

getSys is proud to present its first compact analyzer for online monitoring of blending processes

## Contact-free real-time analysis with our BlendAlyser

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getSys, located in Dresden / Germany and specialized in optical measurement systems, is proud to present with the *BlendAlyser* its latest development for contact-free online monitoring of powder blending processes. This instrument is well tailored for the needs of pharmaceutical industries and research establishments. Due to its extremely light weight (6.5 kg [14.3 lbs]) and its compact design compliant with cGMP and IP65, the system can be easily adjusted and mounted to different blending systems.

Using NIR spectroscopy the *BlendAlyser* analyzes blending behaviors of several powders. Besides online monitoring of product homogeneity and end point of the blend process based on this, quantitative determinations of particular ingredients applying chemometric calibrations are possible, too. Sampling and time consuming and expensive HPLC laboratory analysis are no longer necessary.

### System monitoring by the BlendAlyser

The *BlendAlyser*, which might be used in laboratories and during manufacturing processes, offers a lot of advantages and opens up a lot of new possibilities.

Due to precise end point detection it is possible to reduce blending processes to a minimum of time, avoid faulty batches and prevent substances from being deblended. There is no longer need for taking samples and laboratory analysis which retard manufacturing processes and therewith eventually raise production costs. Moreover, the *BlendAlyser* eases controlling production flows and provides with real time data an improved process understanding. Thus increases quality assurance, yield and effectiveness.



Figure 1: BlendAlyser mounted to a blending system



Figure 2: BlendAlyser and its status-LED

### Latest technology – compact design

The used MEMS technology provides highest reliability and guarantees long-life cycles. Exchanging the light source which is generally common for NIR systems is not necessary due to a laser lifetime of more than 20 years. A tunable laser allows the analysis of reflectance spectra within a wavelength range between 1350 and 1800nm. Significant absorption bands which are extremely important for several active ingredients are therewith detected and clearly increase analyzing accuracies. Furthermore, the optical resolution of up to 1nm opens up new and easier analyzing methods compared to conventional NIR spectroscopy.

The BlendAlyser fulfills the USP<1119> requirements and a superior long-term stability can be guaranteed due to a continuous, internal wavelength and amplitude referencing. The extremely low noise therefore permits highly sensitive measurements.

Recording measuring values is automatically activated at every revolution of the blender via a programmable 3D position measuring system. Controlling and timing as well as data acquisition and processing is done by a measuring device with embedded PC. The real-time transmission

of data via WLAN to the respective supervisory PC is realized by the PC mentioned above. The software of this embedded PC has already been installed and is directly applicable. Due to its wireless communication via remote desktop connections, the BlendAlyser is extremely flexible. Internal data back-up guarantees protection against losing measuring data, especially in case of interrupts in the WLAN communication. The system is accessible at any time using remote maintenance connections. It is even possible to use digital I/O interfaces with blenders disposing of electrical contacts via jumper rings.

All components are integrated into a top-quality and rugged enclosure compliant with cGMP having a smooth and easy to clean surface. This enclosure is designed for the most demanding manufacturing requirements. Every screw is countersunk and sealed according to IP65. The BlendAlyser's compact enclosure dimensions of approx. 23x21x15 cm (approx. 9.1x8.3x5.9 inch) offer the possibility of being used even for limited accessibility and being mounted to smaller laboratory blenders. This is supported by simple handling, e.g. ergonomic handrail design.

### **Highest flexibility and easiest handling**

Due to its compact and integrated design, the BlendAlyser can be easily mounted to different blender sizes and models. It only requires a commercially available flange fastener being mounted on a 4" default flange.

Power supply is done via a mains adapter and a high performance storage battery so operating the system completely wireless system is possible as well. Changing the battery might be executed on a running system. Therefore a system restart is not necessary.

The scope of delivery includes two pre-installed GUI programs compliant with 21CFR-part-11. This measuring software disposes of several user levels used for system configurations as well as routine applications in manufacturing processes. The second software package offers the possibility to treat different spectra in a mathematical way which allows the creation of chemometric calibration models and statistical methods for end point detections. Both programs do have a common interface allowing the application of these methods and models to spectra measured during the blending process.

Regarding software programming, great importance has been attached to usability, flexibility and, of course, highest safety standards. Operating this software is really easy for the user – serious faulty entries are almost impossible.

### **getSys – qualified partner for laboratory and process technology**

Besides development and fabrication of optical measuring systems, getSys offers large services as for its own product range, too. Thus enables us to provide qualification documents such as IQ/OQ/PQ for our BlendAlyser.

The getSys team will always be available to help you concerning individual consulting services for test measurements or the implementation of our systems. Even staff trainings can be realized. You may definitively benefit from our knowledge and experience!

Please find further information at: [www.getSys.com](http://www.getSys.com)

### **Technical specification: BlendAlyser**

**Spectral range:** 1350 - 1800 nm

**Optical resolution:** (FWHM) 1 - 5 nm

**Accuracy:**  $\pm 0.025$  nm

**Reproducibility :**  $\pm 0.01$  nm

**Non-linearity:**  $\leq 5$  %

**Noise – High Flux:** better than  $0.3 \times 10^{-3}$  AU

**Noise – Low Flux:** better than  $1 \times 10^{-3}$  AU

**Sampling interface:** sapphire window

**Measurement spot size:** 25 mm

**Working distance:** Depending on sapphire window (27 mm at 8.5 mm Sapphire)

**Power supply:** hot swappable battery with approx. 3 hrs operation

**Battery recharge time:**  $\leq 3$  hours

**Enclosure:** IP65, NEMA4, GMP

**Dimensions of complete system:** 230 x 210 x 150 (+50\*) mm / 9 x 8.5 x 6 (+2\*) inch

**Weight:** 6.5 kg / 14.5 lb

**Measurement trigger:** internal software controlled 3D position measurement

**Communications:** WLAN (802.11b/g)

**Operating system:** Windows XP Embedded

**Validation:** software features validation routines according to OQ/PQ

\*) length of process flange