QUALITY TECHNICAL AGREEMENT

FOR THE MANUFACTURE AND DELIVERY OF ASEPTIC PRODUCTS KNOWN AS 'SPECIALS'

Between

XXXXXXXXXXXXX

And

ITH Pharma Ltd
(Contract Acceptor – CA)

Validity: This agreement is valid for 12 months after the date of the final signature

Version: Four
Reference:XXXX/Comm.

QUALITY TECHNICAL AGREEMENT
For the Manufacture and Delivery of aseptic products

This Quality Technical Agreement is made between:

Pharmacy Department, XXXXXXXXXXXXXXXXXXXXXXXXXXXX (CG)

and

ITH Pharma Ltd: Unit 4 Premier Park, Premier Park Road, London, NW10 7NZ (CA)

MS number: 33634

This technical agreement is supplemental to any financial agreements and any subsequent agreements, between the two parties and will last for the duration of the agreement. The technical agreement shall be reviewed every 12 months or earlier if requested by either party.

This Technical Agreement is executed in duplicate, all of which shall be deemed to be originals, and all of which shall constitute one and the same Agreement binding upon both parties.

This Quality Technical Agreement shall be effective as of the date of the final signature and shall remain in effect until review or termination.

1. Scope

This agreement defines the roles and responsibilities between CG and CA relating to the manufacture and delivery of unlicensed products know as a 'special' for patients under the care of CG.

ITH Pharma supplies aseptically manufactured specials. A special is an unlicensed medicinal product that is defined as, a product that has been specifically and specially manufactured to the unsolicited order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient ("the Special"). Aseptically manufactured specials are inherently a high risk product made under license granted by the MHRA, that by definition do not undergo terminal sterilisation and whilst manufactured through a process which has undergone a regulatory approved risk assessment, do not go through a formal licensing procedure to assess the safety, quality and efficacy of the product itself as would be the case with a licensed product. Therefore specials always present a higher level of patient risk than licensed products. Whilst all our products are made under license granted by the MHRA you agree to indemnify and hold harmless ITH Pharma against all claims and proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of any party (including third parties) arising out of or relating to the prescribing, the clinical appropriateness, the dose or the administration of the Special. The above indemnity shall not apply to any such claim or proceeding which is for personal injury (including death) which is caused by the negligent or wrongful acts or omissions of ITH Pharma in the manufacture of the Special.

All parties agree as follows:-

2. Subject of the Agreement

CA is a provider of Specials which are manufactured according to an agreed specification and delivered to the CG. See Appendix 5 for product list.

CA shall manufacture and deliver the products in accordance with this technical agreement and in addition to other financial agreements.

CA is subject to registration and inspection by the competent national authorities and holds the necessary manufacturing licence according to the respective legislation.

CG has the responsibility to screen each order for its clinical appropriateness including its pharmaceutical stability where possible or appropriate. However, CA will take responsibility for the assigned stability of each item ordered and will provide stability statements when requested. CA takes no clinical responsibility for any order.

CA hereby acknowledges that CG is relying on the skill and experience of CA in the proper manufacture and delivery of the contractual products under this Agreement and CA accordingly warrants to CG that:

- The product shall be of satisfactory quality and fit for purpose.
- The product shall comply in all respects with the order provided by the CG

Both parties will strictly observe the detailed pharmaceutical responsibilities which are specified in Appendix 1 (“Responsibilities”).

CG and CA must appoint Contact Persons as named in Appendix 2 (“Contact Persons”).

3. Regulatory Information

CA is responsible for ensuring that manufacture and distribution of products meets all current legislation and best practice guidelines.

For the period of the contract CG will ensure that CA holds suitable MHRA approval for the supply of unlicensed products known as ‘specials’.

4. Starting Materials

CA shall source starting materials which possess a UK marketing authorisation or which have been manufactured under a ‘manufacturers specials’ licence. Materials must be sourced from a bona fide Manufacturer or Wholesaler holding a UK Wholesale Dealer’s Authorisation.

5. Manufacture

CA shall provide adequate premises, equipment and staff to satisfactorily carry out the work undertaken. CA shall perform all operations in accordance with Good Manufacturing Practice.

CA shall manufacture the unlicensed products known as a ‘special’ in accordance with the specification provided by CA / CG.

CA shall refrain from performing any activities that could adversely affect the quality of the service provided

Maximum fill volumes of syringes will be in accordance to CA policy. See table below. For PN, volumes over 55ml will be presented in an EVA bag.

MAXIMUM FILL VOLUME OF SYRINGES	
SYRINGE SIZE	**NAMED PATIENT**
1ml	0.1ml – 0.59ml
3ml	0.6ml – 2.5ml and vol. of 2.7ml
5ml	2.51ml – 5ml
20ml	5.01ml – 20ml
30ml	20.01ml – 25ml (30ml Doselock only)
50ml	25.01ml – 55ml

6. Quality Control / Assurance

CA must provide sterility assurance of all products purchased by CG. The method to determine sterility assurance must be in line with current guidance e.g. MHRA Guidance for Specials Manufacturers.

CA shall obtain satisfactory stability information for each product before allocation of an expiry date. This data shall be provided to CG upon request.

Release of each batch of product shall be under the authority of an authorised releasing officer.

CA shall maintain a suitable Pharmaceutical Quality System.

CA acknowledges that CG will perform sample inspection on batches received. Any deficiencies found during sample inspection which relates in some way to the product supplied by CA will be notified back to CA upon receipt or within five working days, this may lead to a formal complaint being raised. For any defects subsequently detected by the CG, notification of the CA will be made within 5 working days of the time of detection and never beyond 5 working days past the expiry date of the supplied product.

CA shall provide Certificates of Conformance for each batch supplied. The Certificate of Conformance shall at a minimum specify:

a. Name and site of manufacture.
b. Name or description of PRODUCT
c. PRODUCT Batch or Lot number
d. Batch size
e. Storage conditions
f. Expiry date
g. Date of manufacture
h. Statement that the product has been manufactured in compliance to applicable GMP requirements
i. Name and Title of person responsible for the validity of the certificate and the data it contains.

With the exception of 3-chamber bags, all PN will be made using the Baxa EM2400 automated pump. Once set up, configuration bags are produced which are tested for sodium, potassium, calcium and magnesium and also glucose. The electrolyte content is analysed using the iCAP spectrophotometer and the glucose content determined using a refractometer. This demonstrates that the machine has been set up correctly. Configuration bags are also produced each time these source containers are changed.

7. Storage and Distribution

CA shall adhere to Good Distribution Practice.
CA shall ensure that product shall be delivered in accordance with agreed procedures and records of delivery and receipt shall be retained by each party to affect a satisfactory audit trail in the event of recall.
CA shall store, handle and distribute the product according to its defined storage conditions.
CA may be required to provide evidence that the appropriate storage temperatures have been maintained and that all systems have been validated upon request.
CA shall ensure all products are packaged in such a way as to give them adequate protection from damage during transit.

8. Documentation

CA will archive completed documentation according to current regulatory guidance.

CA will use an in house computer system to generate labels and accompanying documentation for both chemotherapy and CIVAS named patient and batch items. For PN, the computer system that will be used is Abacus®, distributed by Baxter Ltd. Samples of labels and accompanying documentation can be supplied upon request before the service commences.

9. Change Control

Information related to any planned change to the product, overall process or specification for the product(s) by CA is to be notified to CG in writing at the earliest opportunity and authorised by CG prior to the change being in effect.

It is recognised that problems relating to the supply of starting materials may require urgent action. The substitution of any starting material with an equivalent material that holds a UK marketing authorisation should be notified to CG at the earliest opportunity prior to implementation.

In the event of merger, acquisition or facility closure of CA, CA shall notify CG at least 3 months before the change is implemented.

10. Unplanned Deviations

Information relating to any major or critical unplanned deviation associated with the individual batch supplied or overall process by CA is to be notified to CG verbally to the listed contacts at the earliest opportunity.

The CG requires to be informed XXXX hours in advance so in the event of the above alternative supplies can be sourced or can decide clinically to apply their local contingency.

Unplanned deviations which do not directly relate to a contractual product but could impact on the quality of a product purchased by CG should also be reported at the earliest opportunity.

11. Complaints

Any complaint from CG concerning quality of supplied product shall be acknowledged by CA within 24 hours.

A report containing details of the investigation with corrective and preventative actions as appropriate shall be forwarded to the CG within 10 working days; this may take the form of an interim report if the investigation has not been completed within this timeframe. The CA shall make every effort to complete investigations and provide feedback including actions assigned to CG in a timely manner.

Any complaint regarding non-adherence to this TA by either party should be escalated to the line manager of the relevant signatory for this agreement if a satisfactory outcome cannot be achieved by discussion. Ultimately if a satisfactory outcome still cannot be achieved termination of the contract may be considered.

12. Recalls and Returns

CA shall notify CG of any recall or near miss (company or MHRA led) relating to contracted products manufactured by CA or starting materials / components which were used in their manufacture.

Recalls and near misses which do not directly relate to a contractual product but could impact on the quality of a product purchased by CG should also be reported at the earliest opportunity.

CA shall document the recall process. CG is responsible for coordination and disposal of all products returned by CG patients. CA will co-operate with the collection, logging, storage and segregation of any recalled and returned product as required.

13. Audit

CG is responsible for assessing the competence of CA to carry out successfully the work required, this may be through review of a relevant audit performed on behalf of the NHS.

CA shall perform internal audits and perform audits of any outsourced activities.

CG is entitled to audit CA facilities relevant for the manufacture of the contractual products on a bi-annual basis and on specific occasions, e.g. “For-Cause-Audits”. Dates for bi-annual audits shall be mutually agreed at least 4 weeks in advance, For-Cause-Audits one working day in advance.

14. Confidentiality

The information contained in this agreement is confidential and must not be divulged to any other party without the permission of all signatories.

15. Contingency

CA must ensure a robust contingency plan has been arranged to ensure continuity of service in the event that they cannot provide the pre-defined quantities unlicensed products known as ‘specials’ as defined by CG.

16. Bank Holidays:

CA will inform the CG of bank holiday closures one month in advance to the agreed contact listed.

Final Provision

Amendments of this Quality Technical Agreement and its Appendices may only be carried out by mutual consent and shall be made in writing. Any amendments to the appendices 1-5 may be signed for CG by a responsible Quality representative and together with the signature of CA the appendix will be binding upon the parties.

Appendices

Appendix 1
Responsibilities

	CG	CA	Comments
1. Regulatory Processes			
Hold appropriate 'specials' manufacturing licence of relevant national authority in order to manufacture products as agreed by CG. Comply with any and all EU and other local current applicable laws, regulations and guidelines relating to GMP and GDP. CG is to be informed of any changes to licence, outcome of regulatory inspection and any pending regulatory action.		✓	
Ensure pharmacovigilance systems are in place to collect and collate information concerning all suspected adverse events / reactions reported to CG.	✓	✓	
Ensure competent authorities are notified of all complaints concerning suspected adverse events / reactions / lack of effect according to existing regulations and requirements.	✓	✓	

	CG	*CA*	Comments
2. Starting / Raw Materials and Excipients			
Purchase sterile materials from bona fide suppliers.		✓	
Assessing the quality of starting materials for use		✓	
All starting materials are TSE/BSE free		✓	
Maintain a supplier qualification program.		✓	
Check that the condition of all containers, closures, seals and labelling of delivered starting materials are satisfactory for use.		✓	
Approval of materials for use.		✓	
For Parenteral Nutrition products			
The glucose concentration used on the Baxa EM2400 as a raw material is restricted to 50% w/v which is further diluted with water for injections to achieve the overall correct glucose concentration. Restricting the raw material to a single concentration minimises the risk of errors in manufacturing		✓	
The nitrogen sources available on the Baxa EM2400 pump are limited to Vaminolact®, Aminoven® and Vamin 18 EF®.		✓	

	CG	*CA*	Comments
CA reserves the right to supply a 3-chamber bag to fulfil an order where the order matches the profile of it. Equally, CA reserve the right to fulfil an order using an AIO bag where the profile of the requested 3-chamber bag falls outside the stated requirements. In either case, CG accepts that the volume of the supplied product may or may not match exactly to the requested volume.		✓	
All PN will be supplied in multilayer EVA bags or in the case of 3-chamber bags, the source material.		✓	
For Chemotherapy / CIVAS products			
For infusion bags where the maximum fill volume of the bag allows, a volume that is equivalent to the addition volume of the drug will not be removed from the infusion bag prior to making the drug addition. However, where the volume of the drug to be added would exceed the maximum fill volume of the infusion bag, the volume equivalent to the addition volume of the drug will be removed prior to drug addition. The maximum fill volume information of the infusion bags is provided by the manufacturer and can be made available upon request.		✓	

	CG	CA	Comments
3. Packaging Material			
Only purchase primary packaging materials from approved suppliers in accordance with a specification.		✓	
Maintain a supplier qualification programme.		✓	
Check that the condition of all packaging material is satisfactory for use.		✓	
Approval of packaging for use.		✓	
All products containing vitamins will be supplied with a light protectant bag.		✓	

	CG	*CA*	**Comments**
4. Processing			
Qualification / Validation according to applicable GMP requirements for production equipment, utilities and processes.		✓	
Maintain a suitable environment		✓	
Maintain a specific batch number system to identify individual products.		✓	
Manufacturing process including all necessary activities.		✓	
In-process checks are performed and are deemed satisfactory.		✓	
Appropriate design and use of manufacturing batch documentation.		✓	
All critical automated processes are fully validated and appropriate for use and meet the requirements of GAMP.		✓	
Ensure that all products are manufactured in accordance with the agreed specification and current legislation.		✓	
Medicines will be handled with appropriate safety measures.		✓	
Ensure all labelling of products is in compliance with all laws, regulations and guidelines associated with the labelling of unlicensed specials.		✓	
For Parenteral Nutrition products			
With the exception of 3-chamber bags, all PN will be made using the Baxa EM2400 automated pump. Once set up, configuration bags are produced which are tested for sodium, potassium, calcium and magnesium and also glucose. The electrolyte content is analysed using the iCAP spectrophotometer and the glucose content determined using a refractometer. This demonstrates that the machine has been set up correctly. Configuration bags are also produced each time these source containers are changed. Ingredients that are not tested independently including nitrogen and trace elements are checked in triplicate when the machine is set up and for all subsequent container changes.		✓	

	CG	CA	Comments
5. Stability			
Provide stability data to support the allocated expiry of the products. Methods to determine product stability shall be in line with current regulatory requirements. For PN, stability data is assigned in one of the following ways: Using software known as Datacomp 2 which is provided by and applicable to Fresenius Kabi products, Contacting the medical information department of the company supplying the raw materials, Referring to published literature. In all cases, the stability reference is supplied with or referenced on the order form. In the event that a formulation is unstable, the named contact, on CG behalf will be contacted to agree the necessary amendments and the order will be reprocessed against a re-sent order, supplied by CG. All amendments to order forms agreed verbally between CA and CG must be confirmed by receipt of an amended written order. CA are unable to release a product to the CG without the necessary written authority. For PN for fixed formulations the stability can be provided in advance for ordering. For 3 chamber bags a matrix can be provided in advance of ordering. For tailor made products the above method applies although a statement will not be provided per product but statements can be reviewed by CG during audit. For chemotherapy & CIVAS products stability will be assigned using published data, studies conducted by the manufacturers of the raw materials or 'in-house' studies conducted by a stability consultant.		✓	This data shall be made available to CG upon request.

	CG	CA	Comments
6. Sterility			
Provide sterility assurance using methods defined in current guidelines. For Parenteral Nutrition Products Sterility testing is carried out using random samples of both named patient and batch PN products. Five bags are sampled and sent to an approved contract laboratory for sterility testing each month. The sterility testing is carried out in line with EP requirements and is part of the overall sterility assurance programme in conjunction with weekly product imitation broth fills and daily EM2400 pump broth runs		✓	
Maintain a suitable system to record, investigate and risk assess all microbiological non-conformances (out of limit) results. Implement appropriate corrective and preventative actions following the investigation and root cause analysis.		✓	
Assess the potential impact a microbiological non-conformance (isolated result or 'trend') could have on product quality and patient risk and act accordingly.		✓	
Trend microbiological non-conformances.		✓	
Inform CG of any microbiological non-conformances relating to products received by CG within 72 hours of receipt		✓	It is recognised that this may be in retrospect. Microbiological non-conformances which do not directly relate to a contractual product but could impact on the quality of a product used by a patient of CG should also be reported. The investigation and any associated corrective and preventative actions shall be made available upon request by CG.

	CG	*CA*	**Comments**
7. Product release			
Product release according to agreed criteria.		✓	
Preparation of documentation for release.		✓	
Have satisfactory systems in place that ensures patients only receive released products.		✓	
Released product conforms to order placed by CG.		✓	

	CG	*CA*	**Comments**
8. Storage / Distribution			
Qualification / Validation of storage sites for starting materials and products as appropriate.		✓	
Qualification / Validation of transport of the products from place of manufacture to the CG.		✓	
Store all Products and/or starting materials / other ingredients / excipients / auxiliary materials under appropriate conditions in compliance with GMP/GDP requirements and any licence requirements.		✓	
Maintain an audit trail to the hospital / patient.	✓	✓	
Delivery containers ensure the product is protected during delivery and complies with health and safety standards.		✓	
Distribute to the CG in a timely way as described in this technical agreement and other financial agreements.		✓	

	CG	*CA*	**Comments**
9. Documentation			
CA will only accept orders placed by fax or email on the CA order forms unless prior agreement has been made. For chemotherapy / CIVAS items must be ordered via CA online ordering system unless there is a valid reason for not using this method. Orders placed by any of the available methods by the CG that subsequently require amendment or cancellation must be confirmed in writing, either by email or fax.		✓	
Ensure that prescription forms as well as records of manufacture and distribution are clear, readily available and retained for the period required by current legislation. Records shall ensure the traceability of the origin and destination of Products.		✓	
Ensure written procedures are available to describe all operations that may affect the quality of the products.		✓	
Maintain complete and accurate records relating to the manufacture, packaging and storage of products supplied.		✓	
Store all documents and records so that they are easily retrievable and stored protected from loss and damage.		✓	
Maintain a record of batch numbers of all starting materials and products manufactured, supplied or returned in the event of a recall.		✓	
For Parenteral Nutrition products			
CA have designed a standard template for PN labels and accompanying paperwork. It is possible for CG to request design changes to the standard format before the service commences, except under the aforementioned contingency arrangement where the standard template will be accepted by the CG. Following approval, any subsequent changes to the design must be requested in writing by the CG to the CA and approved before the next version is released. This may take up to five working days depending on the complexity of the request.		✓	

	CG	*CA*	**Comments**
10. Changes			
Maintain a suitable change control system and communicate all information relating to planned changes with quality implications in writing before implementation. This applies to supplied product only.		✓	See above for timelines.
Maintain a suitable unplanned deviation system and communicate all unplanned changes (unplanned deviation excluding microbiological results) deemed to be major or critical. Events shall be reported at the earliest possible opportunity. This applies to supplied product only.		✓	Unplanned deviations which do not directly relate to a contractual product but could impact on the quality of a product used by a CG patient should also be reported. The investigation and any associated corrective and preventative actions shall be made available upon request by CG.
Results of any investigation relating to a major or critical unplanned deviation for a contracted product shall be provided in written format to CG within 72 hours of completion.		✓	This investigation must include proposed corrective and preventative actions.
No work should be sub-contracted without the prior written agreement of CG.		✓	

	CG	*CA*	**Comments**
11. Complaints			
Acknowledge any complaints from CG or patients of CG with quality implications within 24 working hours.		✓	
Investigate and document any complaint relating to the quality of contracted products within 10 days, feedback may be in the form of an interim or final report. This document should include details of all corrective and preventative actions as appropriate.		✓	

	CG	**CA**	**Comments**
12. Recalls			
In the event of product or any starting materials or components being recalled, arrange for the collection, stocking and segregation of products affected. This also includes products which were manufactured using a recalled starting material or component.		✓	Must comply with timelines as specified in regulations
Maintain a product recall procedure for use when it is necessary to recall a defective product from market, and test the procedure at least annually.		✓	This also includes products which were manufactured using a recalled starting material or component.
Advise CG if they have received products which are / contain starting materials which are subject to MHRA Drug Alert or Recall.		✓	Must comply with timelines as specified in regulations
Inform prescribers of any recalls concerning products supplied to patients.	✓		

	CG	*CA*	**Comments**
13. Audit			
Provide reasonable access, at agreed pre-determined times, to permit audits of the relevant facilities and documents by CG or the regulatory authorities.		✓	
Undertake the necessary quality audits of CA	✓		
Conduct internal audit in order to monitor the implementation of and compliance with GMP and GDP.		✓	
Propose necessary corrective measures following internal audit.		✓	
Make available evidence of adherence to internal audit schedules.		✓	
Make available evidence of closure of external audits and inspections, and the anticipated date of the next MHRA inspection.		✓	
CA are audited by QC from various regions and placed on an approved suppliers list. Copies of the audit will be available upon request.		✓	

	CG	*CA*	**Comments**
14. Training			
Staff involved in all aspects of the service will be adequately trained as appropriate to their role.	✓	✓	This includes training to outsourced contractors
Staff will comply with relevant legislation and NHS requirements concerning both patient and commercial confidentiality e.g. Data Protection Act.	✓	✓	

Appendix 2 List of Subcontractors

Same day couriers

Abetta Courier Services
2A Alexandra Grove
London
NW10 7UN

SDB Express
80 Winton Drive
Croxley Green
Hertfordshire WD3 3QT

Deadline Despatch Ltd
Unit 734, Tudor Estate,
London,
NW107UN

Overnight courier

Polarspeed Distribution
Unit 8
Leighton Buzzard LU7 4WG

Appendix 3
Technical Agreement Approval

Agreed on behalf of the Contract Giver

Name:	Name:
Title:	Title:
Signature: _____	Signature: _____
Date:_____	Date:_____

Agreed on behalf of the Contract Acceptor

Name: Karen Hamling	Name: Andrew Winstanley
Title: Managing Director	Title: Commercial Director
Signature: _____	Signature: _____
Date:_____	Date:_____

Appendix 4

Key Contact Persons

Contract Giver

Name	Designation	Contact number	E-mail
	Technical Services Manager		
	Technical Services Pharmacist	N/A	
	Customer complaints		
	Quality Issues		
	Invoice Queries		
	Delivery Queries		

Contract Acceptor - TBA

Appendix 5

Product List

Hospital to list products

Appendix 6

Service Level Agreement

1. Service

CA can provide the following services:

1.1.1 Chemotherapy and CIVAS items have a turnaround of two working days for named patient and three working days for batch items. For example, named patient items ordered before 12:00hrs on Monday will be received by 14:00hrs on Wednesday. For batch items ordered before 12:00hrs on Monday will be received by 14:00hrs on Thursday.

This service will be for **XXXX** named patient items per day (see product list).

1.1.2 Named patient PN bags can be provided on a same day service to locations within a reasonable distance from the CA premises. Where this is practical, named patient items ordered before 10:30hrs on Monday will be received by 17:00hrs on Monday. Alternatively, an overnight service can be provided where orders placed before 12:00hrs on Monday will be received by 14:00hrs on Tuesday.

Batch PN items have a turnaround of three working days, e.g. items ordered before 12:00hrs on Monday will be received by 14:00hrs on Thursday.

Where possible, PN will be prescribed by the CG a day in advance and for more than one day from Wednesday for clinically stable patients. Also, to manage its workload during anticipated busier periods, the CA may request the CG's co-operation to place orders for PN in advance.

This service will be for up to **XX** neonates and paediatrics daily and up to **XX** adult patients.

1.1.3 In all cases, shorter turnaround items may be accepted and items may be delivered earlier in the day if required. These requests should be addressed by the CG to the relevant Unit Manager and where agreed to, should be interpreted by the CG as an exceptional arrangement. Acceptance of shorter turnaround items does not imply an agreed change in the above service terms.

2.1.1 There is a choice of ways an order can be received; either by fax, email or for chemotherapy and CIVAS products ordered online. For chemotherapy / CIVAS items must be ordered via CA online ordering system unless there is a valid reason for not using this method. This must be followed by a phone call to confirm receipt of order.

2.1.2 All faxed orders (fax number for Chemotherapy and CIVAS is 020 8838 8281 and for PN is 020 8838 8271) will require an accompanying cover note to ensure all orders are received and matched. All orders are received into a manned office.

2.1.3 Email orders for chemotherapy and CIVAS products can be sent to chemo@ithpharma.com and for PN to pn@ithpharma.com. The CG should expect all orders placed by email to be responded to by us to confirm receipt within one hour. In the case that an email receipt is not received by you, you should call us to follow up in the event that the transmission has failed.

2.1.4 Online orders can be accepted following a short registration and approval process. Named contacts on behalf of CG should visit www.ithpharma.com to register.

PN Service

2.2 Solivito-N® will be supplied in the lipid phase except where indicated otherwise on the order form or where no lipid is present.

2.3 For neonatal and paediatric orders, the overage of the aqueous phase will be **XX**ml unless specified differently. Overage is not added to AIO or 3-chamber bags, except in the case of a paediatric AIO order where the CG is are required to state the overage required on the order form.

2.4 Volumes over 55mls will be presented in an EVA bag.

2.5 The paperwork that accompanies the product will be a copy of the details sheet.

2.6 A light protection bag will be folded behind the product enclosed in the plastic 500 gauge.

- All ports will be covered with port covers.

2.7 The expiry date for the named patient PN will be seven days when stored at between two to eight degrees Celsius. The administration time at room temperature for the aqueous phase will be up to 48 hours and the lipid phase 24 hours.

2.8 For unmanipulated 3-chamber bags will be that of the manufactured bag.

3. Delivery

3.1 Deliveries made on a same day basis are packed as follows:

Products that require cold chain maintenance will be chilled down prior to despatch and then packed in a box with sufficient air pockets to prevent movement and ice packs to maintain the cold chain.

3.2 Deliveries made on an overnight basis between Monday and Thursday are packed as follows:

Products that require cold chain maintenance will be chilled down prior to despatch and then packed in a box with sufficient air pockets and transported by a refrigerated vehicle.

Prepared items will be collected from us at 17:00hrs and sent on an overnight delivery to CG and will arrive before 14:00hrs on the following day. The CG may request alternative delivery times and this can be organised by the CA. The CG will bear the cost of any additional charges for earlier deliveries arranged by the CA.

Products being delivered to CG are to be delivered to the following address:

XXXXX
XXXXX
XXXXX
XXXXX
XXXXX

4. Monitoring

4.1 Meetings will be held between CA and CG to review the service. The minimum interval will be six monthly and interim meetings can be arranged if necessary.

5. Invoice

5.1 An order number will be generated by the CG to cover the item(s) ordered.

5.2 All invoices should be sent for the attention of XXXX at the following address:-

XXXXX
XXXXX
XXXXX
XXXXX
XXXXX

5.3 The CG shall pay monthly orders raised within thirty days of the date of invoice. If any amount due is not paid within sixty days, the CA shall be entitled to suspend deliveries of products until the outstanding amount has been received.

6. Duration and Notice Periods

6.1 A notice period of one month will need to be provided to the CA by the CG if an extension of service is required.

6.2 A notice period of one month will need to be provided to the CA by the CG when services are to end.

6.3 A notice period of one month will need to be provided to the CG by the CA when services are to end.

Appendix 7

Version History

Version Number	Date of Amendment	Amendment(s) Made
One	April 2016	New document.
Two	July 2016	Section 10 Unplanned Deviation; Notification time Section 16 Notification of bank holidays Appendix 1. Section 9; Online ordering for chemotherapy / CIVAS mandatory Appendix 4; Inclusion of out of hours numbers
Three	October 2016	Addition of timelines for notification of defects (p4)
Four	January 2017	Clearer definition of responsibilities under scope