



Pharmaceuticals, Inc.

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July 22, 2010

Betsy Ulrich, MS, CHP
Senior Health Physicist
Commercial R&D Branch
Division of Nuclear Material Safety
Region I
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Q-5

03035426

Subject: CGI Pharmaceuticals, Inc., Materials License Number 06-30583, Mail Control Number 573037, License Termination, Normalization Standard

Dear Ms. Ullrich,

I am responding to your email of July 14, 2010 inquiring about our possession of materials under a general license. We did have one Normalization Plate that contained both ³H and ¹⁴C (see attached certificate describing the plate) and have disposed of it as radioactive waste by having it removed by Chase Environmental Group, a firm licensed in the State of Kentucky to receive radioactive waste.

Please contact me or Bari Gabbitas, (203) 315-1222 ex.100, bgabbitas@cgipharma.com, if you have any additional questions.

Thank you for your help with this license termination.

Sincerely,

Peter Fuller, COO

cc Bari Gabbitas, Radiation Safety Officer

RECEIVED
2010 JUL 23 AM 11:03

573037

NORMALIZATION STANDARD
for 1,2,3,6 and 12-det MicroBeta[™]
Liquid Scintillation Counter
Product No. 1450-471

CERTIFICATE

Radioactive isotopes: **tritium and carbon-14**

The activities of standards and the reference dates for all standards are as follows:

1,2,3 and 6-det

³H (position G11): 207100 dpm 1 Jun 2002 Ref. Date

¹⁴C (position H12): 126600 dpm 1 Jun 2002 Ref. Date

12-det

³H (position G10): 205800 dpm 1 Jun 2002 Ref. Date

¹⁴C (position G12): 127300 dpm 1 Jun 2002 Ref. Date

The 1450-471 is from the production Lot No. 107063

Product Description

The 1450-471 Liquid Scintillation Standard set consists of four activity standards. The activity standards are precisely calibrated samples of carbon-14 labelled [1-¹⁴C] stearic acid and tritium labelled [7(n)-³H]-cholesterol in scintillation plastic discs based on polyvinyl toluene. The labelled compounds are produced by DuPont NEN, Belgium and Amersham International, UK respectively. The standard discs are glued with paraffin onto the bottom of the sample wells of the sample plate and sealed with a sealing tape.

Activity Calibration

The tritium standards are calibrated against reference standards of tritium labelled toluene by the National Institute of Standards and Technology (NIST), Standard Reference Material (SRM) No. 4947C, the estimated accuracy of which was ± 1.2 %. The Carbon-14 standards are calibrated against reference standards of n-hexadecane-1-¹⁴C supplied by the National Institute of Standards and Technology (NIST), Standard Reference Material (SRM) No. 4222C, the estimated accuracy of which was ± 0.81 %. The tolerance of the activity of the discs is ± 1 %.

Definition of Use

The 1450-471 standard set is intended to use with LS counter MicroBeta

serial No. 4502174

to normalize the instrument and measure day-to-day ³H and ¹⁴C counting efficiencies for comparison with original factory specifications and for verifying stable system performances. For specific instructions on use of these standards with MicroBeta, the instrument manual should be consulted.

Precautions on Storage and Use

Fluors are susceptible to photo-chemical degradation. The standard set should be stored in a dark place at room temperature. The long-term stability for ³H has shown 1 % decrease in activity per year and recommended shelf-life is not more than 3 years.