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PURPOSE

Samples seized from the Southwest border ports of entry by Customs and Border Protection (CBP) were submitted to the Center for Forensic Science Research and Education (CFSRE) for the purposes of qualitative and quantitative testing. The purpose of this report is to provide information on the substances identified in counterfeit tablets seized in 2020—2023.

BACKGROUND

CBP seizes counterfeit tablets monogrammed "M30" that have the appearance of pharmaceutical oxycodone, but are suspected to contain fentanyl. These tablets were analyzed by gas chromatography/mass spectrometry (GC/MS). A total of 1,219 originating from 81 seizures were analyzed. The scope of the GC/MS analysis includes about 11,00 compounds including controlled substances, pharmaceuticals, synthesis precursors and by-products, and adulterants.

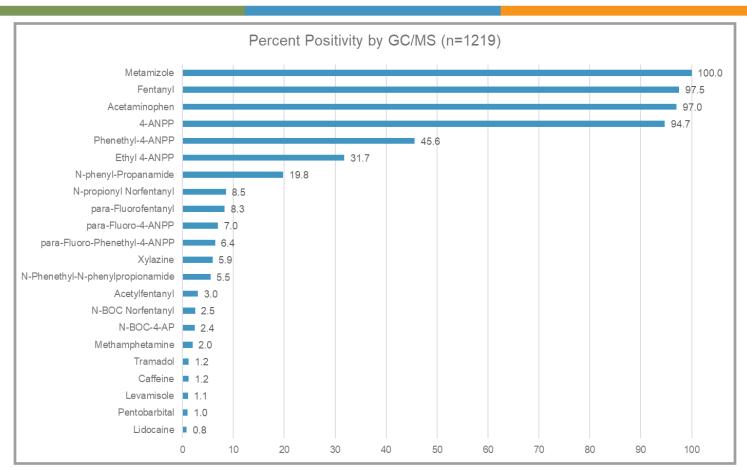


Figure 1: Percent positivity in 1,219 "M30" tablets by GC/MS.

The tablets analyzed contained primarily fentanyl as the only opioid in the sample. However, 8.3% of tablets contained a mixture of para-fluorofentanyl and fentanyl, representing six seizures. Tramadol, an opioid used as an adulterant in drug chemistry samples, was detected in combination with fentanyl in 1.2% of tablets analyzed. Two populations of tablets from one seizure did not contain fentanyl or any other opioid, while a third population from the same seizure was positive for fentanyl.

All of the tablets tested were adulterated with metamizole and the majority also contained acetaminophen (97%). Other adulterants were seen less frequently and represent both controlled and non-controlled drugs. Pentobarbital and methamphetamine were identified in 1% and 2% of samples, respectively. Xylazine, caffeine, levamisole, and lidocaine were the non-controlled adulterants present in the tablets. Of these, xylazine was the most prevalent in 5.9% of samples. All others were less than 2%.

The other components identified in the tablets were compounds related to the synthesis of fentanyl and parafluorofentanyl.

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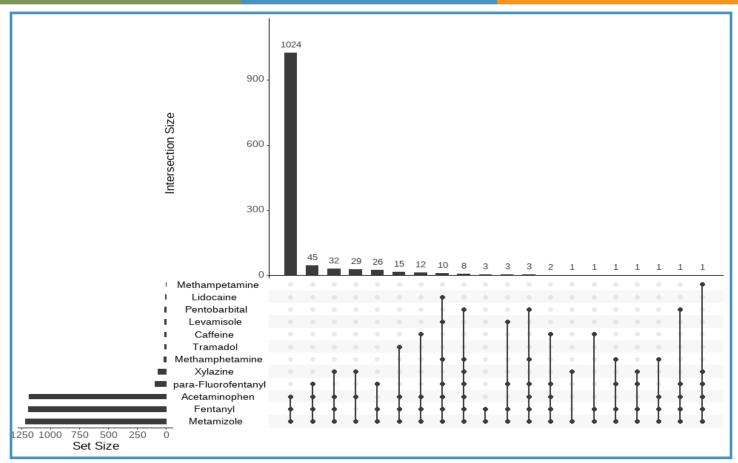


Figure 2: Plot showing the combinations of drugs and adulterants in "M30" tablets.

Most of the tablets analyzed (84%) were a combination of fentanyl, acetaminophen, and metamizole. Other combinations represented a small portion of the overall findings. Variations on that combination including the addition of para-fluorofentanyl, xylazine, or tramadol were present over 1%. When other drugs considered drugs of abuse (methamphetamine, pentobarbital, tramadol) were detected, fentanyl was also identified. Xylazine, however, was identified in tablets that did not contain fentanyl. Some tablets analyzed contained numerous components in the same sample. Five substances, not including precursors and synthesis intermediates and by-products were identified in various combinations in 2% of tablets analyzed. A subset of the tablets were quantitated. The mean, median, and concentration ranges are listed in Table 1.

Table 1: Quantitative data for analytes identified in "M30" tablets.

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Compound	Mean	Median	Range
Fentanyl (n=469)	1.9 mg	1.9 mg	0.012—6.6 mg
Acetaminophen (n=448)	56 mg	57 mg	0.79—88 mg
Para-Fluorofentanyl (n=72)	0.95 mg	1.2 mg	0.014—2.2 mg
Methamphetamine (n=21)	0.034 mg	0.027 mg	0.011—0.085 mg
Lidocaine (n=10)	0.68 mg	0.76 mg	0.44—0.86 mg
Xylazine (n=13)	0.094 mg	0.095 mg	0.088—0.10 mg

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Adulterants Identified in Tablets

Acetaminophen is a non-opioid analgesic available over-the-counter. Acetaminophen can cause liver damage when taken in high doses (over 4000 mg/day) or when combined with alcohol.

Levamisole is a veterinary medicine used for deworming. Use of levamisole can decrease white blood cell count, which can lead to a decrease in ability to fight infections. Levamisole can also cause skin conditions including rash, ulcers, and lesions.

Lidocaine is a local anesthetic. Use of significant amount of local anesthetics may cause cardiotoxicity and methemoglobinemia. Mild toxicity from lidocaine can occur at plasma levels above 5 µg/mL.

Metamizole (dipyrone) is a non-opioid analgesic. Its use is banned in the United States due to side effects associated with use, including blood disorders such as agranulocytosis, but it is still available in some countries in South America, Europe, and Asia. Use of metamizole in combination with other drugs may increase the toxic affects of the drug. It may also affect the ability of naloxone to reverse the effects of opioid overdose.

Pentobarbital is a barbiturate that acts as a sedative and an anticonvulsant. Effects include CNS depression, respiratory depression, and bradycardia. One gram of pentobarbital is considered a toxic dose.

Tramadol is a synthetic opioid analgesic. When used in combination with fentanyl, it can result in further CNS depression including respiratory depression and sedation.

Xylazine is an animal tranquilizer used in veterinary medicine. Xylazine can cause bradycardia, respiratory depression, and sedation. Xylazine use also causes skin lesions. When combined with fentanyl, xylazine can prolong the effects of the drug and increase the risk of overdose and death.

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