[^{11}C]Mes-IMPY FOR INJECTION: STANDARD OPERATING PROCEDURE AND FORM FOR ANNUAL RADIONUCLIDE IDENTITY TEST

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Form Approved by: _____Initial_____ Date:_____

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1. Radionuclidic Identity Batch # MES_____ Test Date: _____

Measure initial radioactivity (Ao) of [^{11}C]Mes-IMPY for Injection in dose calibrator in hot-cell 4 and record time.

Ao = _____ at _____

Wait about 20 min and re-measure radioactivity (A) and record time. Determine time expired (t in min) between measurement of Ao and A.

A = _____ at _____; t = _____ (min)

Solve for decay rate constant (expressed in min^{-1}) according to equation $\ln A/Ao = -\lambda t$

λ = _____ min^{-1}

Solve for measured half-life, $t_{1/2}$ (in min), according to equation $t_{1/2} = -0.693/\lambda$

$t_{1/2}$ = _____ min

Does measured half-life fall within acceptable range of 18−22 min?

Circle one: Yes or No

Date_____ Chemist _____ Signature_____

Radionuclidic identity must be tested on a batch of [^{11}C]Mes-IMPY annually and a copy of this updated radionuclidic purity report placed in the batch production record of the first validating production run of [^{11}C]Mes-IMPY for Injection. Also, radionuclidic identity test must be performed with the use of new ^{11}C target design.