

Instantaneous Screening for Counterfeit Drugs with No Sample Preparation

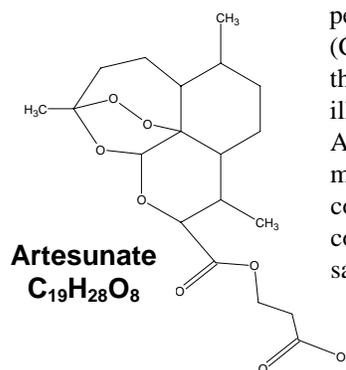
Drug counterfeiting is becoming a serious and widespread public health problem. The number of FDA open investigations into drug counterfeiting rose sharply from 2000 to 2001 and has remained high in recent years¹. Counterfeit drugs are not only illegal, but dangerous; they may contain little or no actual drug content, or they may contain completely different drugs with potentially toxic consequences. The problem is worldwide; it has been reported that nearly 50% of all anti-malarial drugs in Africa are thought to be counterfeit¹.

Direct Analysis in Real Time (DART™) offers a simple solution to screening for counterfeit drugs. DART can detect the presence or absence of drugs in medicines within seconds by simply placing the pill or medicine in front of the mass spectrometer. In combination with the AccuTOF, DART provides exact masses and accurate isotopic patterns that provide elemental compositions for known and unknown substances.

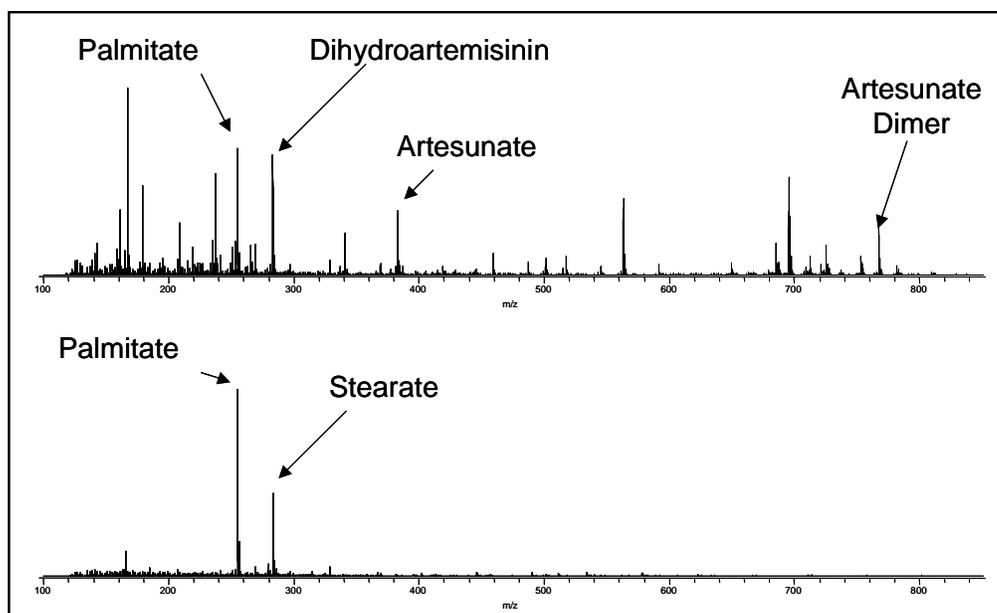
The top spectrum (below left) shows a sample of a genuine drug containing the anti-malarial compound "Guilin B" containing artesunate (structure below right), and the bottom spectrum shows a counterfeit drug containing only binders (stearate and palmitate) and no

active ingredient². The samples were placed in front of the DART with no sample preparation and the mass spectra were obtained within seconds.

It is noteworthy that the peak at m/z 283.15476 in the genuine drug is assigned the composition $C_{15}H_{23}O_5^-$ (dihydroartemisinin or a fragment from artesunate). The measured m/z differs from the calculated m/z by only 0.2 millimass units and is easily distinguished by its exact mass measurement from the



peak at m/z 283.26405 ($C_{18}H_{35}O_2^-$ or stearate) in the phony drug. This illustrates the value of AccuTOF's exact mass measurements in making correct assignments for compounds having the same integer mass.



¹ http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html#scope

² Samples were provided courtesy of Prof. Facundo Fernandez, Georgia Institute of Technology