CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-420

BIOEQUIVALENCE REVIEW(S)

Phenytoin Oral Suspension
125 mg/5 ml
ANDA #40-420
Reviewer: J. Lee
40420STA.701

Morton Grove Pharmaceuticals, Inc.
Morton Grove, Illinois
Submission date:
July 20, 2001

Review of a Study Amendment

This amendment is a response to the deficiencies issued in the review of the bio-study contained in the original submission (Sept 29, 2000).

1. The complete analytical methodology including the preparation of standards and quality control samples, description of instrumentation parameters, sample and standard processing procedure, etc. were not included in the bio-study report. This information plus the analytical SOPs were requested.

☞ The requested information was submitted. **(Not to be Released Under FOI)** The method entailed processing samples using [redacted] Stability and recovery information which were only available electronically in the original submission were included in this amendment.

2. The potency of the reference drug used in the bio-study was not reported. The sponsor was asked to supply the potency of Dilantin-125®, batch #39839L.

☞ The potency of Dilantin-125®, batch #39839L, was stated to be 99.2%.

3. Since the USP dissolution method had changed after receiving the original submission, the sposor was requested to redo the dissolution testing per USP 24, suppl 3 (the latest supplement), using the same batches of test/reference products employed in the bio-study. The sponsor has also attested that the dissolution method in USP 24, suppl 3, will now be their current in-house method.

   Additionally, since the reference drug used in the bio-study had expired, the sponsor was requested to conduct dissolution testing on a fresh reference batch. Potency was also requested to be determined for the fresh reference batch.

☞ See attachments for the dissolution summaries. The potency for the fresh reference batch was 99.1% (batch # 64090L - expiry date: 8/2002). Content uniformity was also determined:

Dilantin-125®, batch #39839L (bio-batch)	101.3%
Dilantin-125®, batch #64090L (fresh ref batch)	101.1%
Morton Grove, batch #A0253 (bio-batch)	100.5%

Comment:

1. The USP 24, suppl 3 dissolution method for phenytoin oral suspension specifies a sampling time (60 min), but not a Q. DBE is applying a Q = — in 60 minutes as an interim specification until such time as the USP issues a Q for the dissolution method.

2. All deficiencies have been satisfactorily addressed.

Recommendation:

1. The bioequivalence study conducted by ——— for Morton Grove Pharmaceuticals, Inc. on its phenytoin 125 mg/5 ml oral suspension, batch #A0253, comparing it to Dilantin-125®, has been found acceptable to the Division of Bioequivalence.

2. The in-vitro dissolution testing data is also acceptable. The dissolution testing should be incorporated into the firm's manufacturing controls and stability program. The dissolution testing should be conducted in 900 ml of 0.05M tris buffer at 37°C using USP XXIV apparatus II (paddle) at 35 rpm. The test product should meet the following specification:

Not less than — of the labeled amount of the drug in the suspension is dissolved in 60 minutes.

3. All bioequivalence criteria have been met.

R. Lee 7/26/01

J. Lee
Division of Bioequivalence
Review Branch II

RD INITIALED SNERURKAR
FT INITIALED SNERURKAR 7/26/2001

Concur: Dale P. Conner Date: 7/30/01

Dale Conner, Pharm. D.
Director, Division of Bioequivalence

JLee/jl/07-26-01

cc: NDA #40-420 (original, duplicate), HFD-630, HFD-655 (Lee, Patnaik), Drug File, Division File

Method Ref.:	USP 24, suppl 3	Medium:	0.05M tris buffer
USP 24 Apparatus:	II	Volume:	900 mL
RPM:	35	Tolerance:	Q=— % in 60 min
No. Units Tested:	12		(interim)
Reference Drug:	Dilantin-125®	Assay Method:	———

Sampling Times (Minutes)	Test Product: Lot No.: A0253 (glass ctn) (bio-batch) Strength: 125 mg/5ml			Ref Product: Lot No.: 39839L (glass ctn) (bio-batch) Strength: 125 mg/5ml		
	Mean (%)	Range	% CV	Mean (%)	Range	% CV
10	15.6		16	24.6		27
20	48.5		13	64.6		11
30	80.3		8.4	89		4.7
45	98.5		2.4	100		2.4
60	101.4		0.7	101.7		2.9
90	101.8		0.7	102.3		2.9

f_2 =53.76

Sampling Times (Minutes)	Test Product: Lot No.: A0253 (PET ctn) Strength: 125 mg/5ml			Ref Product: Lot No.: 64090L (glass ctn) (new ref batch) Strength: 125 mg/5ml		
	Mean (%)	Range	% CV	Mean (%)	Range	% CV
10	25.6		20	24.1		8.7
20	64.3		10	52.2		5.5
30	89.6		4.4	72.6		4.6
45	100.9		1.9	89.3		3.7
60	102.5		1.7	97.4		2.1
90	102.5		1.9	101.7		0.6

f_2 =49.91

CC: ANDA 40-420
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-650/ Reviewer

V:\FIRMSam\Morton\ltrs&rev\40420STA.701
Printed in final on / /

Endorsements: (Final with Dates)
HFD-655/ JLee E.S. 7/26/01
HFD-655/ Bio team Leader
HFD-650/ D. Conner 7/30/01

7/26/01

BIOEQUIVALENCY - ACCEPTABLE

submission date: July 20, 2001

5. **STUDY AMENDMENT** (STA)

Strengths: 125 mg/5 ml
Outcome: AC

Outcome Decisions: **AC** - Acceptable

WinBio Comments:
All deficiencies satisfactorily addressed. Bio-study is acceptable.

APPEARS THIS WAY
ON ORIGINAL

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 40-420 APPLICANT: Morton Grove Pharmaceuticals, Inc.

DRUG PRODUCT: Phenytoin Oral Suspension USP, 125 mg/5 ml

The Division of Bioequivalence has completed its review and has no further questions at this time.

The dissolution testing will need to be incorporated into your stability and quality control programs as specified in USP 24, suppl 3.

Please employ a Q of NLT ⁓ in 60 minutes as an interim specification until such time as the USP issues a Q for the dissolution method.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA 40-420
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-650/ Reviewer

V:\FIRMSam\Morton\ltrs&rev\40420STA.701
Printed in final on / /

Endorsements: (Final with Dates)
HFD-655/ JLee E.J. 7/26/01
HFD-655/ Bio team Leader
HFD-650/ D. Conner 7/30/01

7/26/01

BIOEQUIVALENCY - ACCEPTABLE submission date: July 20, 2001

5. **STUDY AMENDMENT** (STA) Strengths: 125 mg/5 ml
Outcome: **AC**

Outcome Decisions: **AC** - Acceptable

WinBio Comments:
All deficiencies satisfactorily addressed. Bio-study is acceptable.

APPEARS THIS WAY
ON ORIGINAL

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA #: 40-420 SPONSOR: Morton Grove Pharmaceuticals

DRUG AND DOSAGE FORM: Phenytoin oral suspension

STRENGTH(S): 125 mg/5ml

TYPES OF STUDIES: ~~PK~~ fasted

CLINICAL STUDY SITE(S): _____

ANALYTICAL SITE(S): same

STUDY SUMMARY: bio study acceptable.

DISSOLUTION: OK per USP 24, suppl 3

DSI INSPECTION STATUS

Inspection needed: YES / NO	Inspection status:	Inspection results:
First Generic no	Inspection requested: (date)	
New facility _____	Inspection completed: (date)	
For cause _____		
other _____		

PRIMARY REVIEWER: J. Lee BRANCH: II

INITIAL: C.J. DATE: 7/26/01

TEAM LEADER: SG Nerurkar BRANCH: II

INITIAL: [signature] DATE: 7/26/2001

DIRECTOR, DIVISION OF BIOEQUIVALENCE: DALE P. CONNER, Pharm. D.

INITIAL: DPC DATE: 7/30/01

BIOEQUIVALENCY DEFICIENCIES TO BE PROVIDED TO THE APPLICANT

ANDA: 40-420 APPLICANT: Morton Grove Pharmaceuticals, Inc.

DRUG PRODUCT: Phenytoin Oral Suspension USP, 125 mg/5 ml

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified.

1. You have not submitted the complete analytical methodolgy. The method should include the the preparation of standards and quality control samples, description of instrumentation parameters, sample and standard processing procedure, etc. This information may be found in analytical SOP # LMS-M-5972-01. Please also submit SOP # AL-G-1520-09 and AL-G-1520-09.A01 [Reporting of data generated by the Analytical Laboratories].

2. The potency of the reference drug used in the bio-study was not reported. Please supply the potency of Dilantin-125®, batch #39839L.

3. Since the USP dissolution method has changed after receiving your submission, please redo the dissolution testing per USP 24, suppl 3, using the same batches of test/reference products employed in the bio-study.

   900 ml of 0.05M Tris buffer
   Apparatus II (paddle) @ 35 rpm
   Sampling time: 10, 20 30, 45 and 60 minutes

   In addition, since the reference drug used in the bio-study has expired, please conduct dissolution testing on a fresh reference batch. Potency should also be determined for the fresh reference batch.

   Twelve dosage units of both test/reference products should be employed in all dissolution testing.

Sincerely yours,

for Dale P. Conner, Pharm.D.
Director Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

2.

Phenytoin Oral Suspension
125 mg/5 ml
ANDA #40-420
Reviewer: J. Lee
40420S.S00

Morton Grove Pharmaceuticals, Inc.
Morton Grove, Illinois
Submission date:
September 29, 2000

Review of a Bioequivalence Study
(Electronic Submission)

Introduction

Indication: For the control of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures.
Type of Submission: ANDA
Contents of Submission: Fasted bio-study
RLD: Dilantin®-125 Suspension
Recommended Dose: Adults – one ts t.i.d. to start; dosage should be individualized.

Protocol No.: 980090, Comparative, Single-Dose, Fully-Replicated, 4-Period Crossover Bioavailability Study of Morton Grove and Parke-Davis (Dilantin-125(r)) 125 mg Phenytoin/5 mL Phenytoin Oral Suspension in Healthy Adult Males Under Fasting Conditions

Study Information

STUDY FACILITY INFORMATION

Clinical Facility: [redacted]
Medical Director: [redacted]
Scientific Director: [redacted]
Clinical Study Dates: 11/24/99 to 01/30/00
Analytical Facility [redacted]
Principal Investigator: [redacted]
Analytical Study Dates: 02/01/00 to 03/03/00

TREATMENT INFORMATION

Treatment ID:	A	B
Test or Reference:	T	R
Product Name:	Phenytoin	Dilantin-125®
Manufacturer:	Morton Grove Pharmaceuticals, Inc.	Parke-Davis (Div. of Warner-Lambert Co.)
Manufacture Date:	N/A	N/A
Expiration Date:	08/16/01 (temporary)	Feb 01
ANDA Batch Size:	[redacted]	N/A

Batch/Lot Number:	A0253	39839L
Potency:	101.6%	???????????
Strength:	125 per 5 mL	125 per 5 mL
Dosage Form:	suspension	suspension
Dose Administered:	125 per 5 mL	125 per 5 mL
Study Condition:	fasting	fasting
Length of Fasting:	OVERNIGHT	OVERNIGHT

RANDOMIZATION		DESIGN	
Randomized:	Y	**Design Type:**	crossover
No. of Sequences:	2	**Replicated Treatment Design:**	Y
No. of Periods:	4	**Balanced:**	Y
No. of Treatments:	2	**Washout Period:**	21 days

Patients were dosed on the mornings of Nov 24 and Dec 15, 1999 and Jan 5 and 26, 2000.

seq I ABBA subj #1, 3, 4, 7, 9, 10, 13, 14, 17, 18, 19, 20, 23, 25, 27
seq II BAAB subj #2, 5, 6, 8, 11, 12, 15, 16, 18, 21, 22, 24, 26, 28

DOSING		SUBJECTS	
Single or Multiple Dose:	single	**IRB Approval:**	Y
Steady State:	N	**Informed Consent Obtained:**	Y
Volume of Liquid Intake:	240 mL	**No. of Subjects Enrolled:**	28
Route of Administration:	oral	**No. of Subjects Completing:**	28
Dosing Interval:	hr	**No. of Subjects Plasma Analyzed:**	24
Number of Doses:	N/A	**No. of Dropouts:**	0
Loading Dose:	per 5 mL	**Sex(es) Included:**	male
Steady State Dose Time:	N/A	**Healthy Volunteers Only:**	Y
Length of Infusion:	N/A	**No. of Adverse Events:**	2

Dietary Restrictions:	No alcohol- or xanthine-containing beverages and foods for the 24 hours before each dosing and throughout the period of sample collection. No grapefruit-containing beverages and foods for 7 days before dosing and througout the entire study.
Activity Restrictions:	Subjects remained ambulatory or seated upright for the first 4 hours following drug administration, except when prevented by adverse events. No strenuous activity during the housing period.
Drug Restrictions:	No medication (including over-the-counter products) for the 7 days preceding the study. This prohibition did not include vitamins taken as nutritional supplements for non-therapeutic indications.
Blood Sampling:	7 ml was collected pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 12, 16, 24, 36, 48, 72 and 96 hours post-dose.

Study Results

1) Clinical
Adverse Events: 2 reported (trt B) that were possibly related to the study drug [sore throat, trembling (more than usual)]. Both were mild in nature.

Protocol Deviations:
Dropouts:
No Dropouts Reported

2) Analytical (Not to be Released Under FOI)
Pre-Study Assay Validation:

ANALYTE:
ASSAY METHOD:
MATRIX:
INTERNAL STANDARD:
SENSITIVITY:
STANDARD CURVE HIGHEST CONC.:
STANDARD CURVE LOWEST CONC.:
R^2 IS GREATER THAN:
SPECIFICITY:
ANALYTE RETENTION TIME:
INTERNAL STANDARD RETENTION TIME:

Recovery data showed the following:

[ ] [ ]

3) Pharmacokinetic:

Plasma data was analyzed by an analysis of variance procedure to determine statistically significant ($p<0.05$) differences between treatments, sequence of dosing, subjects within sequence and period for the pharmacokinetic parameters. All 28 subjects completed the study. The first 24 subjects were analyzed per protocol.

Results:

Results are given in the appended tables. There was ≤0.4% difference between test and reference formulations in AUC_{0-t} and AUC_{inf} and a 15.5% difference in C_{max}. The 90% shortest confidence intervals for phenytoin are presented below. The DBE statistician verified the ANOVA of the replicate study.

	90% CI [log-transformed]
AUC_{0-t}	[97.3; 102.1]
AUC_{inf}	[97.0; 102.2]
C_{max}	[107.8; 123.6]

In-vitro Dissolution:

The sponsor has conducted dissolution testing with test/reference bio-lots used in this study, using the USP dissolution method in effect at the time of submission (USP 24, suppl 2). Since receiving the submission, the dissolution method has changed (USP 24, suppl3, eff. March 1, 2001). The sponsor will be requested to conduct dissolution testing using the current USP dissolution method.

Comment:

1. The sponsor has not submitted the complete analytical methodolgy. The method should include the the preparation of standards and quality control samples, description of instrumentation parameters, sample and standard processing procedure, etc. This information may be found in analytical SOP # LMS-M-5972-01. The sponsor should

also submit SOP # AL-G-1520-09 and AL-G-1520-09.A01 [Reporting of data generated by the Analytical Laboratories].

2. The potency of the reference drug used in the bio-study was not reported. The sponsor should supply the potency of Dilantin-125®, batch #39839L.

3. The sponsor should redo the dissolution testing per USP 24, suppl 3, using the same batches of test/reference products employed in the bio-study.

   900 ml of 0.05M Tris buffer
   Apparatus II (paddle) @ 35 rpm
   Sampling time: 10, 20 30, 45 and 60 minutes

   In addition, since the reference drug used in the bio-study has expired, the sponsor should conduct dissolution testing on a fresh reference batch. Potency should also be determined for the fresh reference batch.

   Twelve dosage units of both test/reference products should be employed in all dissolution testing.

Recommendation:

1. The bioequivalence study conducted by _____ for Morton Grove Pharmaceuticals Inc. on its phenytoin oral suspension, 125 mg/5ml, batch #A0253, has been found incomplete per comments #1-3.

R. Lee 5/17/01

J. Lee
Division of Bioequivalence
Review Branch II

6/8/2001

RD INITIALED SNERURKAR
FT INITIALED SNERURKAR

Concur: _____ Date: 6/14/2001

for Dale Conner, Pharm. D.
Director, Division of Bioequivalence

JLee/jl/05-17-01

cc: NDA #40-420 (original, duplicate), HFD-630, HFD-655 (Lee, Patnaik), Drug File, Division File

IN - VITRO DISSOLUTION TESTING

Method Ref.:	USP 24, suppl 2	Medium:	0.05 borate buffer
USP 24 Apparatus:	II	Volume:	900 mL
RPM:	50	Tolerance:	Q= — ₀ in 30 min.
No. Units Tested:	see below: 5 ml ea	Assay Method:	——
Reference Drug:	Dilantin®-125		

Sampling Times (Minutes)	Test Product: Lot No.: A0253 Strength: 125 mg/5 ml 12 units tested			Ref Product: Lot No.: 39839L Strength: 125 mg/5 ml 6 units tested		
	Mean (%)	Range	% CV	Mean (%)	Range	% CV
10	87.3	[ ]	7.7	84.6	[ ]	2.8
20	99.2		3.3	95.2		1.2
30	98.1		3.2	97.3		2.7
60	100.0		3.5	96.3		1.3

APPEARS THIS WAY
ON ORIGINAL

FASTING SINGLE-DOSE IN VIVO BIOEQUIVALENCE STUDY #980090
ARITHMETIC MEAN PLASMA CONCENTRATIONS [NG/ML] (CV%)
VERSUS TIME IN 24 SUBJECTS
PHENYTOIN

TIME (HR)	TEST TREATMENT A1		TEST TREATMENT A2		REFERENCE TREATMENT B1		REFERENCE TREATMENT B2		RATIO $\left(\frac{AverageA}{AverageB}\right)\%$
0	0.000	(0.0)	0.000	(0.0)	0.000	(0.0)	0.000	(0.0)	N/A
0.5	851.820	(44.9)	821.111	(40.5)	584.960	(30.2)	586.845	(34.9)	142.8
1	1450.852	(31.3)	1615.837	(33.1)	1128.445	(35.4)	1119.066	(25.0)	136.4
1.5	1827.771	(34.2)	1990.566	(23.1)	1449.305	(30.0)	1457.250	(27.2)	131.4
2	2027.793	(32.3)	2302.941	(29.4)	1745.733	(33.2)	1708.092	(22.5)	125.4
2.5	2159.486	(27.6)	2393.936	(31.2)	1926.923	(37.0)	1946.790	(42.7)	117.5
3	2246.057	(37.7)	2297.315	(22.4)	1902.076	(32.9)	1836.248	(26.3)	121.5
4	2218.725	(22.7)	2434.792	(32.5)	1897.952	(28.3)	2178.200	(33.8)	114.2
5	2072.650	(18.6)	2246.886	(26.8)	1838.170	(28.6)	1952.343	(28.5)	114.0
6	1896.186	(18.2)	2157.283	(26.3)	1810.317	(28.5)	1886.630	(22.2)	109.6
7	1885.070	(17.5)	2060.322	(25.5)	1867.669	(23.9)	1812.712	(23.2)	107.2
8	1842.642	(18.4)	1893.702	(23.8)	1711.905	(25.0)	1815.980	(24.6)	105.9
12	1543.560	(24.6)	1573.619	(25.3)	1516.102	(25.8)	1581.518	(23.8)	100.6
16	1302.759	(29.4)	1371.979	(26.1)	1368.588	(29.9)	1399.359	(28.5)	96.6
24	975.830	(45.0)	1024.803	(42.5)	1065.642	(38.1)	1110.388	(34.7)	91.9
36	588.634	(73.2)	618.913	(69.4)	615.872	(66.1)	657.384	(60.7)	94.8
48	335.615	(104.1)	351.004	(103.8)	366.168	(95.7)	377.667	(94.8)	92.3
72	155.924	(204.2)	150.803	(204.0)	157.856	(228.5)	150.627	(189.3)	99.4
96	79.120	(320.3)	72.660	(314.1)	75.083	(355.6)	69.302	(320.2)	105.1

FASTING SINGLE-DOSE IN VIVO BIOEQUIVALENCE STUDY #980090
LEAST-SQUARES MEANS FOR PHARMACOKINETIC PARAMETERS
PHENYTOIN
(N=24)[1]

	ln AUC 0-t[2] (ng·h/mL)	ln AUCinf[2] (ng·h/mL)	ln Cmax[2] (ng/mL)	tmax (h)	Half-life (h)	kel (1/h)
Morton Grove (A)						
Mean	55986.94	58468.79	2609.7485	3.531	15.458	0.05627
CV%	41.7	49.7	27.9	44.3	84.5	33.6
n[1]	48	48	48	48	48	48
Parke-Davis(B)						
Mean	55821.04	58223.75	2268.0178	5.003	14.924	0.05870
CV%	41.2	50.1	31.4	67.2	94.8	32.0
n[1]	48	48	48	48	48	48
Least-Squares Means						
Morton Grove (A)	55811.53	58218.96	2614.4092			
Parke-Davis(B)	55996.47	58473.60	2263.9746			
Ratio of Least-Squares Means (A/B)%	99.7	99.6	115.5			
90% Confidence Intervals (A/B)%						
Lower limit:	97.3	97.0	107.8			
Upper limit:	102.1	102.2	123.6			
p-Value (ANOVA)						
A vs B	0.8170	0.7759	0.0015			
Period	0.0001	0.0005	0.2091			
Sequence	0.1607	0.1460	0.1331			
Intrasubject CV%	6.6	7.1	19.0			

[1] N is the number of subjects and n is the number of observations
[2] For ln-transformed parameters, the antilog of the mean (i.e. the geometric mean) is reported.

Ingredient	Function	Label Claim Quantity per 5 mL	Quantity per Exhibition Batch	Quantity per Production Batch
Purified Water				
Magnesium Aluminum Silicate, NF				
Glycerin, USP				
Carboxymethylcellulose Sodium, USP				
Purified Water				
Citric Acid Anhydrous, USP				
Sodium Citrate Dihydrate, USP				
Purified Water, USP				
Sodium Benzoate, NF				
Liquid Sugar				
Polysorbate 40, NF				
Phenytoin, USP	Active	125 mg		
Purified Water				
Purified Water				
FD&C Yellow No. 6				
Orange Flavor				
Dehydrated Alcohol, USP				
Vanillin, NF				
Purified Water, USP				
10% Sodium Citrate Solution				
10% Citric Acid Solution				
Purified Water, USP				

[1]Volume is converted to weight by multiplying with the specific gravity of Dehydrated Alcohol, USP

[2]For the exhibition batch, lot #A0253, no Purified Water, USP was used.

[3]For the exhibition batch, lot # A0253, no pH adjustment was needed.

[4]For the exhibition batch, lot #A0253. of Purified Water, USP were used.

CC: ANDA 40-420
ANDA DUPLICATE
DIVISION FILE
BIO DRUG FILE
FIELD COPY

Endorsements:
HFD-655/ JLee e.s. 5/17/01
HFD-650/ Bio Team Leader
HFD-617/ Nwaba
HFD-650/ Conner for Nwp 6/14/2001

6/8/01

Printed in draft on \ \
Printed in final on \ \
V:\firmsam\Morton\ltrs&rev\40420S.S00

BIOEQUIVALENCY - DEFICIENCIES

1. **FASTING STUDY** (STF) Strengths: 125 mg/5 ml
Clinical: ~~fasting~~ ✓ Outcome: IC
Analytical: same

Outcome: AC IC UN NC

OUTCOME DECISIONS:
UN - Unacceptable (fatal flaw) IC - Incomplete

WINBIO COMMENTS:

Bio-study incomplete due to deficiencies.

APPEARS THIS WAY
ON ORIGINAL