Pharmoptima

A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

Douglas Decker

6710 Quality Way

Portage, Michigan 49002

August 3, 2017

Materials Licensing Section

U.S. Nuclear Regulatory Commission, Region III

2443 WarrenVille Road, Suite 210

Lisle, IL 60532-4352

Control number- 594576

Dear Colleen Casey,

I am providing information requested in an email received on August 2, 2017 asking for further information on a wipe test survey for a sink used to dispose H^3. The results of the wipe test survey previously provided showed the results from several sink locations. The wipe test locations included reaching into the drain approximately six inches. No contamination was observed with all of the survey locations showing less than 100 dpm. However, the trap for the sink was not surveyed. In order to provide this information, I disconnected the sink's trap and used six-inch forceps to reach into the trap from both directions (U-shaped trap) to wipe test the trap. The results of the wipe test showed that both trap areas surveyed were below 100 dpm for H^3.

Further information was also requested on the extent of material usage in ventilation systems (fume hoods and biosafety hoods). All radiolabeled material used were non-volatile chemicals provided as stocks in solvent (typically methanol or ethanol). Any material requiring sterile conditions was performed in the Biosafety cabinets. For example, C^{14} was used in several studies where the stock vial was diluted into a sterile medium or dosing formulation and used to perform studies. The fume hoods in the main laboratory and Protocol room 1 were also used to dilute stock vials (both H^3 and C^{14}) into working stocks for use in experiments. Additionally, fume hood 1 in the main laboratory was also used to do extraction of tissues using solvents such as acetonitrile/methanol 50:50 (using a closed tube) followed by concentration of samples under a stream of nitrogen gas. The concentrated samples were used for evaluation by HPLC.

Thank you,

Douglas E. Decker, RSO Douglas Decker

dedecker@pharmoptima.com

RECEIVED AUG 03 2017

PACKARD 1900CA

LIQUID SCINTILLATION COUNTER

SELF NORMALIZATION & CALIBRATION

YSTEM NORMALIZED
14 IPA DATA PROCESSED - 03-Aug-2017 05:53
C14 Eff (0-156 keV) = 95.60 %
14 CHI SQUARE IPA DATA PROCESSED - 03-Aug-2017 06:04
C14 Chi Square = 13.47
3 IPA DATA PROCESSED - 03-Aug-2017 06:05
H3 Eff (0-18.6 keV) = 61.55 %
3 CHI SQUARE IPA DATA PROCESSED - 03-Aug-2017 06:15
H3 Chi Square = 23.06
G IPA DATA PROCESSED - 03-Aug-2017 07:16
Bkg (0-18.6 keV) = 14.73 cpm
Bkg (0-156 keV) = 22.05 cpm
C14 E^2/B (1-156 keV) = 506.59
H3 E^2/B (1-18.6 keV) = 258.49

SINK TRAP Wipe Test

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rotocol #: 5 Name:C14/3H Dual 03-Aug-2017 08:02
egion A: LL-UL= 0.0-12.0 Lcr= 0 Bkg= 0.00 %2 Sigma=2.00
egion B: LL-UL=12.0-156. Lcr= 0 Bkg= 0.00 %2 Sigma=2.00
egion C: LL-UL= 0.0- 0.0 Lcr= 0 Bkg= 0.00 %2 Sigma=0.00
ime = 5.00 QIP = tSIE/AEC ES Terminator = Count
ual C14/H3 curve 01MAY2014
onventional DPM
uclide 1 = 219443 Nuclide 2 = 126029
ata/Application Drive & Path = A:/
ave Data Filename = SDATA5.DAT

H^3-CHANNEL

PID	S#	TIME	CPMA	CPMB	CPMC	DPM1	DPM2	tSIE	FL
20	1	5.00	11.13	13	0.00	32	14.32	350.	
20	2	5.00	14.22	13	0.00	44	14.00	338.	

PHARMOPTIMA 2693294390 08/03/2017 16:43

Column header ID

PID- Cassette ID

S#- sample number from key page

Time- 5 minute count time

CPMA- H^3 channel cpm

CPMB- C^{14} channel cpm

CPMC- channel not used

DPM1- H^3 channel DPM

DPM2- C^{14} channel DPM

tSIE- Spectral index of external standard

Flag- no flags observed

Sink wipe test locations

Sample 1- Wipe test of the sink trap from the right side (U-shaped trap)

Sample 2- Wipe test of the sink trap from the left side (U-shaped trap)

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A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

Fax

Date: [August 3, 2017]

Subject: [Supplementary material for NRC form 314]

To: [Colleen Casey]

Phone: [630-829-9841]

Fax: [630-515-1078]

From: [Douglas Decker]

Phone: [269-492-3886]

Fax: [269-329-4390]

No. of pages: [No. of pages 3]

Message:

[Supplementary information for form 314 control # 594576

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