

INTRODUCTION:

- The proper disposal of unused prescribed medications is a concern. Approximately 40% of the prescribed medications are never used and about 67% of patients retain unused prescribed medications at home.
- Deterra™ Drug Deactivation System is being developed to offer a unique disposal method to deactivate unused, residual or expired medications.
- The system consists of a drug disposal pouch which contains granular activated carbon packaged within a water soluble film reservoir.
- The objective of this project was to develop a disposal system for a controlled substance which has a high abuse potential, i.e., fentanyl transdermal patch.

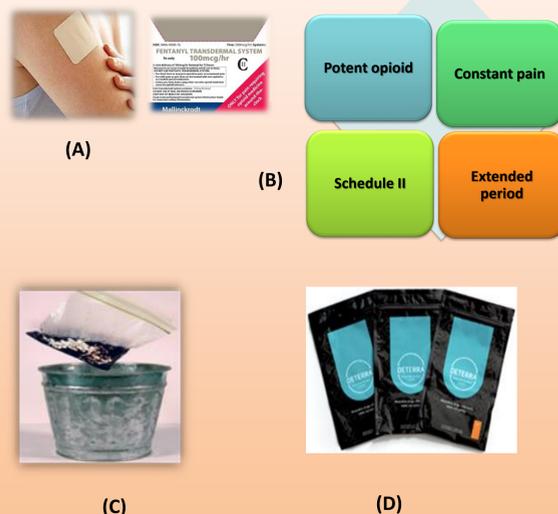


Figure.1: A) Fentanyl prescription medication. B) Characteristics of the fentanyl patch. C) Traditional drug disposal methods. D) Drug Deactivation system.

METHODS

1) HPLC method development and validation for fentanyl was performed using following parameters:

PARAMETERS	CONDITIONS
Column (Size and Particle size)	Gemini NX C18; 250*4.6 mm, 5µm
Pump mode	Isocratic
Mobile phase	ACN : Water (0.2%v/v formic acid containing 10mM sodium-1- decane sulfonate) (60%: 40% V/V)
Run time	10 min
Retention time	3.6 min
Injection volume	20 µl
Detection wavelength	192 nm

Table.1: HPLC parameters for detection of fentanyl by reverse phase chromatography.

2) Adsorption study for deactivation of fentanyl:

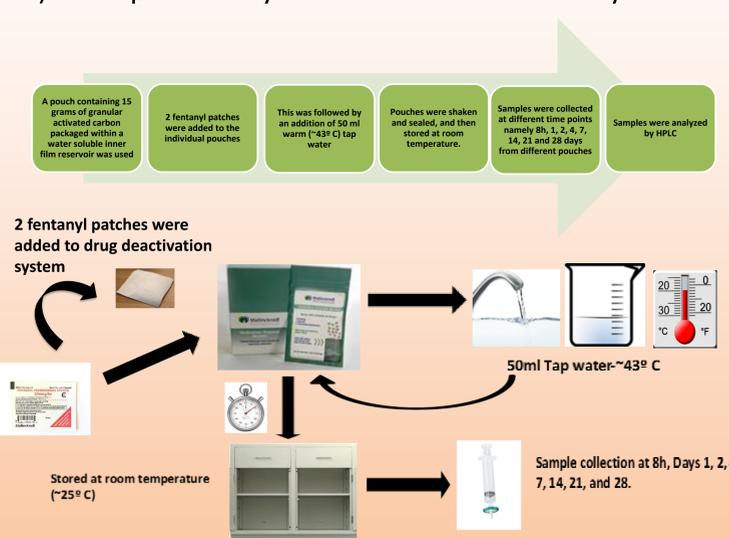


Figure.2 : Protocol- Rate and extent of adsorption for fentanyl patch.

3) Desorption study for washout from water and ethanol:



After 28 days, any potential leaching of the drug adsorbed to activated carbon was examined.

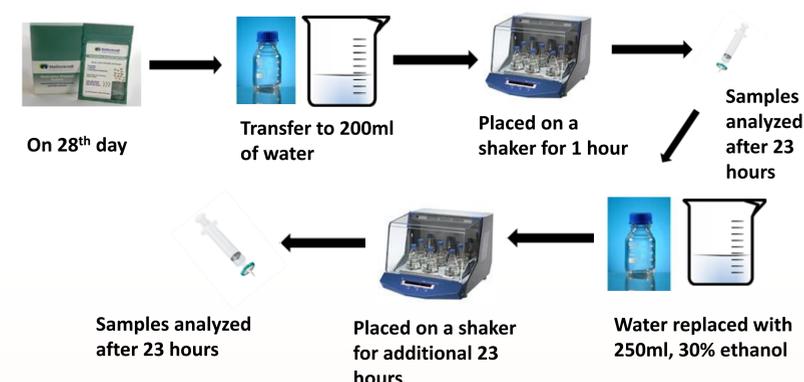


Figure.3: Desorption studies with water followed by ethanol.

4) Release jar study (Residual fentanyl patch)

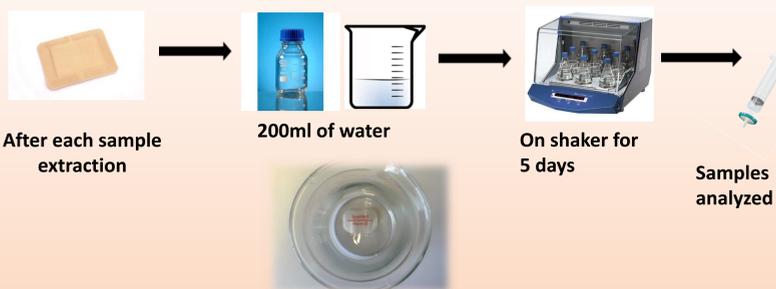


Figure.4: Release jar study to measure the amount of fentanyl remaining in the patch after being exposed to activated carbon.

RESULTS

- Deactivation started immediately after addition of fentanyl patches into the disposal pouches. Within 8 hours, 38.55% of fentanyl was released and adsorbed/deactivated by activated carbon and the remaining 61.45% was released during the glass jar release study.
- For 24 hour time point onwards, 100% deactivation was achieved in the pouch, as also verified by lack of any drug release during the glass jar release study.

Concentration (µg/ml)	Average	SD	Accuracy (%)	Precision (%)
10	9.10	0.12	18.20	1.28
25	24.83	0.13	33.11	0.54
50	52.10	0.20	52.10	0.38

Table.2: Intraday accuracy and precision

Concentration (µg/ml)	Average	SD	Accuracy (%)	Precision (%)
10	8.93	1.05	89.27	11.71
25	24.32	1.09	97.30	4.48
50	51.47	0.97	102.94	1.89

Table.3: Interday accuracy and precision

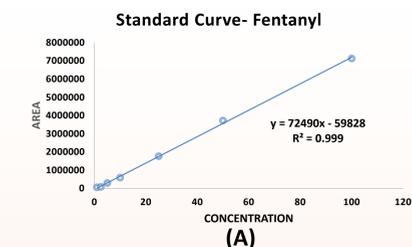
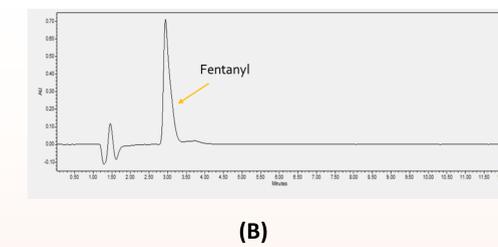


Figure 5: A) Standard curve plot of Fentanyl on three different days.



B) Chromatogram representation of Fentanyl at ~3.6 minutes for 10 µg/mL.

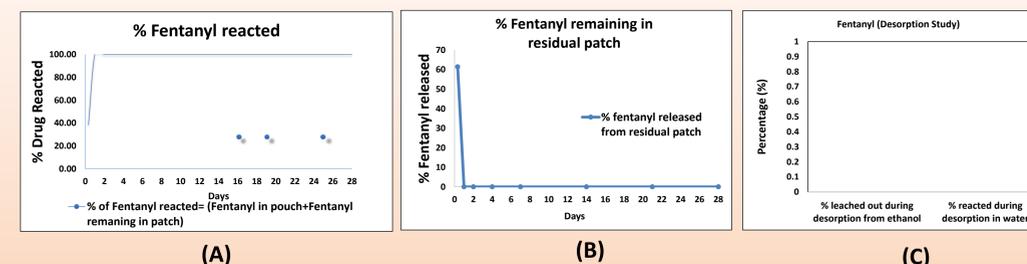


Figure.6: A) % deactivation of fentanyl with activated carbon over a period of 28 days. B) Amount of fentanyl released from the patch during the release jar study. Desorption study of fentanyl: C) Washout in water and ethanol.

CONCLUSION

The efficiency of an activate carbon based disposal system was investigated for fentanyl patches. The deactivation pouch successfully adsorbed fentanyl within 24 hours and did not release adsorbed drug when exposed to large volumes of water and ethanol. Thus, the activated carbon based system offers a simple, safe and effective procedure for prescribed transdermal patches.

Acknowledgment:

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Reference

1. Herwadkar A, Singh N, Anderson C, Korey A, Fowler W, Banga AK. Development of disposal systems for deactivation of unused/residual/expired medications. Pharm Res. 2015 Aug 12. [Epub ahead of print]