SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

TECHNICAL FIELD

[0001] This disclosure relates to lasers and light sources for remote or stand-off identification of counterfeit drugs, detection of illicit drugs, or process control in the pharmaceutical industry including systems and methods for using near-infrared or short-wave infrared light sources for remote detection of counterfeit or illicit drugs and process control at remote or stand-off distances in the pharmaceutical industry.

BACKGROUND AND SUMMARY

[0002] Counterfeiting of pharmaceuticals is a significant issue in the healthcare community as well as for the pharmaceutical industry worldwide. For example, according to the World Health Organization, in 2006 the market for counterfeit drugs worldwide was estimated at around $43 Billion. Moreover, the use of counterfeit medicines may result in treatment failure or even death. For instance, in 1995 dozens of children in Haiti and Nigeria died after taking counterfeit medicinal syrups that contained diethylene glycol, an industrial solvent. As another example, in Asia one report estimated that 90% of Viagra sold in Shanghai, China, was counterfeit. With more pharmaceuticals being purchased through the internet, the problem of counterfeit drugs coming from across the borders into the United States has been growing rapidly.

[0003] A rapid, non-destructive, non-contact optical method for screening or identification of counterfeit pharmaceuticals is needed. Spectroscopy using near-infrared or short-wave infrared (SWIR) light may provide such a method, because most pharmaceuticals comprise organic compounds that have overtone or combination absorption bands in this wavelength range (e.g., between approximately 1-2.5 microns). Moreover, most drug packaging materials are at least partially transparent in the near-infrared or SWIR, so that drug compositions may be detected and identified through the packaging non-destructively. Also, using a near-infrared or SWIR light source with a spatially coherent beam permits screening at stand-off or remote distances. Beyond identifying counterfeit drugs, the near-infrared or SWIR spectroscopy may have many other beneficial applications. For example, spectroscopy may be used for rapid screening of illicit drugs or to implement process analytical technology in pharmaceutical manufacturing. There are also a wide array of applications in assessment of quality in the food industry, including screening of fruit, vegetables, grains and meats.

[0004] In one embodiment, a near-infrared or SWIR super-continuum (SC) source may be used as the light source for spectroscopy, active remote sensing, or hyper-spectral imaging. One embodiment of the SWIR light source may be an all-fiber integrated SWIR SC source, which leverages the mature technologies from the telecommunications and fiber optics industry. Exemplary fiber-based super-continuum sources may emit light in the near-infrared or SWIR between approximately 1.4-1.8 microns, 2-2.5 microns, 1.4-2.4 microns, 1-1.8 microns, or any number of other bands. In particular embodiments, the detection system may be a dispersive spectrometer, a Fourier transform infrared spectrometer, or a hyper-spectral imaging detector or camera. In addition, reflection or diffuse reflection light spectroscopy may be implemented using the SWIR light source, where the spectral reflectance can be the ratio of reflected energy to incident energy as a function of wavelength.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] For a more complete understanding of the present disclosure, and for further features and advantages thereof, reference is now made to the following description taken in conjunction with the accompanying drawings, in which:

[0006] FIGURE 1 shows the absorbance for two common plastics, polyethylene and polystyrene.

[0007] FIGURE 2 illustrates one example of the difference in near-infrared spectrum between an authentic tablet and a counterfeit tablet.

[0008] FIGURE 3 shows the second derivative of the spectral comparison of Prozac and a similarly formulated generic.

[0009] FIGURE 4 illustrates an example of the near infrared spectra for different pure components of a studied drug.

[0010] FIGURE 5 shows the mid-wave infrared and long-wave infrared absorption spectra for various illicit drugs.

[0011] FIGURE 6 shows the absorbance versus wavelength in the near-infrared region for four classes of illegal drugs.

[0012] FIGURE 7 illustrates the diffuse reflectance near-infrared spectrum of heroin samples.

[0013] FIGURE 8 illustrates the diffuse reflectance near-infrared spectra of different seized illicit drugs containing heroin of different concentrations, along with the spectrum for pure heroin.

[0014] FIGURE 9 lists possible band assignments for the various spectral features in pure heroin.

[0015] FIGURE 10 shows the diffuse reflectance near-infrared spectra of different compounds that may be frequently employed as cutting agents.

[0016] FIGURE 11 provides one example of a flow-chart in the process analytical technology for the pharmaceutical industry.

[0017] FIGURE 12 illustrates the typical near-infrared spectra of a variety of excipients.

[0018] FIGURE 13 exemplifies the absorbance from the blending process of a pharmaceutical compound.

[0019] FIGURE 14 shows what might be an eventual flow-chart of a smart manufacturing process.

[0020] FIGURE 15A illustrates the near-infrared reflectance spectrum of wheat flour.

[0021] FIGURE 15B shows the near-infrared absorbance spectra obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit.

[0022] FIGURE 16A is a schematic diagram of the basic elements of an imaging spectrometer.

[0023] FIGURE 16B illustrates one example of a typical imaging spectrometer used in hyper-spectral imaging systems.

[0024] FIGURE 17 shows one example of the Fourier transform infrared spectrometer.

[0025] FIGURE 18 exemplifies a dual-beam experimental set-up that may be used to subtract out (or at least minimize the adverse effects of) light source fluctuations.

[0026] FIGURE 19 illustrates a block diagram or building blocks for constructing high power laser diode assemblies.

[0027] FIGURE 20 shows a platform architecture for different wavelength ranges for an all-fiber-integrated, high powered, super-continuum light source.

[0028] FIGURE 21 illustrates one embodiment for a short-wave infrared super-continuum light source.

[0029] FIGURE 22 shows the output spectrum from the SWIR SC laser of FIGURE 21 when about a 10m length of fiber for SC generation is used. This fiber is a single-mode, non-dispersion shifted fiber that is optimized for operation near 1550nm.

[0030] FIGURE 23 illustrates high power SWIR-SC lasers that may generate light between approximately 1.4-1.8 microns (top) or approximately 2-2.5 microns (bottom).

DETAILED DESCRIPTION

[0031] As required, detailed embodiments of the present disclosure are described herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the disclosure that may be embodied in various and alternative forms. The figures are not necessarily to scale; some features may be exaggerated or minimized to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the present disclosure.

[0032] One advantage of optical systems is that they can perform non-contact, stand-off or remote sensing distance spectroscopy of various materials. As an example, optical systems can be used for identification of counterfeit drugs, detection of illicit drugs, or process control in the pharmaceutical industry, especially when the sensing is to be done at remote or stand-off distances in a non-contact, rapid manner. In general, the near-infrared region of the electromagnetic spectrum covers between approximately 0.7 microns (700nm) to about 2.5 microns (2500nm). However, it may also be advantageous to use just the short-wave infrared (SWIR) between approximately 1.4 microns (1400nm) and about 2.5 microns (2500nm). One reason for preferring the SWIR over the entire NIR may be to operate in the so-called "eye safe" window, which corresponds to wavelengths longer than about 1400nm. Therefore, for the remainder of the disclosure the SWIR will be used for illustrative purposes. However, it should be clear that the discussion that follows could also apply to using the near infrared – NIR -- wavelength range, or other wavelength bands.

[0033] In particular, wavelengths in the eye safe window may not transmit down to the retina of the eye, and therefore, these wavelengths may be less likely to create permanent eye damage from inadvertent exposure. The near-infrared wavelengths have the potential to be dangerous, because the eye cannot see the wavelengths (as it can in the visible), yet they can penetrate and cause damage to the eye. Even if a practitioner is not looking directly at the laser beam, the practitioner's eyes may receive stray light from a reflection or scattering some surface. Hence, it can always be a good practice to use eye protection when working around lasers. Since wavelengths longer than about 1400nm are substantially not transmitted to the retina or substantially absorbed in the retina, this wavelength range is known as the eye safe window. For wavelengths longer than 1400nm, in general only the cornea of the eye may receive or absorb the light radiation.

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