PHARMASSURE

Pharmaceutical Products Proficiency Testing Scheme

Issue: 14
Issue Date: May 2016

Instructions for Handling Test Materials and Recording Results

Receipt and Storage

- On receipt of the test material, store refrigerated at 2-8°C until ready to test
- The test material should be analysed in accordance with the deadlines provided

Sample 1A – pH

- Determine the pH of the solution provided
- Results are to be reported to 2 decimal places

Sample 1B – Acid/Base Titration

- Titrate 10ml ± 0.04ml of the solution provided using 0.1M NaOH (sodium hydroxide) to an end point equivalent to a pH value of 8.75 using either:
    a. A calibrated pH meter (i.e. potentiometrically)
    b. A suitable indicator solution (e.g. phenolphthalein)
- Report your result as the titre standardised to 0.1M sodium hydroxide, e.g. a titre of 25mL using 0.09M sodium hydroxide equals 25 x 0.09/0.1 = 22.50mL
- Report your result to 2 decimal places

Sample 1D – Density

- Determine the density of the material provided at 20°C
- Results are to be reported as g/cm^3 to 3 decimal places

Sample 1E – Refractive Index

- Determine the refractive index of the solution provided
- The refractive index should be measured at 20±0.5°C
- Results are to be reported to 4 decimal places

Details of the additional basic titration and melting point determination will be provided on a separate sheet on a round by round basis.

Advanced Chemical Testing

Receipt and Storage

- On receipt of the test material, store refrigerated at 2-8°C until ready to test, unless otherwise specified on the instructions provided with the samples
- The test material should be analysed in accordance with the deadlines provided

Further details of the analysis of the advanced testing sample will be provided on a separate sheet, on a round by round basis.

Instructions for Handling Test Materials and Recording Results

Microbiology Samples (all sample types)

Receipt and Storage

- On receipt of the test material, store refrigerated at 2-8°C until ready to test.
- The test material should be analysed in accordance with the deadlines provided.

Sample Details

- The test material represents a simulated pharmaceutical sample, which may or may not contain the target organism(s), at a range of inoculum levels
- The test material is supplied as a freeze-dried test material contained within a glass vial
- Occasionally test materials contain high numbers of the target organisms, therefore it may be necessary to perform dilutions. Further guidance on levels is available in the PHARMASSURE Scheme Description.

Resuscitation of all microbiological samples (with exception of Identification test only*, see Level 3 below)

- Prepare 100ml sterile deionised water or suitable alternative microbiological diluent
- Aseptically remove cap and rubber stopper from the vial and resuscitate the freeze-dried test material by adding approximately 10ml of the bulk diluent.
- Replace the stopper and shake to dissolve then add this concentrate to the bulk diluent
- Repeat this procedure two or three times to ensure all the freeze-dried test material is recovered from the vial and added to the bulk diluent.
- Leave the diluted test material to stand for a minimum of 60 minutes but no longer than 90 minutes. Immediately before testing, mix the sample by gently inverting.
- This final 100ml represents a 'neat' sample.

Sample 3 - Microbiology Low-level Enumeration and Identification

For both Enumeration and Identification Test

- Perform membrane filtration on the entire 100ml test material and record the total number of colonies present. It is recommended to use non-selective agar and incubate at mesophilic temperature range.
- Report result as cfu/100ml as the 100ml test material represents a 'neat' sample.
- Identify the colonies present using your normal laboratory procedures.

***Identification Test only**

- If you do not wish to carry out enumeration on this sample, simply add 1ml of sterile diluent to the test material, leave to resuscitate for a minimum of 60 minutes but no longer than 90 minutes, and then inoculate a sample of the test material onto your selected media. Identify the colonies present using your normal laboratory procedures.

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Samples 4A & 4B - Microbiology Enumeration

Testing

- Test for the target organism(s) using your routine laboratory method(s).
- Tests for sample 4A include total aerobic microbial count, total bacterial count, detection and/or enumeration of *Staphylococcus aureus*, detection and/or enumeration of *Escherichia coli*, and detection and/or enumeration of bile-tolerant gram-negative bacteria.
- Tests for sample 4B include detection of *Pseudomonas aeruginosa*, detection and/or enumeration of *Candida albicans*, total yeast and mould count, enumeration of yeast and enumeration of mould.
- Participants are not required to enter results for each parameter, only for those tests performed on a routine basis.
- Report results as cfu/ml
- The reconstituted test material (100ml) should be treated as the 'neat' pharmaceutical sample.

Sample 5 - Sterility Testing

Testing

- The sterility test comprises a set of 5 different samples to test for sterility using your routine laboratory method.
- The reconstituted test material should be treated as the 'neat' pharmaceutical sample.
- Report results as 'Sterile' or 'Not sterile'

Precautions to be taken with microbiology samples

- Test materials contain viable micro-organisms and are supplied on the understanding that the purchaser has suitably competent and qualified personnel to handle them safely. Test materials must only be opened in a laboratory by qualified personnel.
- Test materials may contain micro-organisms classed as Hazard Group 2 according to the Advisory Committee on Dangerous Pathogens (HSE 1998- ISBN0717610381) and should be handled accordingly.
- In case of accidental spillage, contain the spillage and alert nearby personnel. Decontaminate the spillage with suitable disinfectant. Clean using absorbent disposable paper or tissue.
- For further safety information concerning the samples a safety data sheet should be obtained from the scheme provider.

Recording Results

- All results should be submitted using PORTAL
- Please go to https://www.lgcpt.com/portal
- Login using your Lab ID, username and password.

- A PORTAL user guide can be downloaded from the help section.

If you need any help at all please do not hesitate to contact our support team using the details below or your local LGC representative.

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