSD rat, etc.]
CAS No.	Dose Regimen [IV, emulphor; PO, 0.5% MC]
{LAB} Chemical ID Code	Dose Groups [by route, dose concentration]
{LAB} Task No.	Sample Matrices Collected [plasma, liver, urine, etc.]
ChemTask No.	Sample Storage Conditions
Associated ChemTask Nos. [for attached reports, when applicable]	Initial Dosing Date
Lot No. (Vendor, City, State) [Test Chemical]	Sample Acquisition Date(s) [by Study phase or tissue type]
Lot No(s). (Vendor(s)) [Vehicle(s)]	Lab Complete Date

{TEST CHEMICAL STRUCTURE}

Mol. Wt.

Mol. Formula

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{ANALYTE STRUCTURE(S)}

Mol. Wt.

Mol. Formula

{Repeat as needed for each metabolite}	{Repeat as needed for each metabolite}
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Executive Summary

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**Absorption, Distribution, Metabolism, and Elimination Study (ADME) reports**

{Test Chemical Name}	Species/Strain/Sex [Male HSD rat, etc.]
CAS No.	Dose Regimen [IV, emulphor; PO, 0.5% MC]
{LAB} Chemical ID Code	Dose Groups [by route, dose concentration]
{LAB} Task No.	Sample Storage Conditions
ChemTask No.	Test Article Receipt Date [radiolabel]
Associated ChemTask Nos. [for attached reports, when applicable]	Initial Dosing Date
Lot No. (Vendor) [Test Chemical]	Sample Acquisition Date(s) [by Study phase]
Lot No(s). (Vendor(s)) [Vehicle(s)]	Lab Complete Date

{TEST CHEMICAL STRUCTURE}

Mol. Wt.

Mol. Formula

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{ANALYTE STRUCTURE(S)}

Mol. Wt.

Mol. Formula

{Repeat as needed for each metabolite}	{Repeat as needed for each metabolite}
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Executive Summary

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**Special Chemical Analysis (SCA) report**

{Chemical Name}

CAS No.	<i>{Contents determined by assignment type}</i>
{LAB} Chemical ID Code	<i>{Contents determined by assignment type}</i>
{Lab} Task/Log No.	<i>{Contents determined by assignment type}</i>
ChemTask No.	<i>{Contents determined by assignment type}</i>
Program Supported	<i>{Contents determined by assignment type}</i>
Analysis Date(s)	<i>{Contents determined by assignment type}</i>
Interim Results Date	<i>{Contents determined by assignment type}</i>
Lab Complete Date	<i>{Contents determined by assignment type}</i>
Draft Final Report Issued Date	<i>{Contents determined by assignment type}</i>

Mol. Wt.      Mol. Formula

{STRUCTURE}

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Executive Summary