



CRO Outsourcing Case Study

Quality Control Check of Avermectin Batches for Presence of Residual DNA

Customer Need

The avermectins compose a class of polycyclic lactones that are used to treat parasitic worms and insect pests. They are naturally occurring compounds generated in a fermentation process by a soil actinomycete *Streptomyces avermitilis*.

During the production process of biopharmaceuticals, a residual host cell DNA contamination can be introduced. Production companies usually include purification procedures to remove these contaminants; however, it is

still necessary to verify the amount of residual host DNA present in intermediate and final product samples to comply with quality control assessment.

GENERI BIOTECH was approached by an industrial customer to check for traces of *Streptomyces avermitilis* production strain DNA in 3 different production batches of avermectin. The main challenge was to develop a *S. avermitilis*-specific method and a calibration curve using the reference strain gDNA, which is not commercially available.

The Solution

Building on its expertise in host cell DNA analysis, GENERI BIOTECH developed and validated a specific method for determination of residual DNA in 3 batches of Avermectin based on quantitative PCR assay and using gDNA isolate from *S. avermitilis* BCCO-10-0959 culture collection as a standard. In parallel, total DNA amount was verified by nonspecific qPCR assay using degenerated oligo primers (DOPs). In compliance with the International Conference

of Harmonization (ICH) guidelines, the qPCR assays were validated for precision, accuracy, detection and quantitation limits, linearity and specificity. The analysis concluded that in all three tested avermectin batch extracts there was no presence of total or *S. avermitilis* - specific DNA, a favorable result which was far below the acceptance criteria of < 0.3 %.

Customer Benefit

- fast and cost-efficient development and validation of the method in GMP-like mode
- a unique range of comprehensive solutions under one roof: from DNA isolation, specific qPCR assay development, off-the shelf validated qPCR assay, to routine testing
- highly sensitive analysis of the samples

More info on website

<https://www.generi-biotech.com/categories/gmp-glp-testing-en>

„the service was excellent on all fronts and I would recommend the company to others and would of course use it again myself when the situation arises“ - Joe Jennings, Ancare Ireland