South East Coast Ambulance Service NHS
NHS Foundation Trust

Disposal of Controlled Drugs
Standard Operating Procedure

Contents

1 Scope

1.1. The purpose of this procedure is to provide good practice guidance and associated record keeping for the secure destruction and disposal of unused amounts of Controlled Drugs (CDs), broken or damaged ampoules, or out of date (OOD) stock.

1.2. South East Coast Ambulance Service NHS Foundation Trust (the Trust) is committed to providing high quality patient care.

1.3. This procedure is applicable to all clinicians in the Trust and sets out the scope of clinical practice to which clinicians must adhere.

1.4. The Trust has a T28 exemption from the Environment Agency to sort and denature CDs prior to disposal to comply with the Controlled Drugs 2006 Regulations on the disposal of controlled drugs.

1.5. This procedure describes the process that should be followed in accordance with relevant legislation, and that a robust audit trail relating to all CD stock is maintained.

1.6. The main principle for destruction of CDs is that they should be rendered irretrievable prior to been being placed in suitable waste containers and sent for incineration.

1.7. The Trust is not to destroy controlled drugs that have been supplied to individual patients, these are the patients' property. The patient or relative should be advised to return all unwanted medicines including CDs to their community pharmacy. CDs left by patients in any vehicles should be repatriated to the patient.

1.8. The requisition, use, movement and disposal of CDs should be recorded in the CD register which pertains to the particular station or site.

1.9. CD registers must be kept for a minimum of two years from the last date of entry and records of CD destruction kept for a minimum of seven years.

2 Procedure

2.1. CD Administration Waste recording

2.1.1. When a dose is prepared in error or partly administered, or broken and it is safe to secure it in the container, the remaining drug should be discarded into a DOOP (Disposal of old Pharmaceuticals) container.

2.1.2. The amount discarded into the DOOP must be recorded on ePCR and in the CD registers (see SOP for CD record keeping and register entries).

2.1.3. Partially used syringes of CDs must not be handed to another crew member or healthcare practitioner taking over patient care as accountability for the CD remains with the original practitioner.

2.1.4. If an ampoule containing a controlled drug is broken, the ampoule and any remaining particles should be placed in a DOOP container and a datix (DIF1) incident form should be completed. A record of this needs to be recorded in the CD register (see *SOP for CD record keeping and register entries*).

2.2. **Recording of CDs on ePCR**

2.2.1. The quantity of CD disposed of must be recorded within the relevant section in ePCR.

2.2.2. The CD disposal must be observed by a witness. The witness confirms they have observed the process by countersigning the record (*see Appendix A*).

2.2.3. When CD reconciliations audits are completed by the Operational Team Leaders (OTLs), the ePCR documentation will also be checked to confirm the record.

2.2.4. If there is no witness signature within the ePCR, this will be investigated (see Controlled Drugs Stock Check and Reconcilliation SOP).

2.3. **Recording of Controlled Drugs at Stations**

2.3.1. When returning or restocking CDs, the member of staff must record either their administration or return of the CD in the electronic or paper CD register.

2.3.2. This must be observed by a second member of staff who is authorised to act as a witness.

2.3.3. The unused drug will be returned to the controlled drug storage:

- For an **Omnicell** site:
  - the DOOP container must be assigned to the waste bin.
- For a **non-Omnicell** site:
  - the DOOP container will be placed in the CD cupboard until the OTL performs the reconciliation checks and all CD activity is accounted for.

2.4. **During weekly reconciliation checks, the OTL will go through the site waste bin and CD cabinets to check that:**

- DIF1 forms are completed for breakages
- Waste from administration is documented

2.4.1. When all CD waste has been reconciled, the DOOP kits can be placed in the blue lidded pharmaceutical waste bin.

2.4.2. The OTL must record all reconciled CD waste on the 'Drug Waste Transfer Request Document (waste log)' attached to the bin (see Appendix B for details required for completion).

2.5. Disposal of Expired Stock Controlled Drugs

2.5.1. Disposal of expired stock CDs must be witnessed by a Controlled Drug Liaison Officer (CDLO) with appropriate Home Office authorisation controlled drug licence (CDL) or an authorised witness assigned by the Controlled Drug Accountable Officer (CDAO) and listed in the SECAmb CD licence.

2.5.2. All CDs should be destroyed by being denatured and rendered irretrievable before being placed into pharmaceutical waste containers and sent for incineration.

2.5.3. Destruction MUST ONLY be carried out at the Medicines Distribution Centre (MDC) at Paddock Wood. All expired CD returns will be entered into the CD register kept for destruction.

2.5.4. MGT staff will contact the CDLO or authorised witness to determine a date for destruction and ensure sufficient DOOP containers are available at the destruction site. To avoid excessive quantities of out of date stock being stored, destruction should be undertaken with sufficient frequency determined at a local level.

2.5.5. At stations/sites, CDs that require destruction are returned to the relevant store location or MDC via logistic vans.

2.5.6. Stores may only hold OOD controlled drugs in the sealed red CD transfer bag.These CD transfer bags must not be opened outside of the MDC.

2.5.7. Use the Trust form for CD destruction to record the details of the transfer (see Appendix C).

2.5.8. When removing OOD CDs from the CD cupboard/Omnicell, a stock check MUST be conducted and the new balance recorded in the CD Register.

2.6. CD destruction process at the MDC

2.6.1. On the date of destruction, a nominated member of the Medicines Governance Team and a witness will reconcile one entry at a time for destruction. The CDLO or authorised witness MUST be present (see Appendix D).

i. Count the stock to ensure the balance is correct in the register - any discrepancies should be highlighted to the CDAO and Chief Pharmacist, and a DIF1 immediately completed.

ii. Document in the register the total balance remaining and the quantity for destruction.

iii. Wear suitable protective gloves to minimise the risk of sharps injury.

iv. Open liquid ampoules and empty as much of the content as possible into the DOOP container.

v. Ampoules requiring powder reconstitution can be opened, water added and the resultant mixture emptied into the DOOP container. All glass should be placed in a blue lidded waste container.

vi. Tablets and capsules can be removed from blister packaging and placed in the DOOP container.

vii. The register must be signed by the member of the Medicines Governance Team and the CDLO/authorised witness.

viii. When the destruction is completed, all DOOP containers should be placed in a blue lidded pharmaceutical waste bin. Ensure the lid is secure and place in a secure area for the next waste collection.

3 Definitions

3.1. Datix is the Trust's incident management system.

3.2. DIF1 is the report process used by Datix.

3.3. CDAO is the Controlled Drugs Accountable Officer

3.4. CDLO Controlled Dugs local liaison officer.

3.5. CDLIN Controlled Drugs local intelligence network

3.6. DOOP : Disposal Of Old Pharmaceuticals

4 Responsibilities

4.1. The **Chief Executive Officer (CEO)** is accountable for Medicines use and governance in the Trust

4.2. The **Executive Medical Director** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Executive Medical Director has responsibility for the implementation, review, and thus revision where required, of this procedure.

4.3. The **Chief Pharmacist** is the professional medicines governance lead for the Trust and is responsible for producing robust systems and processes which comply fully with legislation, national guidance, and regulatory requirements to ensure the safe and effective management and use of medicines throughout the Trust. The Chief Pharmacist supports the Executive Medical Director and Executive Director of Operations providing

pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.

4.4. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this policy. The Executive Director of Operations has overall responsibility for holding his/her staff to account for any deviations from this policy and is responsible for the operational compliance of this procedure.

4.5. The **Executive Director of Operations**, **Executive Medical Director** and **Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).

4.6. The Executive Director of Operations delegates local responsibilities and accountability for this procedure to the **Associate Directors of Operations**, **Operational Unit Managers, Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics.**

4.7. The **Associate Directors of Operations, Operational Units Managers**, **Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics** delegate their local responsibility and accountability for this policy to their staff including the **Operational Team Leaders (OTLs), Logistics Manager**, and others.

4.8. The **Executive Director of Nursing and Quality** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.

4.9. **Controlled Drug Accountable Officer** is responsible for the safe management and use of Controlled Drugs within the Trust along with co-operating and sharing information relating to concerns about the Trust's use and management under the Controlled Drug (Supervision of Management and Use) Regulations 2013. These responsibilities include keeping records of the investigation of concerns and acting where appropriate.

4.10. The **Medicines Safety Officer (MSO)** is also the **Chief Pharmacist**. The MSO supports local medication error reporting and learning. The MSO acts as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).

4.11. The **Medicines Governance Group (MGG)** is responsible, for providing strategic direction for the implementation of medicines management and practice within the Trust The primary objective of MGG is to ensure appropriate clinical and cost effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of issues relating to

the use of medicines within the organisation as part of the overall clinical and corporate governance structure.

4.12. The role of The **Non-Medical Prescribing (NMP) Group** is to provide overarching multidisciplinary leadership for non-medical prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a non-medical prescriber and to prescribe, taking account of service redesigns and improved patient access to medicines. The NMP Group aims to strengthen and monitor the governance issues associated with non-medical prescribing, to determine potential and support existing non-medical prescribers, advise the MGG on matters relating to non-medical prescribing and will report exceptions relating to non-medical prescribing to the MGG.

4.13. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.

4.14. The **Patient Group Direction (PGD) Approval and Working Group** provides assurance to MGG and ensures the development, review, updates and implementation of PGDs are in line with legislation and national good practice.

4.15. The **Medicines Governance Team (MGT)** are responsible for ensuring the safe and efficient procurement of medicines, including controlled drugs to ensure the quality of the product, safe dispensing/packing into medicines pouches through to safe disposal of pharmaceutical waste. The MGT will support the Chief Pharmacists with drug shortages, drug alerts and relevant information relating to medicines is communicated in a timely manner.

4.16. **All staff** are responsible for their own professional practice. All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must receive appropriate training and assessment of competence before commencing their roles. All staff who handle medicines are personally accountable for complying with this policy and relevant standard operation procedures, for reporting any concerns and for the safe handling of all medicines.

5 Audit and Review (evaluating effectiveness)

5.1. Operational Team Leaders (or other Registered clinicians delegated by local managers) must complete Weekly, Monthly Medicines Security and Storage Audits on the central database to ensure compliance with this SOP.

5.2. Deviations from this SOP must be investigated immediately.

5.3. Any deviations that cannot immediately be resolved must be immediately escalated to the CDAO via an DIF1 report.

5.4. The CDAO with support from the Executive Director of Operations and Chief Pharmacist must report outstanding concerns to the Medicines Governance Group and the CDLO (local liaison officer).

5.5. The CDAO with support from the Chief Pharmacist must report outstanding concerns to the CD LIN (local intelligence network) on a quarterly basis.

5.6. All procedures have their effectiveness audited by the Medicines Governance Group at regular intervals, and initially six months after a new policy is approved and disseminated.

5.7. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

5.8. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.

5.9. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

6 Associated Trust Documentation

6.1. Controlled Drugs Policy

6.2. Administration of Controlled Drugs

6.3. Controlled Drugs Possession Using Body Worn Pouches

6.4. Changing Security Codes for Medicines Storage

6.5. Controlled Drug Stock Checks and Reconciliation

6.6. Disposal of Controlled Drugs

6.7. Security Management Policy

6.8. Expiry Date Checking and Rotation of Medicines

6.9. Ordering and Distribution of Medicines

6.10. Receipt of Medicines from External Suppliers

6.11. Record Keeping and Controlled Drug Register Entries

6.12. Use of the Omnicell Emergency Access Barcode

7 References

7.1. Misuse of Drugs Act 1971, 2001 Regulations.

7.2. Medicines, Ethics and Practice. The Professional Guide for Pharmacists Edition 41 July 2017. Royal Pharmaceutical Society

7.3. The Human Regulations 2012

7.4. The Safe and Secure Handling of Medicines – a team approach (updated Duthie Report) 2005

7.5. Harold Shipman Inquiry Fourth Report - The Regulation of Controlled Drugs in the Community 2004

7.6. Crown Report 1999

7.7. Health and Social Care Act 2001

7.8. Hazardous Waste (England and Wales) Regulations 2005

7.9. Health Act 2006

7.10. Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs DOH 2007

7.11. Safer Management of Controlled Drugs – Annual Report CQC 2011

7.12. Security Standards and guidance for the management and control of controlled drugs in the ambulance sector NHS Protect June 2012

7.13. Controlled Drugs (supervision and management and use) Regulations 2013 Department of Health.

8 Equality Analysis

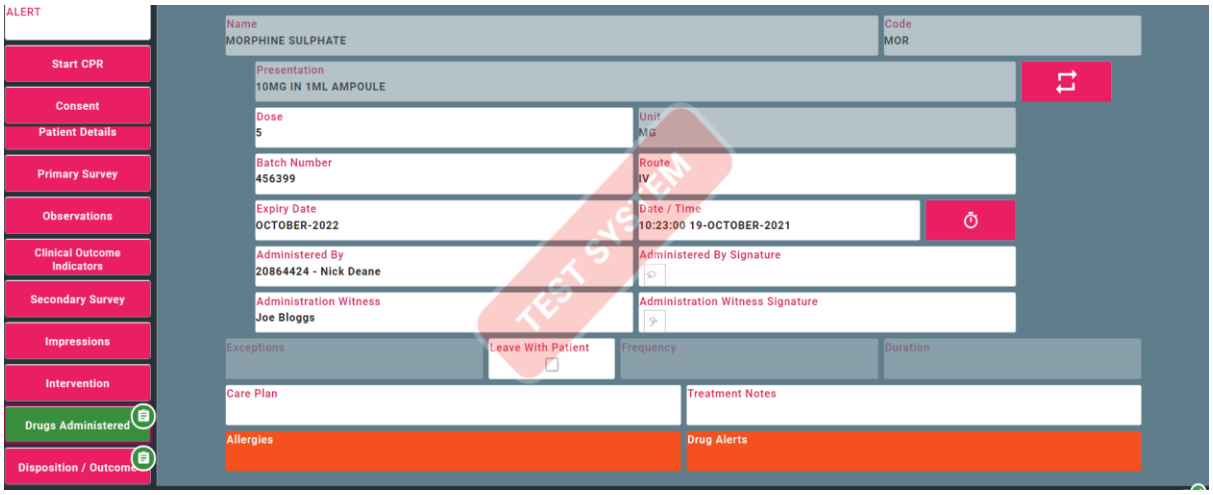
8.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

8.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the

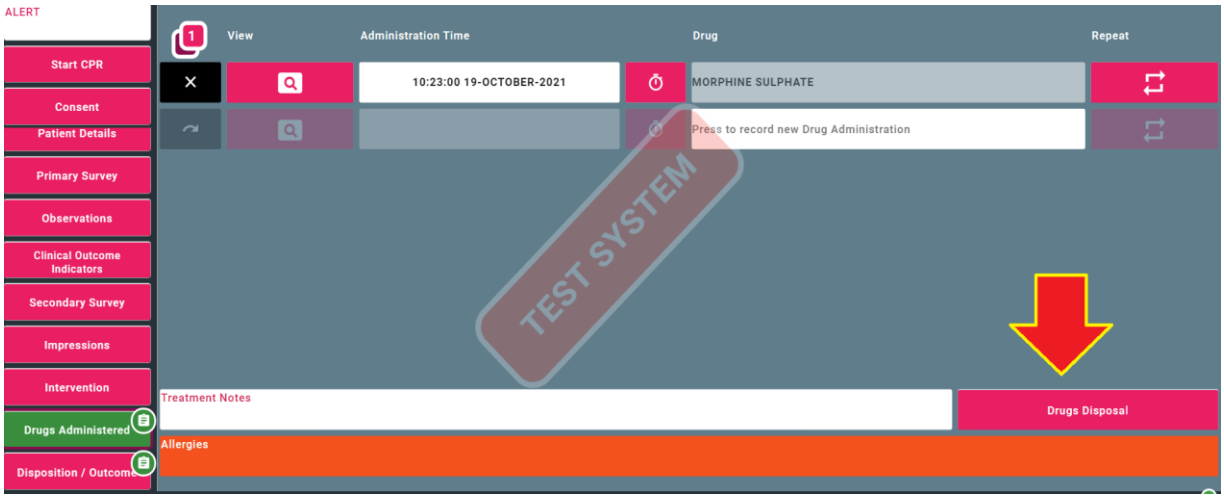
contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.

Appendix A: Completion of waste administration on ePCR

1. Complete the Drug administration section including the correct amount, batch, expiry date, route, and adding a CD witness:

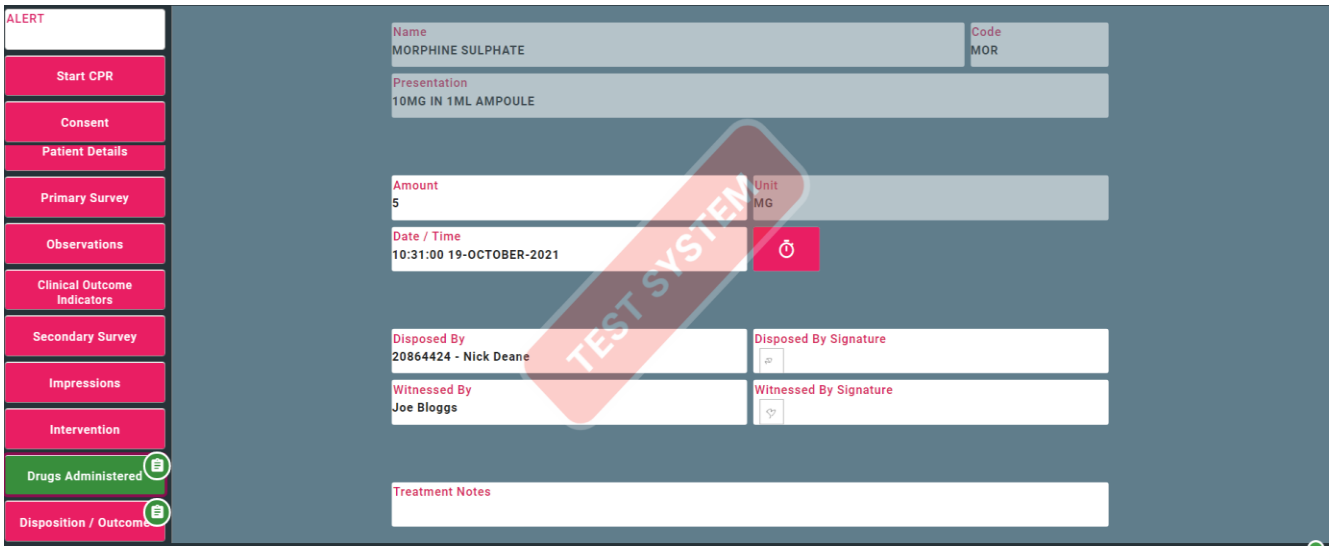


2. Then after completing this screen in Drug administration go to “Drugs Disposal”:



3. Click the ‘drug’ space to add the waste:

4. Fill in the waste screen including the witness details.



5. Once complete the record will be updated

31-DECEMBER-2021	E SULPHATE	1ML AMPOULE	2MG	IV	104004	JANUARY-2024	-	-	-	MOR	-	-	[redacted]
15:01:47 31-DECEMBER-2021	MORPHINE SULPHATE	10MG IN 1ML AMPOULE	2MG	IV	104004	JANUARY-2024	-	-	-	MOR	-	-	
15:11:35 31-DECEMBER-2021	MORPHINE SULPHATE	10MG IN 1ML AMPOULE	2MG	IV	104004	JANUARY-2024	-	-	-	MOR	-	-	

Drugs Disposed

Date/Time	Name	Presentation	Amount	Code	Disposed By	Witnessed By
16:05:00 31-DECEMBER-2021	MORPHINE SULPHATE	10MG IN 1ML AMPOULE	4MG	MOR	[redacted]	[redacted]

Drug Disposal Signatures

Disposal By Signature: D1

Disposal Witnessed By Signature: DW1

Appendix B: Drug Waste Transfer Request (Waste Log) Document

South East Coast Ambulance Service
NHS Foundation Trust

Drug Waste
Transfer Request Document

Station: * * Doc No: D 5743

Date of First Entry: * / / *

	Product Name	Code No	Batch No	Qty	Entered by
1	FOR CONTROLLED DRUGS:				
2	DRUG NAME	CAD NUMBER	"DOOP" AND DATE	UNITS TO DOOP	PRINT NAME + SIGN
3	e.g. MORPHINE SULPHATE 10mg/ml INJ	5452	DOOP 01/01/24	5ml	A. PARAMEDIC AP
4					
5					
6					
7	FOR NON-CONTROLLED DRUGS				
8	DRUG NAME	"OOD"	BN + EXPIRY DATE	UNITS	PRINT NAME + SIGN
9	e.g. ROCURONIUM 50mg/5ml INJ	OOD	10225A 03/2022	10ml	J. BLOGGS JB
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

★ Date Container Sealed: / / Sealed by: ★

Rank/Grade: ★

Remember: Write the document number on the outside of the container.
Attach the top copy of this form to the container SECAM512/Nov2009

Appendix C: Controlled Drug Transfer Form for Destruction only

South East Coast Ambulance Service NHS
NHS Foundation Trust

Controlled Drug Transfer Form for Destruction Only

This form should be completed when returning controlled drugs for **destruction** to your local store, Worthing, Barnstead or Paddock Wood for destruction

DRUG NAME	DRUG FROM	STRENGTH	EXPIRY DATE	QUANTITY for TRANSFER

COLLECTION LOCATION OF DRUGS FOR TRANSFER	CD REGISTER NUMBER (S) UNIQUIE IDENTIFIER ON FRONT COVER
FINAL DESTINATION OF DRUGS	**CD REGISTER NUMBER (S)**

Tag ID number	

	PRINT NAME BELOW	SIGN BELOW	DATE REPORTED
OTL NAME			
	PRINT NAME BELOW	SIGN BELOW	DATE REPORTED
Collection from Station - DRIVER NAME			
	PRINT NAME BELOW	SIGN BELOW	DATE REPORTED
Collection from Hub DRIVER NAME			
	PRINT NAME BELOW	SIGN BELOW	DATE REPORTED
MDC RECEIVING NAME			

Two copies of this form should be printed:
First copy should be signed by both reporter and logistics staff and be retained on station.

This form must be signed by the reporter and sent to medicines@secamb.nhs.uk, westlogisticssupport@secamb.nhs.uk and eastlogisticssupport@secamb.nhs.uk to inform logistics that a collection is required.

Second copy should be signed by both reporter and logistics staff and remain with out-of-date product, this will then be signed by the receiving store and retained by stores.

Appendix D: HOW TO… destroy controlled drugs (CDs) using a destruction kit

All controlled drugs must be denatured before being placed into the blue lidded bins

1. **CD Destruction Kit**
   - CD destruction Kit is a generic term applied to what is sometimes referred to as a DOOP kit or controlled Drug denaturing kit

2. **Procedure for Destroying Controlled Drugs**
   a) Wear gloved
   b) Remove the sachets prior to adding any controlled drugs
   c) Add the CDs to half the capacity of the kit using the methods shown below for each formulation

FORMULATION	METHOD	COMMENTS
Ampoules (Liquid content)	Open and empty contents into the CD destruction kit by shaking or by using a needle and/or syringe.	Add empty ampoules to the CD destruction kit.
Ampoules (Powder content)	Open, add water with a syringe to ampoule powder and add reconstituted contents to the CD destruction kit.	Add empty ampoules to the CD destruction kit.
Vials with bungs	Reconstitute contents with water using needle and syringe add the contents to CD destruction kit	Do not remove bung. Add vials to CD destruction kit.
Large volume infusion/injection	Cut above bung in port access and pour contents into CD destruction Kit	Place packaging in the clinical waste bin

Tablets / Capsules and Lozenges	Remove from outer packaging, remove from blister packaging and place intact into the CD destruction kit. Single tablets or capsules that may have fallen on the ground or been removed from the packaging but not administered require immediate destruction and must not be allowed to remain in a non-congealed kit at risk of retrieval and reuse	Do not crush tablets before adding to the kit.
Liquids	Pour directly from the bottle, measure or syringe pump into the CD destruction kit. Wash out bottles or measures with a small amount of water and add liquid to CD destruction kit	Discard empty bottles in the domestic waste. If denaturing multiple forms of CDs, denature liquids at the end of the process as the desiccant in the CD destruction kit will start to congeal quickly
Powders and Sachets	Open and add contents of the sachets into the CD destruction kit.	Beware of inhalation of dust from powders. Discard the outer packaging into a clinical waste bin
Patches	Carefully remove from outer packaging, fold in half with the sticky side inwards and place in the CD destruction kit.	Discard the patch adhesive backing and patch packet in a clinical waste bin.

d) Place the sachets back into the destruction bottle
e) Fill the CD destruction kit to capacity level with water; do not overfill
f) Replace lid securely
g) Shake thoroughly to disperse. Contents will congeal in 3 – 5 minutes.
h) Dispose in the designated pharmaceutical waste bin
i) Any equipment used to draw up the CD i.e. syringes should be disposed of according to Trust procedure