**Record of Technical Anomaly**

**Technical Anomaly No: TA440**

**PART 1: Issue, impact assessment and signing open**

**Raised by:** Hannah Ford **Date: 18/04/22**

**OP / Method: OP224 Ethyl Carbamate**

**Analytical sequence initiated** *(where appropriate)***: EC0798**

**Details** *(please tick relevant box(es) and provide supplementary information where required)***:**

□ QC point(s) above/below ±2SD □ Bracketing standard(s) outside limits

□ QC point(s) above/below ±3SD □ QC Recovery outside limits

□ QC point(s) outside expanded uncertainty R Other *(add details below)*

Trials were run for OP224 in March/April 2022 to determine the optimum level of copper to add to new make grain spirits so that all precursor was converted to ethyl carbamate.



The amendments to standard sample prep procedure, as indicated by the results of the copper trials, were enacted in run EC0798 after discussion with the Technical Manager, Deputy Technical Manager and Deputy Quality Manager.

However the amendments to OP224 that detail the new procedure, were still in revision at the time of reporting results on run EC0798. This was due partly to time constraints and a great need to reduce a large sample backlog, but also because any issues with the new procedure would only become apparent after it had been piloted on real samples.

Data will be closely monitored until such time as the OP revisions are approved.

□ No apparent reason for this anomaly

**Recommended Action:**

R No action required out with the usual close monitoring of the Quality Control data in subsequent runs.

**Explanation why the issue does not impact data quality & why it isn’t a departure:**

The robust copper trials show the new procedure is a true improvement on the previous iteration of the method. All data, chromatography and results will continue to be closely monitored.

**Management Review:**

***I agree to open this Technical Anomaly and confirm that this would not prevent results from being reported.***

**Authorised by:**

**(Technical/Services/Quality Manager)**

**Date:**

**PART 2: Follow-up actions and close-out**

**Follow-up actions conducted:**

□ No follow up required

**All analytical sequence(s) affected** *(where appropriate)***:**

**Signed off & closed by Quality Manager:**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

