University of Hertfordshire

PROJECT REPORT

Testing of controlled drug destruction kits

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DEFINITIONS AND ABBREVIATIONS

µg	Micrograms
mg	Milligrams
g	Grams
h	Hours
HPLC	High Pressure Liquid Chromatography
LOQ	Limit of Quantification
LOD	Limit of Detection
min	Minutes
RSD	Relative Standard Deviation
SD	Standard Deviation
SOP	Standard Operating Procedure
w/w	weight for weight

EXECUTIVE SUMMARY

Recent publications and discussion in the professional literature have highlighted that many currently available controlled drug destruction/ denaturing kits do not actually chemically denature the drug and that many pharmacists were unaware of this fact. If the drug is still in its active form this leaves the drugs open to potential abuse if the chain of custody is not maintained from the Pharmacy to the incinerator. If addicts are able to remove the used destruction kits at any point in this chain they will have access to a cocktail of controlled drugs in a convenient easy to use semi-solid dosage form.

The aim of this study was to determine if a new kit developed by Yorkshire Hygiene Solutions actually chemical destroys the drug within it. For this purpose one example controlled drug, morphine, was used as a test item.

In order to meet these aims, morphine was chosen as a representative test drug and a HPLC method used for analysis.

Two version of the PolyGuard kit were tested and the ability of these kits to degrade morphine was determined. A known quantity of morphine was added to the kits and the drug content assayed immediately and the assay repeated after 48 hours to determine the extent of drug destruction.

When the full kit containing the SAP as is the case with the commercially available kit 98.45% of the morphine was degraded within 48h. When the kit with the SAP removed (supplied by the manufacture to aid the testing) was used 99.09% of the morphine was degraded within 48h.

1 INTRODUCTION

There are a number of commercially available controlled drug denaturing/ destruction kits available on the market. These kits are supposed to destroy the controlled drugs so that they can be safely disposed of, however a recent publication (Traynor 2014) and discussion in the professional literature have shown that in many cases the drug remains intact and chemically unchanged after 72 hours in these kits. This has led to much discussion amongst Pharmacists, with many confessing to be unaware that these kits were not designed to chemically denature the drugs within them. The danger of this is that current UK guidelines require CD destruction kits to be securely stored for only 48 hours, after which they can be disposed of as pharmaceutical waste. If the drug is still in its active form this leaves the drugs open to potential abuse if the chain of custody is not maintained from the Pharmacy to the incinerator. If addicts are able to remove the used destruction kits at any point in this chain they will have access to a cocktail of controlled drugs in a convenient easy to use semi-solid dosage form. Anyone determined to get controlled drugs could simply swallow the gel from the kits, or in search of quicker drug absorption, rub the gel into any mucosal membrane including the lining of the buccal, nasal or rectal cavities. Following recent publicity of this data a number of countries around the world are known to be considering adoption of similar regulations to those currently in place in the UK.

2 AIMS

The aim of this study was to determine if a new kit developed by Yorkshire Hygiene Solutions actually chemical destroys the drug within it. For this purpose one example controlled drug, morphine, was used as a test item.

3 TEST ITEM

Table 1: Test item details

Test Item 1	Product Name: Morphine Sulphate Salt Pentahydrate Exporter: Sigma-Aldrich Batch Number: SLBG4154V Date of Receipt 4th April 2014 Expiry Date: January 2016 Appearance: White powder Purity (TLC): 100%

Test Item 2	Product Name: PolyGuard (with SAP) Manufacturer: Yorkshire Hygiene Solutions, Northallerton
Test Item 3	Product Name: PolyGaurd (with no SAP) Manufacturer: Yorkshire Hygiene Solutions, Northallerton

4 MATERIALS

Table 2: Materials

Material	**Lot/Batch Number**	**Supplier**
Acetonitrile (HPLC Grade)	1173087	Fisher Scientific, UK
Nylon membrane filter (0.45 µM)	H718740400418	Whatman, UK
Pottassium dihydrogen orthophosphate	1290615	Fisher Scientific, UK

5 TEST SYSTEMS

Table 3: List of test systems and operating procedures (SOP)

Test System	Operating Procedure
HPLC	UM026, CA001,
pH meter (Jenway)	UM005, CA003,
Analytical Balance	UM002, CA008

6 METHODS

6.1 Mobile Phase preparation

20mM potassium dihydrogen orthophosphate was freshly prepared when required on a 2L scale by accurately weighing 5.436g into a 2L volumetric that was made up to volume using deionised water. A magnetic stirrer was then added and the solution stirred until all powder was completely dissolved. The mobile phase was then filtered using a 0.45µM nylon membrane filter under vacuum.

6.2 Analytical method development and validation

A 'fit for purpose' HPLC analytical method with UV detection was used from the literature (Traynor 2014). The method was deemed to be 'fit for purpose' such that the Test Item concentration was able to be determined in the presence of any matrices (e.g. excipients) used in the denaturing kits.

Table 4: HPLC method for morphine

HPLC System	Agilent Technologies: 1260 Binary Pump S/N DEABL00513 1260 Autosampler S/N DEAB305520 1260 Column Heater S/N DEACN06282 1260 VWD VL detector S/N DEAAU01717 Agilent Chem Station Software (version 04.03.054)
Column	Synergi 4µ Hydro – RP 80A
Guard Column	Security Guard Cartridge AQ C18 4 x 3.0mm
Detection	λ=210 nm
Sample Temperature	20±2ºC
Column Temperature	Ambient temperature
Flow Rate	1.5mL/min
Mobile Phase	20mM Potassium dihydrogen phosphate : Acetonitrile - 95:5
Injection Volume	10 µL
Run Time	10 min
Retention time	4.6 min

6.3 Preparation of morphine standards

Morphine standards were prepared between the range of 1-100µg/mL. These were prepared by weighing 10.06mg morphine directly in to a 10mL volumetric flask which was then made up to volume with deionised water to create a 1000µg/mL stock from which the range of standards was prepared by serial dilution in deionised water. The standards were aliquoted in to a series of HPLC vials which were crimped and stored in the fridge at 4ºC. The standards are known to be stable for at least 3 days under these conditions (Traynor 2014). One set of standards were used prior to injection of each set of samples and one after injection of each set of samples.

6.4 Commercially available controlled drug denaturing kits

6.4.1 Compatibility with HPLC methods

In order to confirm non-interference between the excipients of the denaturing kits and the HPLC assay a sample of each type of kit was prepared. Each kit was vigorously mixed by shaking for 2 min with the lid on, then a sample of each kit (1g) was accurately weighed in to a glass vial to which an appropriate amount of water was added by weight. The amount of water added was calculated based on the instructions for use of the kit and the total weight of powder within the kit. The actual amounts of water used for each kit are shown in table 5. The samples were diluted 1:100 prior to injection on the HPLC.

Table 5: Amount of water (g) added per gram of material for each kit tested.

Kit	**Water (g)**
PolyGuard (with SAP)	8.511
PolyGuard (No SAP)	8.523

6.4.2 Destruction of Morphine

In order to assess the ability of the kits to destroy a controlled drug placed within them, Morphine was used as a model drug. A sample of each kit was prepared in separate glass vials to which morphine was also added. Water was then added (w/w) in the proportion indicated on the kit instructions (actual volume added shown in table 5). The kits were immediately mixed using a spatula for 2 min and then left on a roller mixture for 30 minutes. All kits were prepared in triplicate. After this a 1g sample was taken from each kit by weighing directly in to a 100mL volumetric flask and made up to volume using

deionised water. A magnetic flea was then added and the volumetric placed on a magnetic stirrer and left for approximately 2h until all gel had visibly dissolved. A sample was then taken from the volumetric flask, filtered and dispensed in to a HPLC vial for analysis by HPLC and use as a T=0 sample.

After 48h each kit was re-sampled and diluted 1:100 and filtered as described above before analysis by HPLC. The concentrations of the 48h samples were then calculated as a percentage of the drug content measured in the T=0 samples.

7 RESULTS

7.1 Analytical method development and validation

All morphine samples were analysed according to the HPLC method described in section 6.26.2.

Figure 1 shows a typical chromatogram for morphine with a retention time of approximately 4.6 min.

Figure 2 shows a typical calibration curve for morphine standards between the range of 1 to 100 µg/mL.

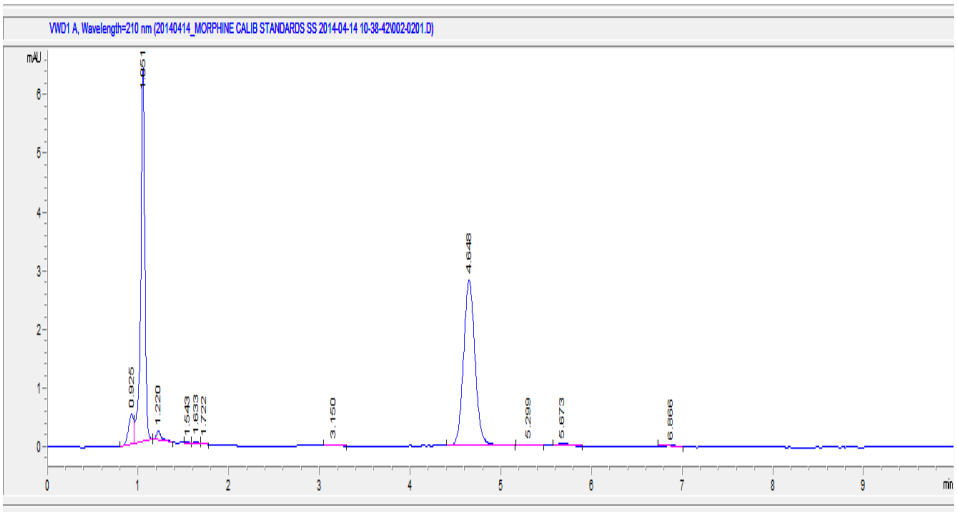

Figure 1: A typical chromatogram of morphine with a retention time of approx. 4.6 min.

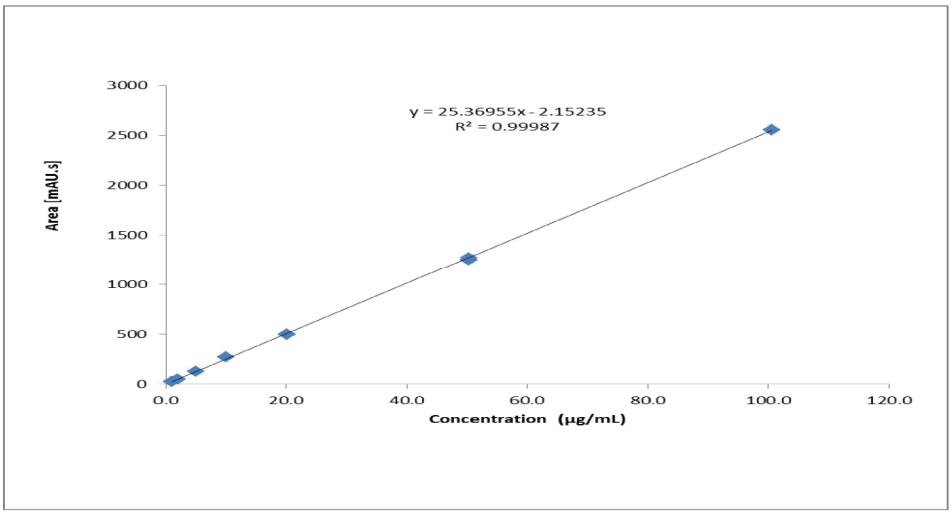

Figure 2: Typical standard calibration curve for morphine.

This method has previously been fully validated on the same HPLC instrument in this laboratory, therefore for the purpose of this study a simple “SLAP” validation was performed to ensure the reliability of the assay. This was compared with historic data (data not shown) and found to be within acceptable limits according to internal HPLC method validation specifications (CA001).

7.2 Drug denaturing kits

7.2.1 Compatibility with HPLC methods

In order to confirm compatibility with the HPLC method a sample of each drug destruction kit was prepared as detailed in section 6.4.1. No peaks were seen for any kit that would interfere with the detection of morphine (Figures 3 and 4).

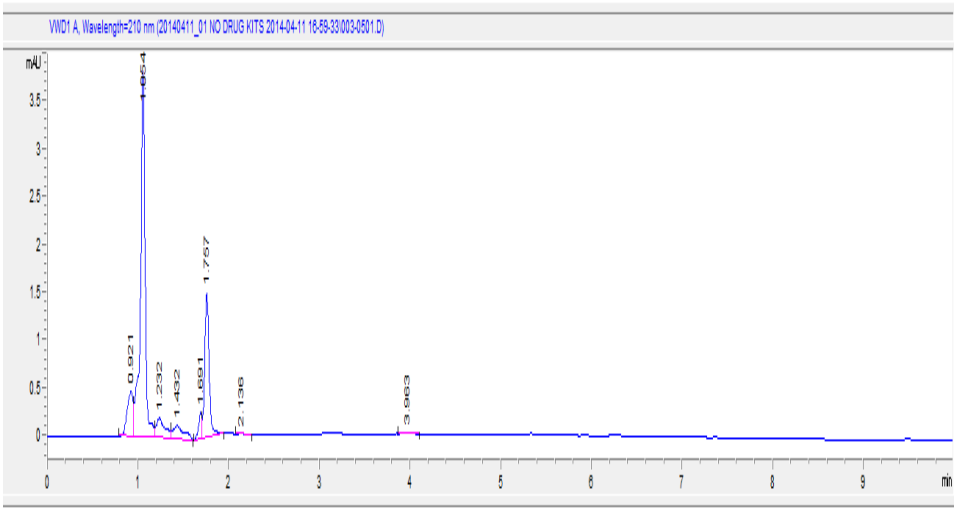

Figure 3: Sample chromatogram for PolyGuard (with SAP) blank.

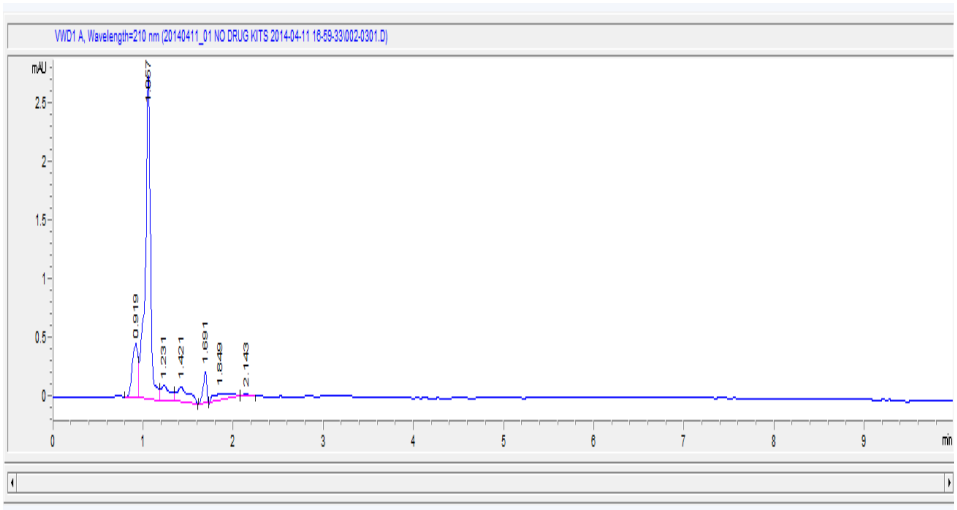

Figure 4: Sample chromatogram for PolyGuard (no SAP) blank.

7.2.2 Destruction of morphine

In order to test the ability of the kits to destroy/ denature controlled drugs Morphine was used as a model drug. The kits were set up with Morphine in them as detailed in section 6.4.2. Samples were analysed at 0h and 48h and the amount of drug present at 48h calculated as a percentage of the drug present at 0h (Table 6). Sample chromatograms showing the controlled drug destruction kit containing morphine after 0 hours are shown in figures 5 and 6 and after 48 hours are shown in figures 7 and 8.

Table 6: Degradation of morphine in drug destruction kits tested. Morphine content at 48h expressed as a percentage of morphine content at 0h (n =3, mean ± SD).

	Morphine content as percentage of content at T=0h	
Kit	**T = 0h (%)**	**T = 48h (%)**
PolyGuard (with SAP)	100	1.55 ± 0.44
PolyGuard (No SAP)	100	0.91 ± 0.08

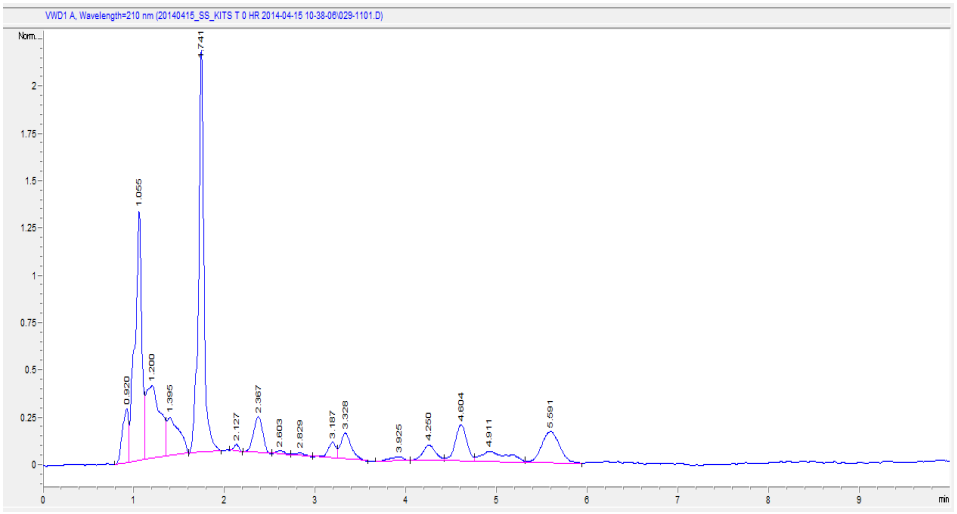

Figure 5: Sample chromatogram for PolyGuard (with SAP) destruction kit containing morphine (retention time 4.6 min) at T=0h.

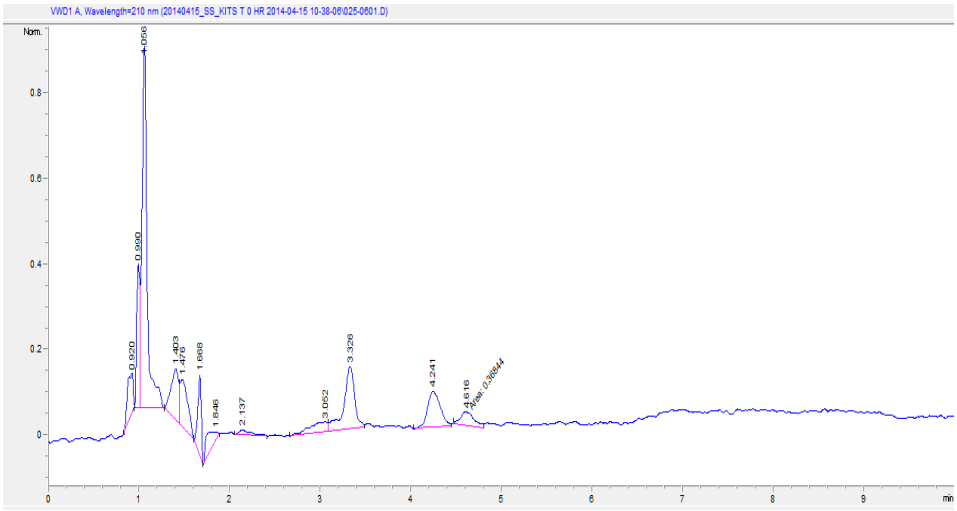

Figure 6: Sample chromatogram for PolyGuard (No SAP) destruction kit containing morphine (retention time 4.6 min) at T=0h.

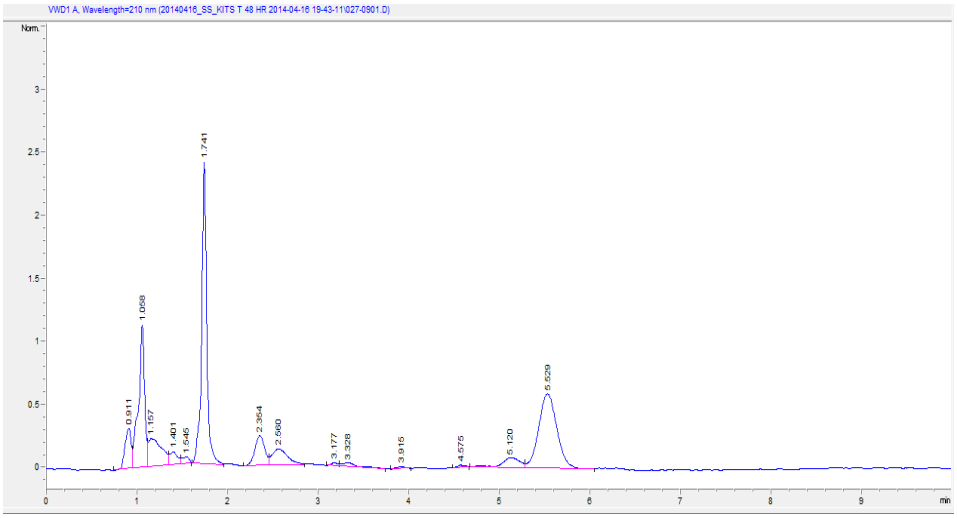

Figure 7: Sample chromatogram for PolyGuard (with SAP) destruction kit containing morphine (retention time 4.6 min) at T=48h.

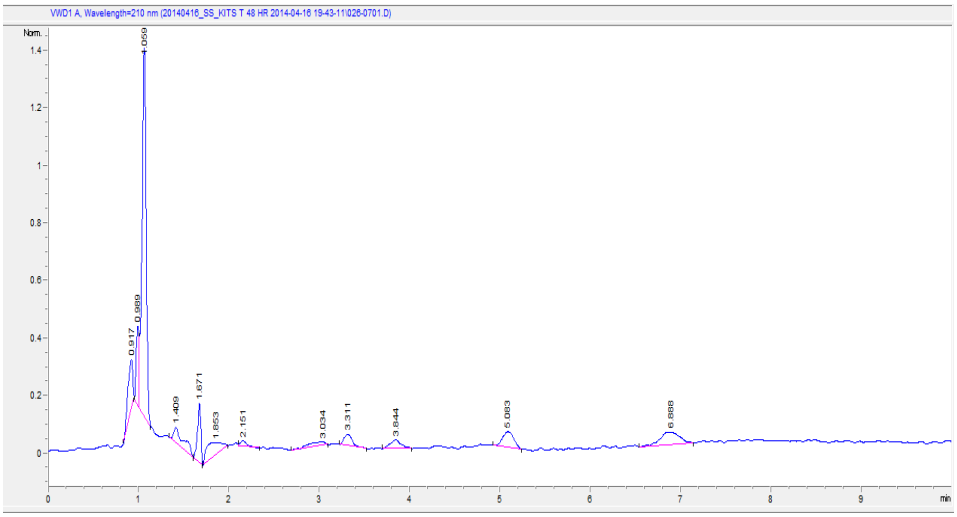

Figure 8: Sample chromatogram for PolyGuard (No SAP) destruction kit containing morphine (retention time 4.6 min) at T=48h.

8 CONCLUSIONS

It has previously been shown that many commercially available drug destruction/ denaturing kits do not chemically destroy or denature morphine within a 48h period (Traynor 2014). In this current study PolyGuard kits manufactured by Yorkshire Hygiene Solutions have been shown to almost completely destroy morphine. In the kit containing no SAP 0.91 ± 0.08% (n = 3) of the morphine dispensed in to the kit was recovered after 48 hours. In the kit tested containing the SAP (which is as the kit is supplied commercially) 1.55 ± 0.44% of the drug was recovered.

9 REFERENCES

Traynor M.J., Investigation in to functionality of controlled drug denaturing/ destruction kits. Drug Dev Ind Pharm. 2014, doi:10.3109/03639045.2013.877484