

IV therapy Policy and SOP pack

Clinique Alpa | Clinical governance | Policy v2.5; supporting SOPs v1.4 | 23 October 2026

FINAL - updated 23 October 2026

Parchment edition with linked CQC, MHRA, GMC and specialist source references. The pack covers clinic hydration, single-ingredient vitamin C and iron infusions, and home IV sodium chloride 0.9%. Multi-ingredient IV formulas are excluded following their withdrawal in October 2026.

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Included practical tools

Product and preparation profile; administration record; patient aftercare leaflet; adverse-event record; supplier, component-batch and recall records; LegitScript evidence map.

Approval and publication

Updated on 23 October 2026 to add the home IV saline pathway: IV sodium chloride 0.9% from a ready-to-administer bag with nothing added, given at home by Dr Parmar or Dr Alpa. IV iron and IV vitamin C remain clinic only. Home IV saline pathway approved by Dr Mitesh Parmar, 23 October 2026. Approval lineage: 22 October 2026; review due 22 October 2027.

How to use the references

Linked references support the product and governance requirements. Match each actual stock label to its product instructions; record container volume and licence in the stock/product file. Completed clinical and staff records remain private. Each document keeps its own page numbering.

Intravenous medicines and fluids policy

Document control

Version 2.5 FINAL, updated 23 October 2026; supersedes v2.4. 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.

Clinique Alpha | 466 Green Lanes, Palmers Green, London N13 5PA. Applies with CA-CLIN-SOP-IV-002 (preparation), CA-CLIN-SOP-IV-003 (adverse events and aftercare) and CA-CLIN-SOP-IV-004 (procurement and recalls).

1. Purpose and confirmed service scope

Version 2.5 adds a home IV saline pathway (IV-002 section 16): sodium chloride 0.9% from a ready-to-administer bag, nothing added, given at home by Dr Parmar or Dr Alpa. IV iron and IV vitamin C remain clinic only. IV-002, IV-003 and IV-004 are v1.4. Earlier issues remain history; replace current links at the existing policy page.

Scope: planned treatment of adults aged 18 and over at the Palmers Green clinic, comprising IV fluids, IV iron and any approved standalone vitamin C pathway, plus IV sodium chloride 0.9% in the patient's home under IV-002 section 16. IV iron and IV vitamin C are given at the clinic only. Multi-ingredient formulas were withdrawn in October 2026. Excluded: paediatric care, home infusion of any medicine or of any fluid other than ready-to-administer sodium chloride 0.9%, any addition, mixing or preparation in a home, emergency resuscitation as a planned service, blood products, parenteral nutrition, chemotherapy, multi-ingredient wellness cocktails and IM injections. No advance preparation, batch production for anticipated demand, custom pharmacy-compounded bags or sale of prepared bags is authorised. Any extension requires separate clinical and medicines risk assessment. Emergency response to a complication remains mandatory.

2. Clinical decision and consent

A GMC-registered prescribing doctor must assess the individual patient, establish a documented clinical rationale and consider oral treatment, usual care or no intervention. Booking or payment does not guarantee an infusion. Review relevant diagnoses, medicines, allergies, previous infusion reactions and the investigations needed for the selected treatment. A requested wellness treatment is not itself evidence of benefit or justification for IV administration.

Discuss expected benefit, uncertainty, alternatives, material risks, follow-up and costs through the clinic's normal consent process. Explain relevant off-label or unlicensed use and document the rationale and information given. Take responsibility for monitoring and follow-up. A signature does not replace an informed discussion. [R06]

3. Approval and operational status

The IV service has operated since May 2024. Dr Parmar and Dr Alpa prepare/administer in rooms 1 and 3. Training and room assessments were completed on 22 October 2026. On 23 October Dr Parmar confirmed that the supporting training/competency records, room assessments and product approvals are complete and signed. Retain the original records and their actual dates privately; no new signatures or test results are created by this policy. Dr Parmar confirmed on 23 October 2026 that the clinic gives IV sodium chloride 0.9% at home (Dr Parmar and Dr Alpa only; IV-002 section 16). No home assessments or home start date are recorded here; the 22 October 2026 IV and resuscitation training applies.

Responsibilities and applicable standards

4. Roles and accountability

Role	Required responsibility
Clinical Director	Approve scope, product profiles, staff authorisations, premises assessment, emergency and aftercare arrangements; review incidents and audit findings; authorise changes.
Reviewing / prescribing doctor	Dr Alpa Morawala or Dr Mitesh Parmar reviews and authorises treatment. Assess and prescribe for the patient; verify indication, dose, preparation and follow-up; remain accessible for clinical decisions.
Authorised preparer/administrator	Dr Mitesh Parmar and Dr Alpa Morawala prepare and administer. Work within competence, patient-specific authority and the approved protocol; record checks, preparation, observations and escalation. For home IV saline, the treating doctor checks the home setting, carries the checked emergency kit, stays with the patient and shares visit details before each visit (IV-002 section 16; IV-003 section 1).
Pharmacist / medicines adviser	Provide specialist advice when the product risk assessment identifies a need. Joint pharmacist/senior-clinician assessment is SPS best practice; doctor review is not pharmacist review. See section 6.
Clinic manager / infection-control lead	Maintain cleaning, stock, equipment, training, controlled documents and emergency arrangements, with named cover for absence.
Stock/alerts lead and deputy	Dr Parmar, Dr Alpa and Dr Amit check daily and cross-cover. The weekly rota names a lead and deputy. The lead records relevance, action ownership, deadlines and closure; Dr Parmar retains overall accountability.
All staff	Recognise urgent concerns, route them promptly to clinical staff, protect confidentiality and report incidents; do not give advice beyond competence.

5. Legal framework and preparation setting

CQC Regulation 12 requires safe care, risk management, competent staff, appropriate premises/equipment, medicines management and infection control. Regulation 17 requires effective governance and accurate records. These duties apply to this England-based clinic; registration is not approval of an individual mixture. [R01-R02]

The Human Medicines Regulations contain conditional exemptions relevant to doctor preparation and specified patient-specific mixing. Record the lawful basis for the actual activity; a wholesale licence, prescriber status or exemption does not by itself establish a preparation's quality or safety. [R04-R05]

For routine clinical-area preparation, select a method for immediate administration supported by the actual product's instructions. Under this clinic SOP, preparation outside those instructions, or for later storage, must be referred to an appropriate pharmacy aseptic service or supplier for assessment and supply; advice alone does not authorise that clinic preparation. An off-label clinical indication is not automatically a deviation from the preparation method. [R07-R08]

QAAPS/pharmacy aseptic-service requirements and manufacturing GMP standards have their own scope. They are not interchangeable with a clean clinical preparation area. GPhC pharmacy standards apply to relevant pharmacy partners; this clinic is not described as a pharmacy. [R11, R30]

Product approval, staffing and assurance

6. Product and process authorisation

Dr Mitesh Parmar and Dr Alpa Morawala both sign each product/process approval against the current SmPC and preparation risk assessment. Either doctor may review/prescribe for an individual patient and check supplier batches/expiry. Record indication, preparation, monitoring, use period, restrictions and review triggers in IV-002. A second doctor checks each preparation when present; record who checked. If the product assessment requires a second check, obtain it before administration.

SPS recommends a pharmacist and senior clinician assess preparation risks as best practice. This policy uses documented doctor-led review for the clinic pathway; record the rationale and residual risks if pharmacy input is not obtained. Seek appropriate specialist advice for uncertainty over compatibility, stability, supply or preparation, or risks beyond the doctors' competence. Resolve safety concerns before use. This is not a blanket legal exemption or a completed pharmacist review. [R08]

7. Staff, environment and emergency readiness

Dr Parmar and Dr Alpa have relevant hospital and IV experience. IV/refresher and resuscitation training was completed on 22 October 2026; Dr Parmar confirms the supporting training/competency records are completed and signed. Retain task-specific evidence for calculation, asepsis, cannulation, monitoring, emergencies and records. Maintain annual resuscitation training and reassess other skills after a lapse, incident or change.

Rooms 1 and 3 are used. Their suitability assessments were completed on 22 October 2026, with signed records confirmed retained. Review changes and check the actual surface, cleaning, equipment and emergency arrangements before each session. Staff treatment and observation safely and use IV-003 for contact and escalation, including Saturday closure. Home IV saline: before cannulation the treating doctor checks the home setting under IV-002 section 16; if it is unsuitable, treatment does not go ahead.

8. Local audit and review programme

Retained clinic standard: review the first five cases after operational release or a material change, then quarterly review all cases if fewer than ten, or a sample of at least ten cases, as required by v1.0. Audit patient-specific prescribing and consent; product/batch traceability; correct preparation and timing; observation; aftercare; and completion of follow-up. Review every serious incident and each recall action. These are retained local requirements, not statutory quotas. Target 100% compliance for prescription, assessment/consent, traceability/preparation and observation/discharge; every deviation needs an owner, due date and closure review. Home saline infusions are included in this audit programme.

Track deficiencies and corrective actions. Include batch-to-patient linkage in routine record audits and review failures, recalls and record-system changes. Use a practical retrieval exercise when needed to establish reliability; no fixed annual mock-recall test is a release condition. No completed mock test is claimed. Allergy checks do not replace recall tracing. Suspend an unsafe affected process and arrange onward care.

9. Document and website control

Keep one approved master and a revision log. Retain superseded versions marked as historical. Review this package annually and sooner when warranted. Keep service pages consistent with the approved scope; preserve the current removal of withdrawn treatments. Publish only the approved version and describe only verified operating controls. CQC, MHRA and source references do not endorse this clinic or guarantee certification.

Confirmed practice and controlled records

10. Confirmed clinic arrangements

Item	Confirmed arrangement / record
Service	Operating since May 2024; adults; clinic, plus home IV saline only; no multi-ingredient formulas. Home IV saline pathway approved 23 October 2026. Updated 23 October 2026.
Products and supply	Venofer [R37]; Ascorbic Acid Pascoe 150 mg/ml, PL 14369/0009 [R23]; Ecoflac saline supplied by AAH. Exact container/label details are retained in stock records.
Signed records	Dr Parmar confirms training/competency, rooms 1 and 3 assessments and product approvals complete and signed. Training/room assessments: 22 October 2026.
Traceability	Each component batch/expiry is linked to the patient infusion. Supplier checks apply. Risk-based assurance; no mock-recall pass claimed. Home saline: bag and giving set batch/expiry recorded at the visit.
Aftercare	Mon-Fri 09:00-20:00; Sun 09:30-17:30. Saturday closed: NHS 111/999. Other out-of-hours diversion: Dr Parmar/Dr Alpa; response not guaranteed.
Alerts	Direct MHRA/GOV.UK alerts to enquiries@cliniquealpa.co.uk are active and distributed to clinicians. CAS also arrives via Dr Parmar's NHSmail and is forwarded. Daily checks; weekly lead/deputy.

Document authority - Approval lineage: 22 October 2026; consolidated final issue: 23 October 2026.

Service and review - Service since May 2024. Next review 22 October 2027.

Private evidence index - Reference the completed signed approvals, competence/training and room records:

11. Sources and scope of evidence

Product references checked 23 October 2026. Confirm current product instructions at review and for any change. Pascoe and Ecoflac supply are confirmed; record exact saline strength, volume and licence from the stock label. The B. Braun source is a reference for matching the actual presentation [R38].

- R01. CQC: Regulation 12 - safe care and treatment
- R02. CQC: Regulation 17 - good governance
- R04. Human Medicines Regulations 2012: regulation 3
- R05. Human Medicines Regulations 2012: regulation 20
- R06. GMC: prescribing unlicensed medicines
- R07. NHS SPS: aseptic manipulation of injectable medicines
- R08. NHS SPS: assessing risks when reconstituting injectable medicines
- R11. MHRA: good manufacturing and distribution practice
- R23. Ascorbic Acid Pascoe: UK SmPC - confirmed clinic vitamin C product
- R37. Venofer: UK SmPC - confirmed clinic iron product
- R38. B. Braun sodium chloride 0.9% IV infusion: SmPC - match the actual stock label

Implementation records and session checks

12. Implementation and records

- Keep service history separate from document issue dates: May 2024 is the service commencement, not approval of later policies.
- Dr Parmar confirms completed, signed product/process approvals by both doctors. Retain the current SmPC, preparation risk assessment, monitoring, restrictions and any specialist advice; review material changes.
- Training/competency and room-assessment records are confirmed complete and signed. Retain the original assessor, scope, findings and dates. Training and room assessments were completed on 22 October 2026.
- Maintain consent, emergency/extravasation and infection-control procedures, equipment checks and patient aftercare. Keep personal contacts and call-routing records privately.
- Operate the active direct MHRA inbox and the additional CAS NHSmail forwarding route. Use the weekly lead/deputy rota, daily checking, named actions and cross-cover; preserve the actual delivery settings.
- Maintain patient-linked batch records and proportionate traceability assurance. No mock-recall or phone-test result is inferred from signed training or product approvals. Check safety before every treatment.

13. Session release

Before each treatment verify identity, current assessment/results/medicines/allergies, approved product protocol and prescription, consent, staff and emergency cover, intact products and traceable batches, required checks and label, cannulation and baseline observations, monitoring, post-treatment observation, aftercare and follow-up. Use the IV-002 administration record; a previous signature does not waive reassessment. For home IV saline, also confirm the home setting check, a complete in-date emergency kit and that visit details were shared; otherwise treatment does not go ahead.

Product/process records - Reference the signed two-doctor approvals, current SmPCs and risk assessments:

Implementation records - Location of completed competence/training and room-assessment records; subsequent actions:

Controlled master - Current issue 23 October 2026; next review 22 October 2027:

Version history and confirmed practice

v2.5 / SOPs v1.4: Home IV saline pathway approved by Dr Mitesh Parmar, 23 October 2026.

Issue / change	Disposition in this revision
v0.1 / v1.0, 20 October 2026	Initial draft; then v1.0 approved by Dr Parmar. Operational release remained separate. Historical baseline retained.
v2.0, 22 October 2026	FINAL, approved by Dr Parmar on 22 October 2026; supersedes v1.0. Operational release remains separate. Publish at the existing canonical page.
v2.1 / SOPs v1.1, 22 October 2026	FINAL update authorised by Dr Parmar. Adds Venofer/SmPC, named clinical reviewers/authorisers and confirmed patient-linked batch/expiry records. Other release checks stay separate.
v2.2 / SOPs v1.2, 23 October 2026	Names preparers, rooms, training/assessment dates, contacts and alerts. Two-doctor product approval; pharmacy advice by risk. Removes mandatory annual mock test; retains tracing and assurance.
v2.5 / SOPs v1.4, 23 October 2026	Adds home IV saline (sodium chloride 0.9% only) by Dr Parmar or Dr Alpa; iron and vitamin C clinic only.
Document structure	Preparation, adverse events and supply/recall detail moved into subordinate IV-002, IV-003 and IV-004 v1.0; no competing governance policy.
Scope and review controls	Adult-only scope, observations, weekly equipment checks, annual resuscitation training and first-five/quarterly-ten audit retained. Earlier blanket pharmacy condition revised in v2.2.
USP and timing	Added qualified distinction between administration, preparation per approved labelling and immediate-use CSPs. Four hours concerns starting administration, not shelf life. No four-hour storage rule existed in the inspected v1.0.
Vitamin C / preparation	Added documented laboratory G6PD-result review before proposed high-dose treatment, explicit glass-ampoule particulate filtration and clearer product timing/traceability forms. Actual product protocol remains essential.
Iron safety	Retained hypersensitivity exclusions, no routine initial test dose, at least 30-minute observation and phosphate precautions. Clarified potentially permanent staining and the need for accurate product-specific adverse-effect information.
Aftercare and reporting	Expanded delayed-event triage, actual contact-cover requirements, patient leaflet and record; clarified independent-provider candour and separate CQC notifications.
Procurement / recalls	Supplier/manufacture checks, patient batch linkage, alerts and recall action retained. Earlier annual mock test replaced by risk-based assurance in v2.2.
Status and evidence	Added consolidated confirmation register and 12-question evidence map. No claim of ISO facilities, USP compliance, specific supplier/product use or 24-hour cover without evidence.

SPS joint pharmacist/clinical risk assessment remains recommended best practice. Signed clinic records are confirmed by Dr Parmar and retained privately. Doctor review is not pharmacist review; no mock-recall or phone-test pass is claimed. Review due 22 October 2027.

IV preparation, administration and monitoring

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 planned treatment of adults aged 18 and over within policy IV-001: at the clinic, and home IV sodium chloride 0.9% only under section 16. Excludes paediatric IV, any other home infusion, any addition, mixing or preparation in a home, blood products, parenteral nutrition, chemotherapy, IM injections and multi-ingredient cocktails. Emergency treatment of an infusion complication remains required. Read with IV-003 and IV-004. Use a product/process approved under IV-001 and a patient-specific prescription; this SOP does not prescribe an unspecified medicine or dose. Dr Parmar and Dr Alpa prepare and administer.

1. Before an appointment is confirmed

- Identify the treatment; Dr Alpa Morawala or Dr Mitesh Parmar performs clinical review and authorisation. Establish whether assessment, examination, blood tests or specialist input is required before an infusion can be offered.
- Check that the actual product and preparation method are covered by a signed profile, authorised staff and an assessed clinical setting. Confirm adequate time for treatment and observation.
- Do not promise a product, benefit or course solely from a booking request. Where essential evidence or safe facilities are unavailable, arrange assessment or an alternative rather than improvise.

2. Patient assessment and written direction

Confirm the patient's identity using at least two identifiers and reconcile the intended treatment with the clinical record. Review current symptoms, diagnoses, allergies, prior reactions, medicines, pregnancy/breastfeeding where relevant, renal/cardiac/liver disease, infection, fluid restrictions and haematological risks. Reconcile supplements as well as medicines. Obtain the investigations required by the actual product and clinical indication; record results and dates, not simply 'bloods checked'.

The patient-specific prescription/direction must identify the medicine, formulation, dose with units, route, diluent and volume when required, intended concentration, rate/duration, date and prescriber. Resolve any incomplete or ambiguous instruction before preparation. Record weight and calculation where the regimen depends on them. Do not translate website package names into prescriptions.

3. Consent and a treatment plan

Explain the reason for IV treatment, alternatives, uncertainties, material risks and relevant unlicensed/off-label use. Agree the monitoring and follow-up plan and the circumstances in which treatment will stop. Document capacity and consent. Check patient understanding and communication needs. Consent can be withdrawn during treatment. [R06]

Retained v1.0 baseline: perform a focused examination and ordinarily record blood pressure, pulse, respiratory rate, oxygen saturation and temperature; weight where needed. Record relevant hydration, circulation and cannulation findings. This is the local minimum, not a claim about previous records. Reconfirm health/medicine changes and consent at every attendance. Acute instability or suspected sepsis requires urgent onward care; chronic illness or blood-borne virus status alone is not an automatic exclusion. [R31, R34]

Treatment-specific checks

4. Hydration

Document the reason for IV rather than oral fluids and select the fluid, volume and rate for the patient's clinical state. Review fluid balance, renal and cardiac function, electrolyte/glucose considerations and concurrent treatment as indicated. Specify a review point and stopping criteria, reassessing before any further bag. A licensed bag may be administered as supplied where prescribed. Do not add substances to a hydration bag without a separately authorised preparation profile. If the patient needs acute resuscitation or monitoring beyond clinic capability, arrange appropriate urgent care. At home, hydration is limited to sodium chloride 0.9% under section 16.

5. Single-ingredient vitamin C

Confirmed product: Ascorbic Acid Pascoe 150 mg/ml concentrate for injection/infusion, PL 14369/0009; holder Pascoe pharmazeutische Präparate GmbH. Its adult indication is vitamin C deficiency not treatable adequately by diet or oral replacement. The SmPC allows up to 7.5 g/day by infusion according to clinical need; this is not a routine prescribed dose. A physician administers it. Off-label use requires rationale, evidence and consent. [R23]

Exclude hypersensitivity, G6PD deficiency, oxalate stones/hyperoxaluria, iron storage disorders or overload, and GFR below 30 ml/min/1.73 m². Assess renal function, sodium/fluid load, interactions, pregnancy/breastfeeding and interference with laboratory or glucose tests under the SmPC. For proposed high-dose use, review a documented laboratory G6PD result and renal assessment and approve monitoring before treatment. Defer if suitability is unresolved. A product change requires separate approval. [R23]

Use the Pascoe SmPC for dose limits, dilution, administration and monitoring. Its peripheral-infusion instructions require one part concentrate to two parts isotonic saline. Use immediately after opening/dilution and discard unused contents. Do not mix with other medicines except the specified diluent. The prescribed dose and rate remain patient-specific. Ecoflac saline is supplied by AAH; verify the exact label, presentation and compatible diluent before use. [R23, R38]

6. Iron infusion: Venofer

Confirmed product: Venofer (iron sucrose), 20 mg iron/mL; UK PL 15240/0001; authorisation holder Vifor France. Confirm laboratory-supported iron deficiency and an appropriate indication; low haemoglobin alone is insufficient. Apply its current SmPC to eligibility, dose/interval, dilution, rate and monitoring. For infusion, use only sterile sodium chloride 0.9%, immediately before administration; do not add other medicines. Assess infection, hepatic and pregnancy precautions; exclude non-iron-deficiency anaemia and iron overload. IV treatment does not eliminate gastrointestinal effects. [R37]

Exclude known hypersensitivity to the product/excipients or known serious hypersensitivity to another parenteral iron product. Review other risks and explain that serious reactions can occur despite previous tolerance. Trained staff and resuscitation facilities must be immediately available. Observe throughout and for at least 30 minutes after every IV iron administration, longer if required. Routine initial test doses are not recommended; follow any product-specific initial infusion-rate instructions. [R13]

Explain extravasation and potentially permanent skin staining; monitor the cannula site. A change from Venofer needs separate product approval. If ferric carboxymaltose is selected, assess hypophosphataemia risk and arrange phosphate monitoring where indicated by current guidance, including repeat/high-dose or prolonged exposure and other risk factors; reassess persistent hypophosphataemia before further treatment. [R14-R15]

Aseptic preparation at the clinic

7. Prepare the setting and staff

Use the designated clean surface in room 1 or room 3; signed suitability assessments were completed on 22 October 2026. Keep the area uncluttered and protected from splashes, food, waste and interruption. Perform hand hygiene, apply appropriate protective clothing, and clean/disinfect the surface with the required drying time. Prepare one patient's medicines at a time.

Confirm that sterile consumables, suitable sharps disposal, administration equipment and the current prescription/product instructions are available. Check expiry, package integrity and storage history. Do not use damaged, cloudy, contaminated or unidentified products. Isolate any suspect stock and follow IV-004.

8. Prepare and check the product

- Read the exact product and diluent labels against the prescription. Verify strength, dose calculation, volume, concentration and route. Record all component batch numbers and expiries before labels or packaging are discarded.
- A second doctor checks each preparation when present. Record the check of prescription, patient, medicine, calculation, dilution, expiry, route and rate. Obtain any second check required by the product/process risk assessment before administration. Where not required and only one doctor is present, use a documented deliberate self-check; do not invent a second signature.
- Protect syringe tips, needles, connections, vial access points and bag ports as key parts. Disinfect access points with a compatible agent using the manufacturer/local validated method and allow to dry. Do not prescribe one disinfectant for every device without checking compatibility.
- Use sterile single-use devices and only the approved method. When withdrawing from glass ampoules, use appropriate particulate filtration with documented product/device compatibility; obtain specialist advice if compatibility is uncertain. Do not touch key parts or reuse needles, syringes or single-dose containers between patients.
- Complete the authorised dilution or addition only. No extra ingredient, pooling of remnants, topping up or extrapolation to an unapproved mixture. Discard residual single-use contents after preparation in accordance with medicines-waste procedures. [R09]

9. Inspection and identification

Inspect the prepared solution and container for expected appearance, leakage, particles and labelling. Normal appearance does not establish chemical compatibility or sterility. If a breach or discrepancy occurs, stop, segregate the preparation and arrange a fresh supported preparation when appropriate.

Label with patient identifiers, medicine and dose, diluent/total volume and concentration where relevant, route, rate, preparation date/time, latest permitted start/completion instructions and preparer/checker identification. Keep the manufacturer's batch information traceable and do not obscure essential bag information. Even where the same practitioner administers immediately, apply the clinic's identification label.

Timing, administration and discharge

10. In-use limits and disposal

Distinguish the unopened manufacturer's expiry from the use period after opening or preparation. For this clinic process, prepare only when the patient, staff and equipment are ready, and begin administration immediately after the final checks. Record every discarded dose and reason. Do not prepare for later appointments, transport a prepared bag off-site or for later administration, refrigerate it for reuse or assign an extended storage life. Unopened, in-date manufacturer bags of sodium chloride 0.9% in their original packaging may be taken to a home visit under section 16; a spiked, opened or prepared bag is never transported.

The approved product profile must specify any shorter time limit, infusion completion limit and any product-specific light/temperature requirements. Record preparation, start and completion times. If the expected immediate start is interrupted, do not default to a one-hour or four-hour allowance: the clinician must assess the exact product's supported limit and contamination risk; discard if safe use cannot be established. Discard if treatment is cancelled, the container is compromised or the supported limit is exceeded. [R07]

11. Administer and monitor

- Perform a final bedside check of identity, consent, prescription, product, route, label and cannula. Record baseline observations appropriate to the treatment and patient. Confirm required emergency equipment and clinical cover remain available.
- Use the approved cannulation procedure: check antiseptic/latex/adhesive allergies; choose a suitable site/device; apply skin antiseptic and drying time, aseptic non-touch technique, securement and dressing. Record insertion details/difficulty. Check patency and escalate difficult access under a defined attempts limit. Explain symptoms to report. [R33]
- Use the specified rate and delivery equipment, including any independent device check required by the risk assessment. Record observations at the frequency in the product profile, including after rate changes and whenever symptoms or clinical concern arise. Keep the patient under competent supervision; do not leave an ongoing infusion without appropriate cover.
- For symptoms suggesting hypersensitivity, extravasation, fluid overload or another serious problem, stop the implicated infusion and assess immediately under IV-003. Do not automatically flush a line when extravasation is suspected.
- Record the actual amount administered, start/finish times, interval and final observations, site assessment, any interruption or reaction, and the practitioner. Remove the cannula when no longer needed, confirm it is intact, provide local care and record removal; check nothing remains inadvertently attached. Dispose safely.

12. Safe discharge

Complete the required post-infusion observation. Iron requires at least 30 minutes after each administration. Discharge only when clinically stable and the clinician is satisfied that onward travel and support are appropriate. Give the completed aftercare sheet, actual clinical contact hours and urgent-care instructions. Document follow-up tests/review and who will act on results. A delayed result must have an identified recipient and follow-up process. [R13]

Appendix A: product and process profile

Dr Parmar confirms the signed product/process approvals are complete and retained privately. Products are Venofer, Ascorbic Acid Pascoe and Ecoflac saline supplied by AAH. This reusable template supports future product changes and reviews; its blank fields do not represent missing current approvals. Use a separate profile for each product and materially different method.

Product identity - Product, formulation and strength; actual container/presentation; route:

Supplier / manufacturer - Ecoflac saline supplier: AAH. Record each product's legal supplier/manufacturer and verification:

Product status and evidence - Venofer PL 15240/0001 [R37]; Pascoe PL 14369/0009 [R23]. Saline licence/presentation from stock label [R38]:

Pascoe product record - Ascorbic Acid Pascoe 150 mg/ml; PL 14369/0009; holder Pascoe pharmazeutische Präparate GmbH; SmPC R23. Actual presentation and supply evidence:

Population and indication - Clinical rationale; age/pregnancy limits; alternatives; restrictions:

Prescription and preparation - Dose calculation/limits; diluent; volume; concentration; compatibility; equipment:

Timing and storage - Unopened storage; preparation-to-start/completion requirements; disposal rule:

Assessment and monitoring - Contraindications; investigations; observations; adverse-event risks; follow-up:

Risk assessment - Preparation location; manipulations; checks; staff competency; residual risks/advice:

Approval and review - Product approval: Dr Mitesh Parmar and Dr Alpa Morawala; actual signatures/date. Risk assessment, advice if needed, restrictions and protocol version:

Change control

Reassess a change in brand, strength, diluent, concentration, preparation device, process, population or evidence. A new supplier's marketing name is not a substitute for this profile. Retain superseded profiles with the dates they applied. If uncertainty concerns one product, resolve that product's pathway rather than treating the uncertainty as a universal legal ban on IV preparation.

Appendix B: administration record and checks

Confirmed current practice: each bag/additive's batch number and expiry is recorded against the individual patient infusion. Continue this in the clinical record or linked register, with all fields below. Never publish completed patient records.

Patient / encounter - Two identifiers; date/time; prescriber; indication; consent; relevant results:

Prescription - Product; strength; dose/units; route; diluent/volume; rate/duration; profile version:

Component traceability - For each fluid, diluent and additive: brand, manufacturer, batch, expiry, quantity:

Preparation / checks - Location; preparer; checker if required; intact/within expiry; preparation time; label:

Administration - Baseline and interval observations; cannula/site; start/finish; amount delivered; staff:

Outcome and discharge - Observation end; reaction/action; clinical review; aftercare/contact issued; follow-up:

Audit and competency evidence

The clinic confirms completed, signed training/competency records. Maintain registration/role, training, assessment, authorised tasks, assessor and review dates in the staff register. Audit records against IV-001 and review preparation discrepancies, aseptic breaches, timing deviations and incomplete observations. Retain existing signed records; use this template for subsequent administrations and reviews.

Sources: product updates checked 23 October 2026

R06. GMC: prescribing unlicensed medicines
R07. NHS SPS: aseptic manipulation of injectable medicines
R08. NHS SPS: assessing risks when reconstituting injectable medicines
R09. NHS SPS: use of injectable medicines for multiple doses
R13. MHRA: intravenous iron and serious hypersensitivity
R14. MHRA: ferric carboxymaltose and hypophosphataemia
R15. NHS SPS: minimising risks with injectable iron
R23. Ascorbic Acid Pascoe: UK SmPC - confirmed clinic vitamin C product
R33. NICE CG139: infection prevention and vascular access
R34. GMC: decision making and consent
R37. Venofer: UK SmPC - confirmed clinic iron product
R38. B. Braun sodium chloride 0.9% IV infusion: SmPC - match the actual stock label

UK practice and USP terminology

13. Describe the actual preparation accurately

The clinic remains subject to UK law and professional obligations. A US compendial classification is not a substitute for product approval or lawful UK preparation. No Category 1, 2 or 3 compounding is authorised by this clinic policy. The authorised scope is immediate administration of verified products; no claim of USP compliance is made before the actual process is assessed.

USP distinguishes administration and qualifying preparation per approved labelling from sterile compounding. Where an activity is compounding, section 1.3 can apply only if every immediate-use condition is met. Immediate use does not itself mean "not compounding". [R24]

14. Record the classification and evidence

- For a ready-to-administer bag, record what manipulation occurs. For dilution, record the exact product instructions and whether the relevant approved-labelling conditions are satisfied.
- If relying on section 1.3, document aseptic competence/SOPs, compatibility evidence, no more than three different sterile products, single-patient use of single-dose containers, required labelling and the administration-start deadline. Count the fluid/diluent and drug products, not simply the number of nutrients. [R24, R36]
- The four-hour limit runs from the start of preparation to the start of administration. It is not an infusion-completion deadline or a four-hour shelf-life guarantee. [R36]

15. The clinic rule remains stricter

Begin administration immediately after preparation and final checks. Record preparation start, preparation completion, administration start and finish. Apply any shorter product-supported limit and any maximum infusion duration. No advance storage or extension is authorised. If delayed, use the approved product procedure and discard whenever safe use is unresolved. A four-hour USP provision cannot be used to bypass this clinic rule.

The product review must document classification, preparation evidence and any specific LegitScript requirement before a compliance claim. Seek appropriate specialist pharmacy advice where needed under IV-001; do not imply it has occurred. An assessed environment, aseptic technique and suitable equipment remain necessary. Label every prepared bag under this policy, including where an external standard permits a limited exception.

R07. NHS SPS: aseptic manipulation of injectable medicines

R08. NHS SPS: assessing risks when reconstituting injectable medicines

R24. USP: official chapter 797 FAQs

R36. USP: chapter 797 implementation presentation, immediate-use requirements

Home IV saline

16. Home IV saline

Dr Parmar or Dr Alpa may give IV sodium chloride 0.9% in the patient's home from a licensed ready-to-administer bag, as supplied, with nothing added. IV iron and IV vitamin C are given at the clinic only. No addition, mixing or preparation of any kind takes place in a home. Home IV saline pathway approved by Dr Mitesh Parmar, 23 October 2026.

- Eligibility: Adults aged 18 and over only. The doctor's assessment documents why IV rather than oral fluids, fluid balance, renal and cardiac status, medicines and allergies. A patient-specific prescription states the fluid, volume, rate and duration. Exclude, and refer to urgent care, any patient with acute instability, suspected sepsis, a need for monitoring beyond a home visit, significant heart or kidney failure or fluid restriction, or no safe home environment. Home IV is not a substitute for emergency care.
- Home setting check: Before cannulation, the doctor checks for adequate space and lighting, a clean surface, hand-washing facilities, phone signal and ambulance access, and has the full address and access instructions ready for a 999 call. If the setting is unsuitable, treatment does not go ahead.
- Stock and transport: 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.
- Emergency readiness: The doctor carries an anaphylaxis kit (intramuscular adrenaline 1 mg/ml with Resuscitation Council UK dosing guidance), a pocket mask, and observation equipment (blood pressure monitor, pulse oximeter and thermometer). The kit is checked complete and in date before each visit, and treatment does not start unless it is. For suspected anaphylaxis or another serious reaction: stop the infusion, call 999 giving the home address, treat in line with Resuscitation Council UK guidance, stay with the patient and hand over to the ambulance crew.
- Administration: Check identity with two identifiers, confirm consent, cannulate using aseptic non-touch technique as in this SOP, label the bag for the patient, add nothing to it, and record baseline and interval observations.
- Supervision: The doctor stays with the patient throughout the infusion and for at least 30 minutes afterwards. No infusion is left running unattended. The cannula is removed and checked intact before the doctor leaves.
- Traceability: 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.
- Waste: The doctor removes sharps and clinical waste from the home and disposes of them through the clinic's clinical waste arrangements.
- Lone working: Visit details are shared with the clinic or the other doctor before each visit.
- Aftercare: The patient receives the same written aftercare sheet, the clinic number 020 8882 8088 and clinic hours, the out-of-hours diversion to Dr Parmar or Dr Alpa, and the NHS 111 and 999 routes, all as in IV-003.
- Audit: Home saline infusions are included in the IV-001 section 8 audit programme.

Rules 4, 7 and 11 also sit in IV-003, IV-004 and IV-001. The doctors' IV and resuscitation training (22 October 2026) applies.

IV adverse events and emergency response

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.

Scope: reactions during or after adult clinic hydration, vitamin C and iron infusions and home IV sodium chloride 0.9% infusions (IV-002 section 16), including suspected reactions, administration errors, extravasation and delayed patient-reported concerns. Applies with IV-002 and IV-004. This is an approved supporting SOP under IV-001 v2.5. Keep staffing, equipment, training and clinical contact records current; verify safe arrangements for every session.

1. Readiness before each treatment

Confirm a competent clinician and trained responders are available for the planned treatment and observation period. Check immediate access to working monitoring/resuscitation equipment, oxygen with delivery equipment, an AED and appropriate emergency medicines; record expiry, access and function. Retain session checks and documented checks at least weekly. Staff receive resuscitation training at induction and at least annually. [R31-R32] Keep the current Resuscitation Council UK algorithm readily accessible. Confirm how to call 999, the full clinic address and access instructions, and who meets the ambulance. [R01, R16]

Review the patient's risks and explain symptoms to report. Record baseline observations and the planned monitoring. For IV iron, trained staff and resuscitation facilities must be immediately available, with monitoring during administration and for at least 30 minutes afterwards. Previous tolerance does not remove hypersensitivity risk. [R13] Home IV saline: The doctor carries an anaphylaxis kit (intramuscular adrenaline 1 mg/ml with Resuscitation Council UK dosing guidance), a pocket mask, and observation equipment (blood pressure monitor, pulse oximeter and thermometer). The kit is checked complete and in date before each visit, and treatment does not start unless it is.

Immediate response to a serious reaction

2. Immediate response to a suspected serious reaction

- Stop the implicated infusion, summon the responsible clinician and assess airway, breathing, circulation, disability and exposure. Record the onset time and observations while prioritising treatment.
- For suspected anaphylaxis or another life-threatening problem, call 999 without waiting for the clinic's internal escalation process. Use the current Resuscitation Council UK algorithm: trained staff give age-appropriate intramuscular adrenaline promptly when indicated, provide oxygen/resuscitation as required and reassess. IV adrenaline requires specialist expertise and is not a routine clinic substitute.
- At a home infusion: for suspected anaphylaxis or another serious reaction, stop the infusion, call 999 giving the home address, treat in line with Resuscitation Council UK guidance, stay with the patient and hand over to the ambulance crew.
- Position and support the patient according to the clinical situation and current guidance; do not allow a patient with suspected anaphylaxis to stand or walk. Monitor continuously and repeat emergency treatment according to the algorithm. If cardiac arrest occurs, commence CPR/AED management.
- Preserve or obtain appropriate IV access when clinically indicated, but do not continue the suspect product. If extravasation is suspected, follow section 3 rather than automatically flushing the line.
- Hand over the product, dose, dilution, timing, symptoms, observations and treatment to emergency clinicians. Do not discharge a patient with suspected anaphylaxis simply because symptoms initially improve. [R16]

Do not label a reaction as benign until assessed. Any restart requires an explicit prescriber decision supported by the product guidance and clinical assessment; never automatically restart a stopped infusion.

Extravasation, delayed concerns and reporting

3. Pain, leakage or swelling at the cannula

Stop the infusion immediately and assess the site and patient. Do not flush a cannula through which extravasation may have occurred. Keep access initially only as required for assessment/aspiration under the product-specific extravasation procedure, then remove/manage it as clinically directed. Identify the drug, concentration, estimated escaped volume and time. Obtain appropriate specialist advice for management, compresses or other treatment; do not improvise an antidote.

Document extent, symptoms, circulation and neurological findings where relevant; obtain consent for clinical photographs when useful. Explain the risk of persistent or permanent iron staining and arrange review. Escalate severe pain, progressive swelling, skin injury or neurovascular concern urgently. Record and report the event; preserve relevant packaging and evidence safely. [R15, R37]

4. Patient reports after discharge

Any staff member receiving a possible adverse-event report must identify emergency symptoms first and direct the patient to 999 when indicated. Record patient identifiers, callback number, current location, symptoms/onset, infusion date/product and immediate action. Do not require a complaint form or wait for proof of causation. Administrative staff must not offer clinical reassurance beyond their training.

Clinic hours: Monday-Friday 09:00-20:00; Sunday 09:30-17:30. Clinical concerns on 020 8882 8088 are routed to a doctor. Saturday: clinic closed; NHS 111 for urgent advice or 999 for emergencies. Outside other staffed hours, calls divert to Dr Parmar and Dr Alpa. Diversion is not guaranteed availability; if urgent help is needed and no clinician responds, use NHS 111 or 999 as appropriate. Keep cover and routing records privately.

The clinician must assess, arrange examination/tests or emergency transfer as needed, give clear safety-netting and document a follow-up plan. Record attempts to contact the patient and the action if contact fails. A normal immediate post-infusion period does not exclude a delayed reaction. Consider product-specific risks, including hypophosphataemia after ferric carboxymaltose where relevant. [R14]

5. Reporting and preservation of evidence

Record all suspected events locally, including near misses and preparation/administration errors. Report serious suspected reactions to established medicines and all suspected reactions to additional-monitoring products through MHRA Yellow Card; suspicion is sufficient. MHRA's IV iron advice asks for any suspected iron ADR, identifying the exact product. Record the report reference and any follow-up. [R12-R13, R29]

If a quality defect or contaminated product is suspected, segregate affected stock, preserve identifying evidence safely and notify the supplier/manufacturer and MHRA as appropriate. Use the confirmed patient-linked bag/additive batch and expiry records in IV-004 to identify other potentially exposed patients. Do not return or destroy evidence until the reporting/investigation requirements are agreed. [R28]

Candour, review and continuity of care

6. Duty of candour and statutory notifications

Be open and honest with the patient about what is known, what is uncertain and the next steps. The Clinical Director must assess whether the statutory duty of candour applies. For this independent provider, use Regulation 20(9), not the NHS-body 'moderate harm' shorthand. Qualifying outcomes include specified lasting impairment or harm, structural bodily change, reduced life expectancy, incident-related death, or treatment needed to prevent death or qualifying injury. Apply the complete legal definition to the case. [R03]

Where the duty applies, notify the relevant person as soon as reasonably practicable, offer support, give a truthful account of the known facts, explain further enquiries and apologise. Keep a secure record and follow up in writing with the required information and investigation outcome. Record unsuccessful contact attempts or refusal to engage. An apology does not require waiting for a completed investigation.

Separately assess CQC notification duties, including serious injuries and deaths under the Registration Regulations. Submit required notifications without delay and keep the reference. A Yellow Card, complaint or candour conversation does not replace a statutory notification. Not every ADR meets every reporting threshold. [R19-R20]

7. Follow-up and investigation

- Assign a clinician to follow the patient's recovery, outstanding investigations and treatment consequences. Agree responsibility for any referral or transfer of care and confirm receipt of time-critical information.
- Share relevant information with the patient's usual clinician with consent or another appropriate lawful basis; document the basis and any urgent justification. Update adverse-reaction/allergy records appropriately, preserving uncertainty where the cause is not established.
- Review the assessment, product selection, batch, preparation, storage, administration, observations, staffing and aftercare. Review serious events before resuming the implicated pathway. Distinguish patient report, observed findings, recorded facts and clinical opinion.
- Determine whether other patients, the same batch or a wider process may be affected. Pause only the unsafe affected activity while arranging alternative care. Record corrective actions, owners and evidence before resumption.
- Explain findings and next steps to the patient, close outstanding follow-up and share learning with relevant staff. The complaints route remains available and must not delay clinical care.

8. Review standards

The Clinical Director reviews serious events promptly and all other events through a risk-based governance process. Audit time to triage/escalation, complete records, reporting decisions, patient communication and closure. Reassess staff competencies or procedures where the event identifies a gap. Review this SOP annually and sooner after material change.

Patient information: after your IV infusion

Give this information after treatment, including after a home infusion, and complete the patient-specific fields. Contact arrangements below reflect the clinic's confirmed hours and Saturday closure. Personal mobile numbers are not published; use the clinic number.

Get emergency help immediately

Call 999 if you develop difficulty breathing, swelling of your tongue or throat, collapse, severe chest pain or another severe or rapidly worsening reaction. Tell the call handler that you recently had an IV infusion. Do not wait for the clinic to reply to an email or message, and do not drive yourself if seriously unwell. [R17]

Get prompt clinical advice

Contact the clinical service below for a new rash, fever, persistent dizziness, worsening symptoms, or pain, redness, swelling or discolouration around the infusion site. If urgent advice is needed and you cannot reach a clinician, use NHS 111. If symptoms become severe, call 999.

After iron, leakage around the vein can cause long-lasting or permanent staining. Report new site pain, swelling or skin changes promptly. Delayed aches or fatigue can have several causes; worsening or persistent symptoms need assessment. If your product requires phosphate checks or other follow-up, the clinician will record the plan below.

Your treatment and follow-up

Patient / date

Product(s) and dose - Infusion fluid and medicine; attach batch details or treatment summary:

Individual instructions - Expected effects, specific warning signs and activity/travel advice:

Follow-up - Tests/review date; responsible clinician; how results will be communicated:

Clinical contact - 020 8882 8088. Mon-Fri 09:00-20:00; Sun 09:30-17:30. Clinical concerns are passed to a doctor.

Outside clinic hours - Saturday closed: NHS 111/999. Other out-of-hours calls divert to a doctor; response is not guaranteed. If urgent and unanswered, use NHS 111; emergencies 999.

For urgent problems when the clinical service is unavailable: NHS 111. For an emergency: 999. General booking email and WhatsApp are not emergency channels; do not send confidential medical details through general enquiry routes. You can also report suspected medicine side effects to the MHRA Yellow Card scheme; reporting does not replace medical assessment.

Appendix: adverse-event record and references

Patient / reporter - Identifiers; reporter and contact; date/time received; current location:

Exposure - Infusion date; product/dose; fluid and additive batches; preparation/administration times:

Event and assessment - Patient account; onset; observations/examination; severity; suspected causes:

Immediate action / outcome - Infusion stopped; treatment; escalation/transfer; times and responsible clinicians:

Reporting / notifications - Incident ID; Yellow Card; supplier; CQC/candour assessment; references/dates:

Follow-up / closure - Advice; review/tests; patient/GP communication; investigation; actions/owner; closure:

Practical control

Use a secure clinical record and incident log. Restrict access to authorised staff, retain dated, attributable corrections without overwriting original entries, and record decisions not to report as well as reports made. Retention follows the clinic's approved records schedule. Blank templates may be published; completed records and staff-sensitive operational details must remain private.

Sources checked 22 October 2026

R01. CQC: Regulation 12 - safe care and treatment
R03. CQC: Regulation 20 in full - duty of candour
R12. MHRA: Yellow Card guidance
R13. MHRA: intravenous iron and serious hypersensitivity
R14. MHRA: ferric carboxymaltose and hypophosphataemia
R15. NHS SPS: minimising risks with injectable iron
R16. Resuscitation Council UK: emergency treatment of anaphylaxis
R17. NHS: anaphylaxis - patient emergency advice
R19. CQC Registration Regulations: regulation 18 notifications
R20. CQC Registration Regulations: regulation 16 death notifications
R28. NHS SPS: managing defective medicines
R29. GMC: reporting adverse reactions and patient safety incidents
R32. CQC: emergency care in general practice
R37. Venofer: UK SmPC - confirmed clinic iron product

IV procurement and batch traceability

Document control

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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.