Positive Material Identification (PMI) for incoming materials and impurities in APIs – Element Analysis with XRF – fast, easy, and 21 CFR Part 11 compliant!

For pharmaceutical and biotechnological companies, fast positive material identification (PMI) is needed to decrease production time and plays an integral role in allowing products to be released to the market sooner. The S6 JAGUAR (a powerful benchtop WDXRF instrument) and the S2 PUMA (high-end EDXRF instrument) make testing of elemental compositions simple, fast, accurate, and traceable.

Both spectrometers can be operated easily after minimal training via TouchControl™. The intuitive touchscreen software allows the routine operation of the instrument without external PC. Ease-of-use, simple sample preparation, and overall short time-to-result are some of the key advantages of XRF when compared to methods such as ICP-MS.

Many areas of the pharmaceutical and biotechnological industries fall under regulations as defined by the FDA under 21 CFR Part 11 and others. These regulations describe how data integrity should be achieved and specify the analytical requirements for many elements, which might occur as contamination.

The S6 JAGUAR and the S2 PUMA operate with the 3rd generation of Bruker’s instrument software SPECTRA.ELEMENTS. The software is specifically designed to match the requirements of 21 CFR Part 11. The compliance is ensured e.g. through a dedicated user management system, electronic record keeping, electronic signature, and audit trailing. Optional IQ/OQ procedures are offered with the installation of both instrument types.