



## **bioMérieux Unveils its Groundbreaking Culture Media Range for Sterility Control of Aseptic Pharmaceutical Plants**

*New range will simplify testing for the pharmaceutical industry*

*Marcy l'Etoile (France), April 7, 2009* – bioMérieux, a world leader in the field of *in vitro* diagnostics and a leading provider of microbiological solutions for the pharmaceutical industry, launches two innovative culture media for Media Fill Tests (MFT): TSB 3P™ with Animal Peptones and TSB 3P™ with Vegetable Peptones and a color indicator to enhance efficiency and reduce potential errors.

Good Manufacturing Practices (GMP)\* require that pharmaceutical companies regularly verify the sterility of their production processes for injectable medical products such as vaccines, insulin, intravenous fluids or therapies, etc. Media Fill Tests are used for this microbiological control. They simulate the normal manufacturing conditions by replacing the product with culture media. Current practice requires the manual reading of several thousand containers filled with this culture media for each MFT. Since each container must be checked individually, this practice is extremely time-consuming and can be a source of potential errors.

To address these issues, bioMérieux has pioneered two new dehydrated culture media products designed for use in MFT. Both media are TSE-free to prevent any risk of transmitting animal spongiform encephalopathy. The TSB 3P with Vegetable Peptones features a unique and patented color indicator that changes from pink to yellow if a bacterial contaminant is present. This visual indicator simplifies the interpretation of the test result and reduces the possibility of errors. In addition, the vegetable peptones perfectly suit pharmaceutical companies that have “animal-free” production processes.

*“Simulating sterile filling is critical for our Pharmaceutical customers,”* stated Alexandre Mérieux, bioMérieux Corporate Vice President, Industrial Microbiology. *“This new range of MFT products deliver quality advantages and greater ease of use. It also complements BacT/ALERT®, our automated solution for in process sterility control.”*

The TSB 3P range with Animal or Vegetable Peptones meets the highest performance standards and complies with the requirements of American, Japanese and European Pharmacopoeias for the growth of non-fastidious microorganisms (bacteria, yeasts, fungi and certain anaerobic bacteria). Both formulations are cold-filterable to avoid any warming step to dissolve the dehydrated medium, and gamma irradiated to ensure the absence of viable microorganisms and mycoplasma.

\* GMP are regulations promulgated by the U.S. Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act.

## About bioMérieux

### ***Advancing Diagnostics to Improve Public Health***

A world leader in the field of *in vitro* diagnostics for 45 years, bioMérieux is present in more than 150 countries through 39 subsidiaries and a large network of distributors. In 2008, revenues reached €1.111 billion with 84% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products. bioMérieux is listed on the NYSE Euronext Paris market (Code: BIM – Code ISIN: FR0010096479). Other information can be found at [www.biomerieux.com](http://www.biomerieux.com).

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