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UKAS TESTING
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Glenn Kennedy BSc PhD CChem FRSC
Head of Chemical Surveillance Branch
Veterinary Sciences Division, AFBI
Stoney Road, Stormont,
Belfast BT4 3SD, Northern Ireland, UK

Tel +44 28 90 525 651
Mobile +44 787 639 5170
Fax +44 28 90 525 626
Email glenn.kennedy@afbini.gov.uk

Dear Dr San Martin,

The FAVET laboratory, which is part of the Faculty of Veterinary Medicine in the University of Chile, has continued to make considerable improvements since I first visited it in 2004. Without doubt it is now a state-of-the-art laboratory which exceeds the standards achieved in some National Reference Laboratories in some EU Member States. The laboratory has an excellent record in participation in Proficiency Testing Schemes for a wide range of compounds. Since 2006, it has recorded 39 satisfactory z-scores for veterinary medicinal products and only three questionable results. The follow-up actions taken by the laboratory in response to two of the questionable results was audited and found to be clear & comprehensive. It was suggested that in both cases (in one of which a false positive result for OTC using HPLC-DAD was reported) the Laboratory investigation revealed that partial sample deterioration during transportation was the probable cause.

Following the findings of an FVO audit in 2007, the laboratory stores its calibration standards at -70°C, to minimise risks arising from stability problems, in single-use vials. This is a very strong precautionary measure & demonstrates the wish of the laboratory to avoid any further criticism. However, formal stability studies n standard solutions are not carried out. The do, however, have a control chart for standard areas and replace standards when they fail to meet internal QA requirements (± 15%). While this was a stronger approach than in other laboratories visited in 2011, it could be argued that, using their criteria, standards were replaced when it was "just too late" rather than "just in time".

It was noted that the matrix, used by FAVET, at the request of SAG, for the microbiological growth inhibition test used to screen for the presence of antibiotic residues was muscle and that the detection limit was 240 ppb. This does not meet the EU MRL for the tetracyclines, which is 100 ppb in muscle. However, if SAG requested the use of either liver or kidney the screening test would be fit-for-purpose because of the higher MRL in these matrices (300 & 600 ppb in liver & kidney, respectively.

Calibration is achieved through the use of extracted standard curves, containing at least 5 points. The regression coefficient (r^2) of calibration curves must be at least 0.95, but no assessment/control of residuals is made. Validation files were clear and well presented. The laboratory does not, however, calculate CCα & CCβ in the same was as EU laboratories. In the EU, CCα for an MRL substance is always higher than the MRL, by an amount roughly equating to the Uncertainty of the method at the MRL. As a result of Chile having to meet different MRLs for different markets, the FAVET laboratory prefers to calculate CCα and CCβ using zero, rather than the MRL as the level of interest. This is a reasonable approach to take, given the special circumstances of the country having to meet a range of technical requirements in their various export markets.

Of the laboratories that I have visited in Chile (approximately 12 public & private sector laboratories, in total and 5 laboratories during my 2010 visit, I have little doubt that FAVET is one of the leading (if not THE leading) residues testing laboratory in Chile. It was also noted, outside the scope of my visit, that FAVET is investing in a new dioxin testing facility that will reinforce its position as one of the leading residues laboratories in the country.

Best regards,

Glenn Kennedy.

Glenn Kennedy
29th March 2011.