

IV procurement and batch traceability

Document control

Version 1.4 FINAL, updated 23 October 2026; supersedes v1.3. Owner: Dr Mitesh Parmar, Clinical Director, GMC 6113670. Home IV saline pathway approved by Dr Mitesh Parmar, 23 October 2026. Approval lineage: 22 October 2026; service operating since May 2024. Signed records remain in the clinic governance file. Review due 22 October 2027 or sooner after a relevant change.

Applies to Venofer, Ascorbic Acid Pascoe and clinic IV fluids, including Ecoflac saline supplied by AAH. Product approvals are confirmed signed by Dr Parmar and Dr Alpa. Either doctor may review individual patients and check supply/batch/expiry. Each component batch and expiry is linked to the patient infusion. Use the stock label for exact container, volume and product licence. Includes sodium chloride 0.9% taken to home IV saline visits (IV-002 section 16).

1. Approve the product and supply route

Before first purchase or a material change, record the actual product, manufacturer and supplier; confirm suitability for the intended injectable route and obtain the current SmPC or equivalent manufacturer documentation. Check product marketing authorisation where present, or the lawful unlicensed/special/import route and supporting clinical rationale. A foreign label or catalogue listing alone is insufficient evidence.

Verify the supplier's role and appropriate authorisation through the relevant regulator's register. Separately record manufacturing authorisation/scope and relevant quality evidence. A wholesaler's WDA(H) concerns distribution; it does not establish a manufacturing licence or approval of every product. A manufacturer's Specials licence does not turn an unlicensed product into a licensed medicine. If pharmacy preparation under an exemption is involved, document that lawful route and quality arrangements rather than assuming an MS licence is universal. [R10-R11]

Keep verification evidence, source/date, responsible checker and triggers for rechecking, including a new supplier, licence concern or product change. Do not use non-sterile raw ingredients or undertake clinic sterilisation. Obtain specialist advice for uncertain classification, unlicensed supply or preparation suitability.

2. Receipt and storage

- Match the delivery to the authorised order. Record product, supplier, manufacturer where identified, batch, expiry and quantity. Check tamper evidence, sterile-container integrity and any transport-temperature requirement.
- Quarantine damaged, expired, suspect, incorrectly labelled or temperature-compromised stock. Resolve discrepancies before release; document the decision and evidence.
- Store according to the actual manufacturer's conditions, including any light or temperature requirement. Maintain appropriate monitoring and excursion records; do not assume all IV products belong in a refrigerator.
- Separate usable and quarantined stock, rotate by expiry and restrict access. Record movement or disposal so stock can be reconciled.
- Home visits: Only unopened, in-date manufacturer bags of sodium chloride 0.9% in their original packaging are taken to a visit, carried in a clean dedicated container and protected from the temperature extremes stated on the label. A spiked, opened or prepared bag is never transported. The bag is spiked at the bedside immediately before use.

Batch traceability to the patient

3. Link components to the patient

Confirmed practice: record the batch number and expiry of each fluid bag and additive against each patient infusion, so affected patients can be identified from a supplier batch. Include each component's product/strength, dose or quantity, treatment date/time and administrator. Retain original-component links after relabelling. The reviewing doctor checks supplier details and expiry/dates; preserve the supply trail. A purchase invoice alone does not replace patient-level linkage. Home IV saline: The batch number and expiry of the bag and the giving set are recorded in the patient's clinical record at the visit and entered in the patient batch register (IV-004 Appendix B), exactly as for clinic infusions.

Alerts, defects and recall response

4. Receiving and assessing alerts

Direct MHRA/GOV.UK alerts to enquiries@cliniquealpa.co.uk are active and distributed to all three clinicians, independently of Dr Parmar's availability. CAS alerts also arrive in his NHSmail and are forwarded to that inbox. GOV.UK delivery is a daily digest; no change of setting is assumed. Dr Parmar, Dr Alpa and Dr Amit check daily and cross-cover. From 26 October the weekly rota names the lead for triage, action and logging; the next week's lead deputises. Record handovers; act urgently on receipt when required.

MHRA category	Typical action framework
Class 1	Immediate action.
Class 2	Action within 48 hours.
Class 3	Action within five days.
Class 4	Caution-in-use notification, not an automatic recall.

Follow the specific notice's scope, deadline and instructions. Class 1 requires immediate action on receipt, including out of hours; a routine review must not delay it. A daily digest is additional information, not the sole urgent-alert route. Maintain monitored urgent notifications and absence cover; record changes to delivery settings when made. Log relevance and closure, including non-applicable notices. [R18, R39]

5. Action when stock or patients may be affected

- Identify the exact product, strength, batch range, expiry and reason. Stop use where directed or where safety is uncertain; physically segregate and clearly label affected stock 'DO NOT USE'. Record quantity and locations.
- Search stock, purchase and administration records across the relevant period. Identify all potentially exposed patients, including each additive rather than only the infusion-fluid batch. If records are incomplete, widen the search and escalate the uncertainty; do not assume no patients were affected.
- Dr Alpa Morawala or Dr Mitesh Parmar reviews clinical risk and authorises the response under the alert's patient-contact instructions; use actual available cover for urgent action. Arrange timely advice, examination, tests or referral where required. Do not notify every patient identically without considering the notice and exposure.
- Contact the supplier/manufacture or MHRA as directed. Preserve suspected-defect evidence; agree returns or disposal. Track stock reconciliation and any replacement supply. Use IV-003 for suspected harm, Yellow Card and notification decisions.
- Document contacts and unsuccessful attempts, required follow-up and outstanding actions. Assign an owner to every unresolved item. Close only after the Clinical Director or delegated competent reviewer confirms completion.

6. Locally identified defects

Apply the same protective steps before a formal recall exists if contamination, packaging failure or another defect is suspected. Record product details and preserve safe evidence. Report appropriately to the supplier/manufacture and MHRA; distinguish a suspected product defect from a local storage or preparation failure. [R28]

Appendices: registers and recall record

A. Approved supplier/product register

Supplier and product - Legal supplier/manufacturer names; product/strength/form; contact for quality concerns:

Authority and evidence - Supplier licence/register; manufacturer authority/quality evidence; product status; checked by/date:

Receipt / storage - Delivery reference; batch/expiry/quantity; condition/temperature evidence; storage location:

B. Patient batch register

Use one row for every component, linked to the administration record. Suggested columns: encounter ID; treatment date; component name/form/strength; manufacturer; batch; expiry; amount used; preparer/administrator; location of full clinical record. Keep patient identifiers secure. Do not use the public website or an unrestricted spreadsheet.

C. Alert / recall action record

Notice - Reference/source; received date/time; category; product/batches; required deadline:

Stock action - Locations checked; affected quantities; quarantine; person/date; supplier response:

Patient tracing - Search method/period; patients identified; uncertainty; clinician risk assessment:

Communication / follow-up - Who contacted whom; advice/tests/review; failed contacts; reporting references:

Closure - Reconciled stock; return/disposal evidence; completed actions; approver/date:

Audit

Audit component-to-patient linkage and stock records proportionately; review missing data, recalls and system changes. A practical retrieval exercise may help establish reliability where needed; no fixed annual or 20-minute mock test is mandatory under this issue. No completed mock test is claimed. For actual recalls, trace all relevant components and patients and reconcile affected stock. Allergy screening does not detect a recalled batch or replace this process.

LegitScript evidence map and source references

Dr Parmar confirms active alert receipt and completed signed product, training/competency and room records. Retain originals privately. No mock-recall or telephone-test result is inferred.

Question	Policy evidence / verification needed
1. Manufacturing facilities	Venofer/Pascoe confirmed; Ecoflac from AAH. Signed supply approvals and manufacturer evidence retained; WDA(H) concerns distribution.
2. Preparation location	Rooms 1 and 3, assessed 22 October 2026; home saline: IV-002 section 16.
3. Who prepares	Dr Parmar and Dr Alpa. Training/competency records confirmed complete and signed; training 22 October 2026.
4. Beyond-use period	IV-002 section 10 and signed product profiles; actual timing records.
5-7. Events and aftercare	IV-003: confirmed hours, Saturday closure, 111/999; no 24-hour cover. Home: doctor stays 30 minutes after, checked kit, 999 with home address.
8. Recall tracing	Patient batches with home saline bag and giving set; MHRA alerts, CAS forwarding; daily checks, lead/deputy. No mock-test pass claimed.
9. Reviewed SOPs	IV-001 v2.5; IV-002, IV-003 and IV-004 v1.4. Updated 23 October 2026; review due 22 October 2027.
10. Extended use periods	IV-002 section 10: no-advance-storage rule; confirm actual practice.
11. ISO environment	State actual facilities. Clinical cleanliness or ANTT does not establish ISO classification.
12. USP 797	Explain UK framework; seek assessor clarification and evidence any specific compliance claim.

USP and UK terminology

There is no single UK document automatically replacing USP <797>. Use the classification and evidence checks in IV-002 section 13-15. Answer all twelve questions with the actual operational status, then request clarification of any additional certification requirement. Do not substitute the clarification request for the answers. [R24-R25]

Sources: product/alert updates checked 23 October 2026

R10. MHRA: manufacturer and wholesaler licences
R11. MHRA: good manufacturing and distribution practice
R18. MHRA: safety communications and medicine recall classes
R23. Ascorbic Acid Pascoe: UK SmPC - confirmed clinic vitamin C product
R24. USP: official chapter 797 FAQs
R25. LegitScript: healthcare certification primer
R28. NHS SPS: managing defective medicines
R37. Venofer: UK SmPC - confirmed clinic iron product
R38. B. Braun sodium chloride 0.9% IV infusion: SmPC - match the actual stock label
R39. MHRA CAS: registration and independent-provider guidance
R40. MHRA: AAH Pharmaceuticals wholesale authorisation UK WDA(H) 11545

Ecoflac saline is supplied by AAH Pharmaceuticals, UK WDA(H) 11545 [R40]. Retain actual product labels and supply records. SmartRx dispensing does not establish an IV supply or preparation role.