ALMAC

Partnering to Advance Human Health

CASE STUDY

REQUIREMENT FOR SYNTHESIS OF NON-GMP ^{14}C API

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The approach taken for a client who trusted Almac for the supply of non-GMP ^{14}C API for their drug development programme.

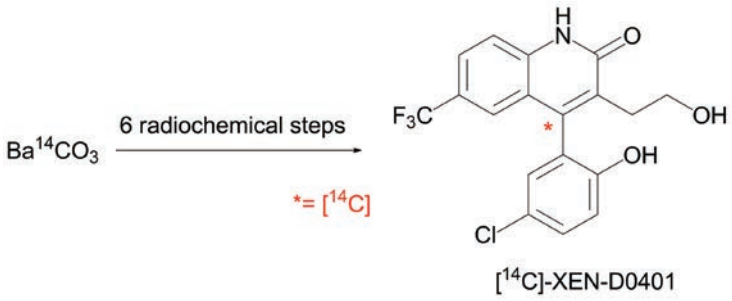
OUR ESTABLISHED TRACK RECORD, COUPLED WITH OUR STRONG QUALITY CULTURE, ENSURES OUR SERVICES WILL MEET YOUR QUALITY, COST AND DELIVERY EXPECTATIONS.

BACKGROUND

Almac was approached by a pharmaceutical company and asked to provide 25mCi of ^{14}C-labelled XEN-D0401. Almac were also asked to evaluate the feasibility of synthesis and suggest a suitable labelling position which was both metabolically stable and cost effective.

ALMAC APPROACH

A literature review was performed for the synthesis of ^{14}C-labelled XEN-D0401 and identified three alternative positions that could be labelled. On considering the relative costs of synthesis and metabolic stability, labelling of the quinolinone ring at the 4-position was the preferred option.



Kitson et al, J. Lab. Compd. Radiopharm., 2010, 53(3), 140-146.

A trial chemistry phase was undertaken to ensure that the chemistry was fit for purpose before committing the expensive radiolabelled starting material to the synthesis.

RESULT

25mCi of the ^{14}C-labelled XEN-D0401 was provided for ADME studies. All customer specifications were met for the purity of the product.

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