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

The aim of this study was to determine if a new kit manufactured by Combined Distributors Inc. actually chemically 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.

The Pill Terminator was tested and the ability of the kit to degrade morphine was determined. A known quantity of morphine was added to the kit and the drug content assayed immediately and the assay repeated after 48 hours to determine the extent of drug destruction.

When using the Pill Terminator kit 98.45% of the morphine was degraded within 48h.

# 1 AIMS

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

# 2 TEST ITEM

Table 1: Test item details

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

| | |
|---|---|
| Test Item 2 | Product Name: Pill Terminator<br>Manufacturer: Combined Distributors Inc., USA |

# 3 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 |
| Potassium dihydrogen orthophosphate | 1290615 | Fisher Scientific, UK |

# 4 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 |

# 5 METHODS

## 5.1 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.

## 5.2 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 kit.

Table 4: HPLC method for morphine

| | |
|---|---|
| HPLC System | Agilent Technologies:<br>1260 Binary Pump S/N DEABL00513<br>1260 Autosampler S/N DEAB305520<br>1260 Column Heater S/N DEACN06282<br>1260 VWD VL detector S/N DEAAU01717<br><br>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 |

## 5.3 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.

## 5.4 Commercially available controlled drug denaturing kits

### *5.4.1 Compatibility with HPLC methods*

In order to confirm non-interference between the excipients of the denaturing kit and the HPLC assay a sample of the kit was prepared. The kit was vigorously mixed by shaking for 2 min with the lid on, then a sample (1g) was accurately weighed in to a glass vial to which an appropriate amount of water (8.511g) 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.

### *5.4.2 Destruction of Morphine*

In order to assess the ability of the kit to destroy a controlled drug placed within them, Morphine was used as a model drug. A sample of 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 (8.511g of water per 1g water). The kits were immediately mixed using a spatula for 2 min and then left on a roller mixture for 30 minutes. The kit was prepared in triplicate. After this a 1g aliquot was taken from each sample 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. An aliquot 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.

# 6 RESULTS

## 6.1 Analytical method development and validation

All morphine samples were analysed according to the HPLC method described in section 6.25.2.

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.

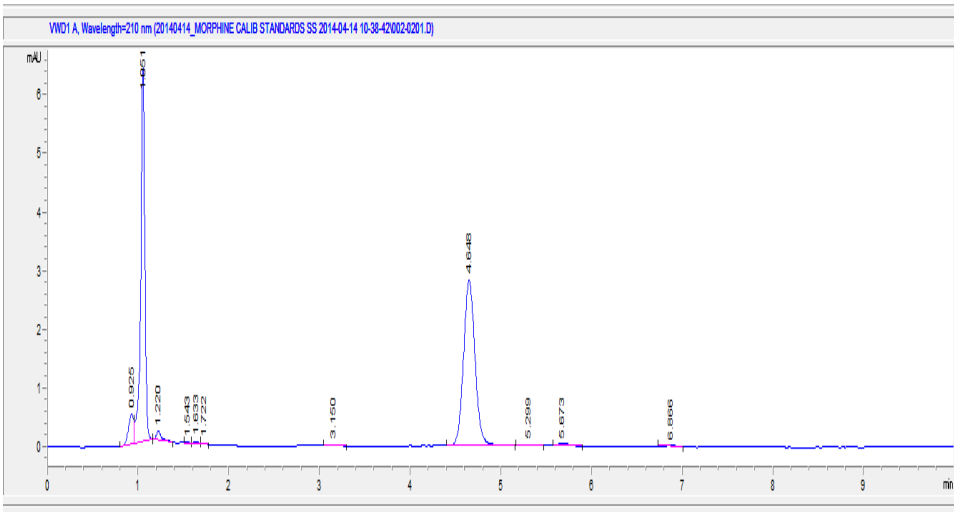


Figure 1: A typical chromatogram of morphine with a retention time of approx. 4.6 min.

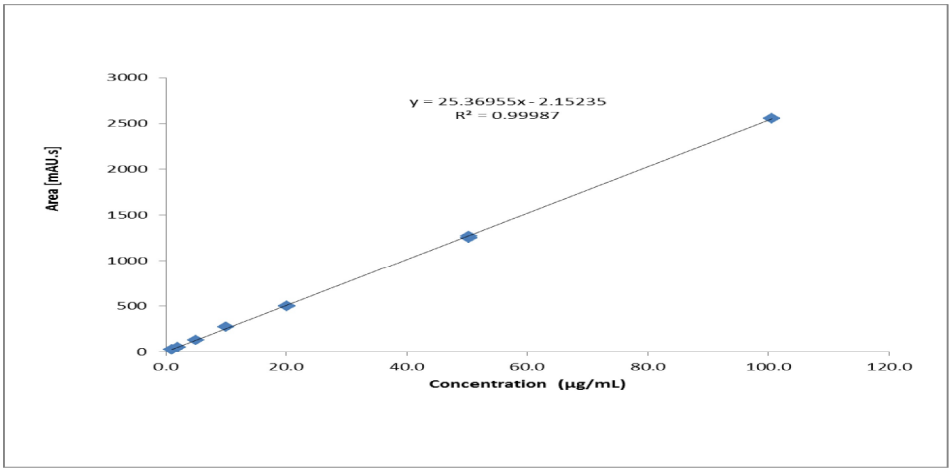


Figure 2: Typical standard calibration curve for morphine.

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).

## 6.2 Drug denaturing kits

### *6.2.1 Compatibility with HPLC methods*

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

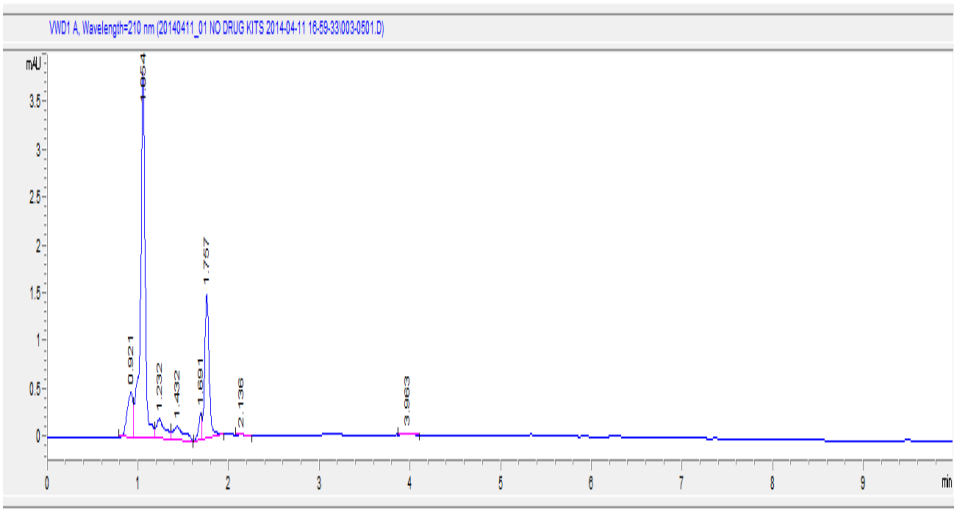


Figure 3: Sample chromatogram for Pill Terminator blank.

### *6.2.2 Destruction of morphine*

In order to test the ability of the kit to destroy/ denature controlled drugs Morphine was used as a model drug. The kit was set up with Morphine as detailed in section 5.4.2. 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 5). Sample chromatograms showing the controlled drug destruction kit containing morphine after 0 hours are shown in figure 4 and after 48 hours in figures 5.

Table 5: 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 (%)** |
| Pill Terminator | 100 | 1.55 ± 0.44 |

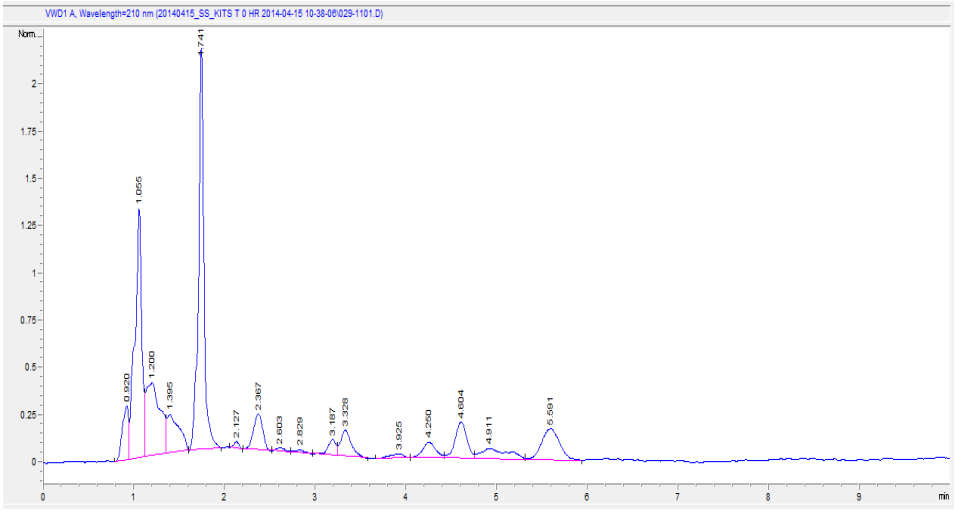


Figure 4: Sample chromatogram for Pill Terminator destruction kit containing morphine (retention time 4.6 min) at T=0h.

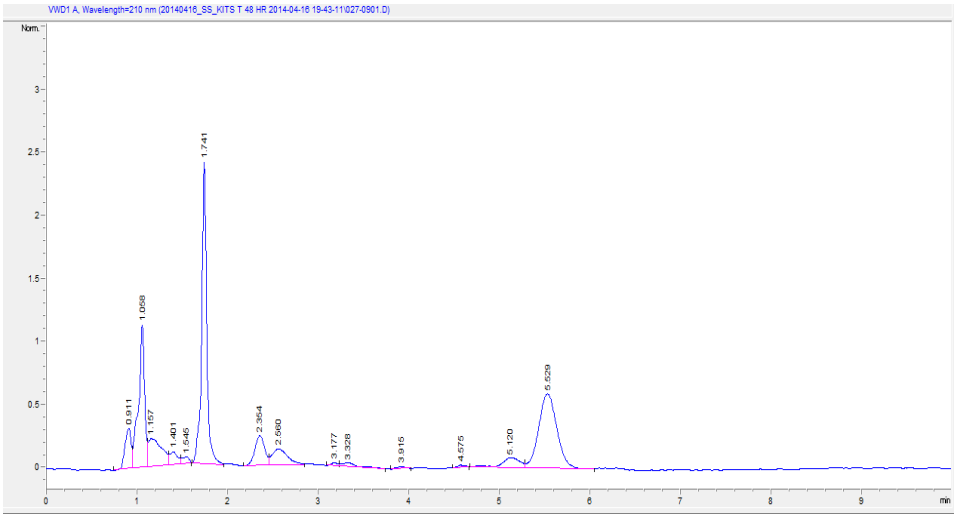


Figure 5: Sample chromatogram for Pill Terminator destruction kit containing morphine (retention time 4.6 min) at T=48h.

# 7 CONCLUSIONS

In this current study Pill Terminator kits manufactured by Combined Distributors Inc. USA, have been shown to almost completely destroy morphine. In the kit 98.45 ± 0.44% (n = 3) of the morphine was destroyed after 48 hours.

# 8 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