



SPECTRUM
PHARMACEUTICALS

Turning Insights into Hope

May 11, 2010

Dear Radiopharmacist:

Spectrum Pharmaceuticals, Inc. received FDA approval on April 8, 2010 to use an additional supplier of Yttrium-90 (Y90) for the Zevalin® therapeutic regimen.

The additional supplier is Eckert & Ziegler Nuclitec, Inc. of Hopkinton, MA using their Auriga Medical™ branded Y90 produced at their cGMP manufacturing facility in Braunschweig, Germany.



Eckert & Ziegler
Nuclitec



aurigamedical

Beginning June 1, 2010, Y90 will be available five (5) days a week, Monday through Friday. Nuclitec has two manufacturing days: Wednesday and Friday.

The ordering process will remain the same. All Y90 orders will need to be placed with Zevalin Support Services at least one (1) week in advance of the Y90 treatment date.

Zevalin® Support Services phone number is 866-298-8433, Option 1.

Nuclitec Y90 is shipped and routed across US and its territories via FedEx under the usual Shipper's Declaration For Dangerous Goods.

Nuclitec will provide a Certificate of Analysis and the FedEx tracking number to each radiopharmacy in advance of the shipment date. Each shipment is expected to arrive at least one day **before** the calibration date. An example of the Certificate of Analysis is attached for your reference. It is batch specific.

All printed label data shown on the vial and package labels relating to product calibration and expiry will cite US EDT at 1200h.

Please note that the delivery vial is a 3 mL V-vial (Kimax) with substantially thicker walls. The vial is contained within a beta (& Bremstrahlung minimization) shield of clear acrylic with a removable top. The assembly is contained within a typical lead shield, as shown in the "thumbnail" picture below:





Turning Insights into Hope

We look forward to working with Nuciltec and each radiopharmacy to provide flexibility in the treatment schedule for Zevalin® patients.

ZEVALIN Support Services
PHONE: 866-298-8433
FAX: 877-264-8483
ZevalinSupport@sppirx.com

Eckert & Ziegler
 Nuclitec GmbH

 Gieselweg 1
 38110 Braunschweig
 Deutschland
 www.nuclitec.de

 Dr. Sven Dittrich
 Head of Quality Control Medical
 Telefon +49 5307 932-261
 Telefax +49 5307 932-451
 E-Mail sven.dittrich@ezag.com

CERTIFICATE OF ANALYSIS

[⁹⁰Y]Yttriumchloride
in aqueous solution (0.04 M HCl)

Batch: YKD09

30 April 2010

Characteristics	Requirement	Result
General data		
Production date	-	2010-04-30
Reference date (as required by the customer)	Date, 12h	as required by the customer
Expiry date (as required by the customer)	Reference date + 3 days	as required by the customer
Chemical or Physical Properties / Methods		
Appearance/visual check	Clear and colourless	passes test
Identity of Y-90/LSC	corresponds to	passes test
Gamma-emitting impurities (by the specified date)/gamma-spectrometry	1×10^{-4} Bq/Bq Y-90 (by the specified date)	$< 3 \times 10^{-5}$ Bq/Bq Y-90 07 May 2010, 12h CEST*
Sr-90 activity related to the Y-90 activity (by the specified date)/LSC	$< 1 \times 10^{-5}$ Bq Sr-90/Bq Y-90 (by the specified date)	$< 2 \times 10^{-7}$ Bq Sr-90/Bq Y-90 07 May 2010, 12h CEST*
Volume (as required by the customer)/weighing (related to the customer requirements)	0.02 – 5.0 ml 90 – 110 %	passes test
Activity (given at reference date as required by the customer)/ionization chamber (related to the customer requirements)	0.1 – 300 GBq 90 – 110 %	passes test
DTPA-Binding/TLC	> 95 %	99.7 %
Radiochemical purity/TLC	> 99 %	99.8 %
Other Tests		
Visual inspection of visible particles	free of particles	free of particles
Microbiological Specifications		
Autoclave parameters: examination of the autoclave log sterilising temperature [°C], sterilising time [min]	$\geq +121.0$ °C ≥ 20 min	$\geq +121.0$ °C 20 min

* CEST = Central European Summer Time (UTC + 2h)

Eckert & Ziegler
 Nuclitec GmbH

 i. A. Dr. Sven Dittrich
 Head of Quality Control Medical

 Geschäftsführer
 Joseph Hathcock
 Dr. André Heß
 Wilhelm Wartenberg

 Sitz Braunschweig
 Amtsgericht Braunschweig
 Reg.-Nr. HRB 4647
 USt-IdNr. DE193324337

 Bankverbindung
 Commerzbank Braunschweig
 Bankleitzahl 270 400 80
 Konto-Nr. 530 2591