Pharmacy Manual for FT576

For Intravenous (IV) Infusion

Version: 2.0

Version Date: 25 October 2022

NOTE: The Pharmacy Manual was formerly referred to as the Storage, Handling, and Administration Guidance.

IND Sponsor:
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CONFIDENTIALITY STATEMENT

Signature Approval Page

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1. CONTACT INFORMATION

Name	Email Address
FATE Quality Assurance	qa@fatetherapeutics.com
FATE Clinical Drug Supply	clinicaldrugsupply@fatetherapeutics.com
FATE Clinical Trial Manager (also referred to as Study Management Team Lead) and/or Site Monitor	Refer to the study contact list

2. OVERVIEW

Caution:	FT576 investigational medicinal product (IMP) is limited by United States law to investigational use and must be administered under the oversight of the Principal Investigator (PI) or qualified designee. FT576 may only be used for subjects consented to the applicable Institutional Review Board (IRB)-approved protocol.
Description of Drug Product:	FT576 drug product comprises expanded allogeneic natural killer cells, derived from a clonal, CD38 knockout, human-induced pluripotent stem cell line, that expresses anti-B-cell maturation antigen (BCMA) chimeric antigen receptor (CAR), high-affinity, non-cleavable CD16 receptor (hnCD16), and interleukin (IL)-15/IL-15 receptor fusion protein (IL-15RF). FT576 cells are suspended in infusion medium consisting of Plasma-Lyte A (pH 7.4) with albumin (human) and dimethyl sulfoxide. The drug product is not manufactured with antibiotics. The formulated drug product is aseptically filled into pre-sterilized, single-use cryopreservation bags with approximately: • 5×10^7 viable cells (VCs) in 18 mL/bag (2.8×10^6 VC/mL) • 3×10^8 VC in 18 mL/bag (1.7×10^7 VC/mL) • 5×10^8 VC in 18 mL/bag (2.8×10^7 VC/mL). Dosing is based on CAR expression, where $\geq 80\% \pm 10\%$ of administered FT576 cells express BCMA-CAR. For details on dose and schedule for a specific study, refer to the applicable IRB-approved protocol.
Storage:	FT576 must be stored in the vapor phase of liquid nitrogen (VPLN) at ≤-150°C, in a temperature-monitored and alarmed VPLN freezer in a controlled-access room with limited personnel access.

	Temperature excursions up to -135°C for 10 minutes due to normal equipment use (e.g., opening and closing of the storage unit) are allowed. If the temperature warms to >-150°C up to -135°C for >10 minutes or >-135°C for any amount of time, Fate Therapeutics (FATE) must be notified (see Section 12.2 for further details). VPLN temperature logs and calibration records must be available to Site Monitors for inspection.
Product Labeling:	FT576 labeling will include product name, volume, manufacturer, date of manufacture, Product Lot #, Bag ID #, and number of viable cells. The label will also contain the following statement: "Caution: New Drug – Limited by United States Law to Investigational Use." See Appendix 1 for an example of FT576 labeling.
Product Appearance:	Upon thaw, FT576 should be a colorless to yellow suspension of cells.
Route of Administration:	FT576 is thawed and administered as an intravenous (IV) infusion via gravity. The following are acceptable forms of IV access in order of preference: 1. Central venous catheter (CVC; e.g., Hickman) – **Do not use implanted ports.** 2. Non-valved peripherally inserted central catheter (PICC) 3. Large-bore (18-gauge) straight IV needle – Use of this form of IV administration should be considered as a last resort if IV administration by CVC or non-valved PICC is not possible. FT576 must be administered using an IV administration set with an in-line filter. The B. Braun SafeLine® Y-Type Blood Set (REF NF5140), Baxter CLEARLINK System (2C8750), or FATE-approved equivalent, must be used for FT576 administration (see Section 10 for additional details).

3. SUPPLIES

3.1. Items Supplied by FATE

- FT576 drug product

3.2. Items Supplied by the Clinical Study Site

- Warming device
  - A water bath and/or use of alternate equipment (e.g., Plasmatherm) or procedures approved by FATE are acceptable.
  - Cart for warming device storage and transport is optional.
- Pre-filled sterile IV bag of 0.9% sodium chloride for injection (USP)
- If applicable, VPLN freezer and frames for storing FT576 (frames may be supplied by FATE upon site request)
- Validated puncture-proof VPLN transport container that maintains temperature at ≤-150°C
- Cryogenic personal protective equipment such as gloves, apron, lab coat, face shield, and eye protection
- Sterile overwrap bag for thawing cells
- Alcohol wipes and non-sterile gloves
- B. Braun SafeLine® Y-Type Blood Set (REF NF5140), Baxter CLEARLINK System (2C8750), or FATE-approved equivalent

4. FT576 PRECAUTIONS

- Do not irradiate FT576.
- Each FT576 bag is single use only.
- Do not administer FT576 using an IV pump.
- Do not use FT576 after expiration date (if applicable).
- Administration of FT576 must comply with the protocol.
- Administration of FT576 should be initiated as soon as practical after thawing, preferably within 20 minutes. Do not initiate infusion of drug product that has been thawed for more than 60 minutes. Infusion of all thawed product (including subsequent saline rinse of empty bag) must be completed within 90 minutes from when the bag was first thawed. Please note that infusion of one bag typically takes approximately 15-20 minutes.

- Contact both FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1), and, if applicable, the Contract Research Organization (CRO) Site Monitor immediately if:
  - upon visual inspection of thawed FT576, the bag is found to have visible defects, leaks, or is compromised in any manner;
  - upon visual inspection of thawed FT576, product does not match "Product Appearance" as described in Section 2;
  - upon visual inspection of thawed FT576, visible foreign particulate matter (i.e., non-cellular material) is observed; or
  - FT576 is thawed but not administered.

Refer to the applicable IRB-approved protocol for study conduct information. Refer to the FT576 Investigator's Brochure for product profile, including safety information.

5. DRUG SHIPMENT, SUPPLY, AND RESUPPLY

5.1. Shipment of FT576

- FT576 drug product is only for use in clinical trial(s) sponsored or endorsed by FATE and will be shipped to clinical study sites by a FATE-approved storage and distribution vendor(s).
- Prior to FT576 shipment, clinical sites will receive an e-mail notification containing courier tracking information from Cryoport or other approved cold chain logistics vendor(s).
- FT576 bags are cryopreserved within cassettes for storage in VPLN at clinical study sites. See Appendix 1 for a sample image of the cassette.
- FT576 shipments will arrive at clinical study sites in a VPLN shipper.
- Any issues related to shipping or resupply should be directed to the FATE Clinical Trial Manager (see Section 1) and the Site Monitor.

5.2. Supply of FT576

- FT576 may be provided in a single shipper or in multiple shipments, depending on expected enrollment projections and clinical site storage capabilities.
- If applicable to the study, the FATE Clinical Trial Manager, or designee, will complete the Notification of Subject Enrollment form before the beginning of each treatment cycle and provide to FATE Clinical Drug Supply and the study site.
- If an Interactive Response Technology (IRT) system is used in the study, bags will be assigned through the IRT at the time of subject enrollment. Otherwise, the FATE Clinical Trial Manager or designee will provide the Notification of Subject Enrollment form to the clinical site with the assigned dose for each subject, and the clinical site will assign

the Bag ID for the subject. Please refer to the IRT Site User Manual or contact the FATE Clinical Trial Manager with any questions.

5.3. Resupply of FT576

- The supply of FT576 will be closely monitored by FATE Clinical Drug Supply, and sufficient bags for the upcoming subject dosing will be shipped to the site prior to the scheduled visit. Supply may be replenished sooner if site storage capacity allows.
- Sites are not required to take any action for resupply; however, contact the Site Monitor with resupply questions.
- Contact the FATE Clinical Trial Manager (see Section 1) or designee and the Site Monitor should you require an expedited shipment or if there are problems or questions regarding the shipment.

6. RECEIPT AND STORAGE OF FT576

Details regarding receipt and storage of FT576 are provided below. For information on managing potential drug product quality complaints upon receipt and during storage, please refer to Section 12.

6.1. Receipt

- Upon receipt of the VPLN shipper, verify that the shipper is for the intended site/recipient by checking the courier waybill on the outside of the shipper.
- Open the outer lid and retrieve the packing slip and incoming shipment notification email from FATE to complete paperwork verification.
  - If using the LN_2 dewar as Temporary Onsite Dewar Storage (TODS) unit, do NOT proceed with visual inspection until day of conditioning.
  - Complete the appropriate shipment receipt confirmation form and return a copy to FATE Clinical Drug Supply.
  - If using onsite VPLN storage unit, proceed with visual inspection steps below.
- Check the contents of the shipper against the packing slip. The shipping documentation should remain on file with other IMP documentation at the clinical study site.
- Carefully open cassettes and confirm the product label against the packing slip. Visually inspect each FT576 bag to ensure it is not compromised in any manner and that there are no visible defects or leaks. Use care to conduct this inspection under temperature control to avoid temperature excursions.
- Confirm that the contents arrived frozen.

- Once the temperature monitoring data has been received and reviewed for any temperature excursion, this documentation must be filed in the study investigator files (e.g., Pharmacy Manual, Investigator Site File, or per institutional policy).
- Document the Product Lot #, Bag ID #, Date Product Received, and the Product Received By (name) on the Investigational Medicinal Product Accountability Log (see Appendix 2). See Appendix 1 for samples of FT576 labeling.
- Register shipment receipt in the IRT system, if applicable. Please refer to the IRT Site User Manual or contact the FATE Clinical Trial Manager with any questions.

6.2. Storage

- FT576 is stored in VPLN at ≤-150ºC.

Sites with VPLN Storage Unit

- To avoid temperature excursions, quickly transfer FT576 from its shipping container to the VPLN storage unit; this should take no more than 1-3 minutes.
- Complete the appropriate shipment receipt confirmation form and return a copy to FATE Clinical Drug Supply.

Sites Using LN_2 Dewar as TODS Unit

- Keep the FT576 in the dewar until the day of conditioning.
- Conduct a visual inspection and reseal the dewar lid with the new blue tamper seal (included with paperwork).
- Record the time the dewar lid was opened and the serial number on the new tamper seal on the shipment receipt confirmation form.
- Transport the dewar to a secure location until ready for subject administration.
- Complete the appropriate shipment receipt confirmation form and return a copy to FATE Clinical Drug Supply.

7. TRANSPORT OF FT576 TO CLINICAL UNIT

Transport FT576 to the clinical unit (e.g., bedside for subject administration) in a validated, puncture-proof, temperature-controlled transport container. Follow institutional guidelines and/or site Standard Operating Procedures (SOPs) for chain of custody and temperature-monitoring processes reviewed/approved by FATE.

8. DIRECTIONS FOR PREPARATION

General Information

- All dose preparation is to be performed by qualified and trained personnel using aseptic technique per institutional guidelines and/or site SOPs.

- When multiple FT576 bags will be administered, sequentially thaw and administer bags.
- A water bath or FATE-approved thawing device (e.g., Plasmatherm) must be used for thawing FT576 drug product. Please refer to the manufacturer's instructions for using the device.
- Devices must be cleaned and disinfected following manufacturer's and/or institutional SOPs prior to thawing and after administering product to each subject.

Instructions During Thaw

In addition to following the manufacturer's instructions for the applicable thawing device used, the following instructions must also be followed:

1. For sites using a water bath, place product bag in an overwrap, remove as much air as possible, and seal bag.
   - Water bath should be pre-warmed to 37°C.
   - Gently massage the bag continuously while thawing.
2. For sites using a Plasmatherm, place product bag in an overwrap, remove as much air as possible, and seal bag.
   - Plasmatherm should be pre-warmed to 37°C.
   - Use the *Plasma* program to thaw cells.
3. After 3-5 minutes of thawing, inspect the product to confirm that there is no visible ice in the infusion bag and the infusion bag is cool to the touch.
   - If the product cells are still slightly frozen, place the cells back in the thawing device and continue to thaw for an additional 1-2 minutes until there is no visible ice in the infusion bag and the infusion bag is cool to the touch.
4. Remove the bag from the thawing device.
5. Visually inspect the contents of the FT576 bag for presence or absence of visible cellular clumps or visible foreign particles. Document the results of visual inspection on the FATE Investigational Medicinal Product Administration Record (Appendix 3).
   - If any visible cellular clumps are noted after product thaw, gently massage the product to dissipate. Small clumps of cellular material should disperse with gentle massaging. Do not infuse FT576 if clumps are not dispersed.
   - Inspect the thawed product for visible foreign particulate matter (i.e., non-cellular material). **If visible foreign particulate matter is seen**, do not use that FT576 bag for infusion. Immediately quarantine the FT576 bag(s) in the IRT, if applicable, and contact both FATE Quality Assurance and the FATE Clinical Trial Manager with your Site Monitor (see Section 1).

6. If leakage is noted during the thaw process, do not use that FT576 bag for infusion. Immediately quarantine the FT576 bag and contact both FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1).
7. Quarantined FT576 bag(s) should be stored separately from acceptable FT576 bag(s) and should clearly be designated as "Quarantined, Not for Use" until a decision on use is provided by FATE. FATE will notify the site about the disposition of the affected FT576 bag(s) and in collaboration with the site, will ensure that the bags are either marked as available or damaged in the IRT, if applicable.
8. If no issues are identified, proceed with administering FT576 (Section 10).
9. Document the thaw start and end time and visual inspection of each FT576 bag on the FATE Investigational Medicinal Product Administration Record or FATE-approved, site-specific equivalent (Appendix 3).

9. STABILITY OF THAWED FT576

Administration of FT576 should be initiated as soon as practical after thawing, preferably within 20 minutes. Do not initiate infusion of drug product that has been thawed for more than 60 minutes. Infusion of all thawed product (including subsequent saline rinse of empty bag) must be completed within 90 minutes from when the bag was first thawed. Please note that infusion of one bag typically takes approximately 15-20 minutes.

Contact both FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1), and, if applicable, the CRO Site Monitor, if administration of all thawed product (including subsequent saline rinse of empty bag) cannot be completed within 90 minutes from thaw.

10. ADMINISTRATION OF FT576

10.1. IV Access

The following are acceptable forms of IV access in order of preference:

1. CVC (e.g., Hickman)
   - **Do not use implanted ports.**
2. Non-valved PICC
3. Large-bore (18-gauge) straight IV needle
   - Use of this form of IV administration should be considered a last resort if IV administration by CVC or non-valved PICC is not possible.

10.2. Administration

Administer pre- and post-study medications relative to FT576 administration in accordance with the applicable IRB-approved protocol.

- FT576 should be administered under the supervision of a qualified healthcare professional.
- FT576 must be administered using an IV administration set with an in-line filter.
  - The B. Braun SafeLine® Y-Type Blood Set (REF NF5140) or Baxter CLEARLINK System (2C8750) should be used for FT576 administration. The Blood Set should be primed with sterile normal saline (0.9% sodium chloride in water) prior to spiking the bag containing FT576.
  - An equivalent in-line filter of comparable composition and filter pore size may be used with prior written authorization from FATE.

NOTE: Do not administer FT576 in the same IV tubing concurrently with products or solutions other than 0.9% sodium chloride for injection (USP). Do not use an IV pump during FT576 administration.

Depending on the type of Y-type blood set used, follow the directions for priming and set up per the applicable package instructions.

Instructions for FT576 administration (after priming and set up have been performed) are as follows:

1. Close all roller clamps on the infusion set.
2. Fully spike saline source container and prime the infusion set following the applicable package instructions.
3. Connect set to recipient.
4. Fully spike an inverted FT576 bag with the unused Y-lead. Do not spike FT576 bag while it is hanging.
5. Slowly open the roller clamp below FT576 bag and adjust for desired flow rate.
6. When FT576 bag is empty, close all clamps.
7. To rinse the empty FT576 bag, open clamp below saline solution container. Open clamp below FT576 bag.
8. Allow approximately 50 mL of 0.9% sodium chloride to flow into FT576 bag. Close all clamps and invert FT576 bag 2-3 times to ensure thorough rinsing.
9. Open the roller clamp that is nearest to the subject and then slowly open the roller clamp below FT576 bag and adjust for desired flow rate.
10. When FT576 product container is empty, close the clamp below the FT576 bag.

11. If additional FT576 bags are to be infused, slowly open the clamp below the 0.9% sodium chloride and allow the saline solution to continue to flush the remaining cells in the tubing while the next FT576 bag is being thawed.
12. Once the new FT576 bag is thawed, remove the empty FT576 bag and spike the new FT576 bag. Repeat Steps 1-11 for each additional bag.
13. Once the last bag of FT576 is rinsed and administered, close the clamp below the FT576 bag. Open the clamp below the 0.9% sodium chloride and allow the saline to flush the remaining cells in the tubing until the fluid in the tubing is clear confirming all cells have been infused.

Issuance, thawing, and administration of bags should be documented on the FATE Investigational Medicinal Product Administration Record (Appendix 3) or FATE-approved, site-specific equivalent and available for review by the Site Monitor.

The end of administration time should be recorded after the rinse step has been completed.

When the study drug administration has been completed, discard the empty study drug bag/tubing in accordance with local site policy.

11. DRUG PRODUCT ACCOUNTABILITY AND DISPOSITION

Study sites will also document drug product accountability and disposition in the IRT system, if applicable. Please refer to the IRT Site User Manual or contact the FATE Clinical Trial Manager or Site Monitor with any questions.

The study site cell processing facility or pharmacy, as a delegate of the PI, must maintain accurate records by documenting the following information for each FT576 bag on the FATE Investigational Medicinal Product Accountability Log or FATE-approved, site-specific equivalent (Appendix 2):

- **Product Lot #**, **Bag ID #**, **Date Product Received**, and **Product Received By** (name)
- Confirmation of **Visual Inspection Passed**
- **Date Product Issued to Subject** (if not issued, accounting for FT576 not otherwise administered to subjects, e.g., bag leakage, compromised bag integrity, accidentally or deliberately destroyed product); **Study-Assigned Subject ID #**; and **Product Issued By** (name)
- **Site Monitor Verification**

All FT576 bags must be accounted for. A written explanation is required for any discrepancies on the FATE Investigational Medicinal Product Accountability Log (Appendix 2) or FATE-approved, site-specific equivalent. Documentation must be made available for review upon request from the Sponsor.

If any unused study drug supplies are to be destroyed at the site, the institution/PI must obtain prior written approval from FATE. FATE must approve the site's drug destruction policy in advance of any study drug's destruction. After such destruction, the institution/PI must notify FATE, in writing (preferably on company letterhead), what was destroyed (including lot numbers), the method of destruction, the date of destruction, and the location of destruction (e.g., site destruction certificate).

11.1. Drug Product Waste Disposal

Solid waste: When drug product administration has been completed, discard the empty drug product bag/tubing in accordance with institutional guidelines and/or SOPs.

Sharps: Use sharps container for disposal of sharps. Waste should be collected and disposed of in accordance with institutional guidelines and/or SOPs.

Liquid waste: Liquids containing FT576 can be inactivated using chlorine bleach (20%-25%) diluted to 1/10 (2% final concentration) for an exposure time of 10 minutes then disposed of in the sink in accordance with institutional guidelines and/or SOPs.

12. DRUG PRODUCT COMPLAINTS

12.1. Overview

All clinical drug product complaints must be reported immediately to both FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1 for contact information). Any FT576 bags that are the subject of a complaint must be placed in quarantined storage until instructed otherwise by FATE. Examples of product complaints include, but are not limited to:

- Product shipments that experience temperature excursions (see Section 12.2 below)
- Damaged shipping container
- Illegible product label
- Visibly compromised drug product container closure
- Visible particulate matter in the drug product
- Receipt of wrong drug product for a given study

If applicable, you will be sent form QA-016-F01 (Complaint Report; see Appendix 4) to document the complaint and to return to FATE Quality Assurance for review.

12.2. Temperature Excursions

FT576 is shipped in an LN_2 dewar at ≤-150°C with a temperature monitor that can be accessed via the system link (e.g., Cryoport Live View). Confirm the temperature during transport before opening the dewar. Notify all FATE contacts listed in Section 1 when:

- The shipping temperature monitoring data indicates that the temperature warmed to >-150°C up to -135°C for >10 minutes or >-135°C at any point during shipment.

Sites with VPLN Storage Unit

FT576 must be stored in VPLN at ≤-150ºC in a temperature-monitored and alarmed VPLN freezer in a controlled-access room with limited personnel access.

VPLN temperature logs and calibration records must be available to Site Monitors for inspection and collection for the study master files (e.g., electronic trial master file [eTMF]). FATE Quality Assurance, the FATE Clinical Trial Manager, and the Site Monitor should be notified when:

- The storage temperature at the clinical site warms to >-150°C up to -135°C for >10 minutes or >-135°C for any amount of time; or
- A thawed bag is not administered for any reason (e.g., if FT576 administration is not initiated within 60 minutes following completion of thaw, does not pass visual inspection, etc.).

Sites Using LN_2 Dewar as TODS Unit

FT576 must remain in the LN_2 dewar at ≤-150°C in a controlled-access room with limited personnel access until ready for the subject administration.

Note: FATE will conduct daily monitoring on the internal temperature of the LN_2 dewar. If the temperature is trending up or an excursion occurred since the last check, FATE will contact the site immediately to address the issue.

Prior to removing FT576 from the dewar, use the appropriate temperature-monitoring link (e.g., Cryoport Live View) to confirm the temperature was ≤-150°C since the day the shipment was received and inspected. File a copy of the temperature chart in the study investigator files. If there was a temperature excursion above -150°C, do not open the dewar and notify all FATE contacts listed in Section 1.

The following steps must occur for every temperature excursion:

1. As soon as the temperature excursion is discovered, send an email notification including temperature recordings (as applicable) to FATE Quality Assurance and the FATE Clinical Trial Manager at the email addresses indicated in Section 1. Also include the Site Monitor at the applicable email address. You will be sent form QA-016-F01 (Complaint Report; see Appendix 4) to document the temperature excursion and then return the completed form to FATE Quality Assurance.
2. FATE will review the available documentation and will notify the site in writing if the product is cleared for use or should be returned/destroyed (see Section 8 for quarantine details).

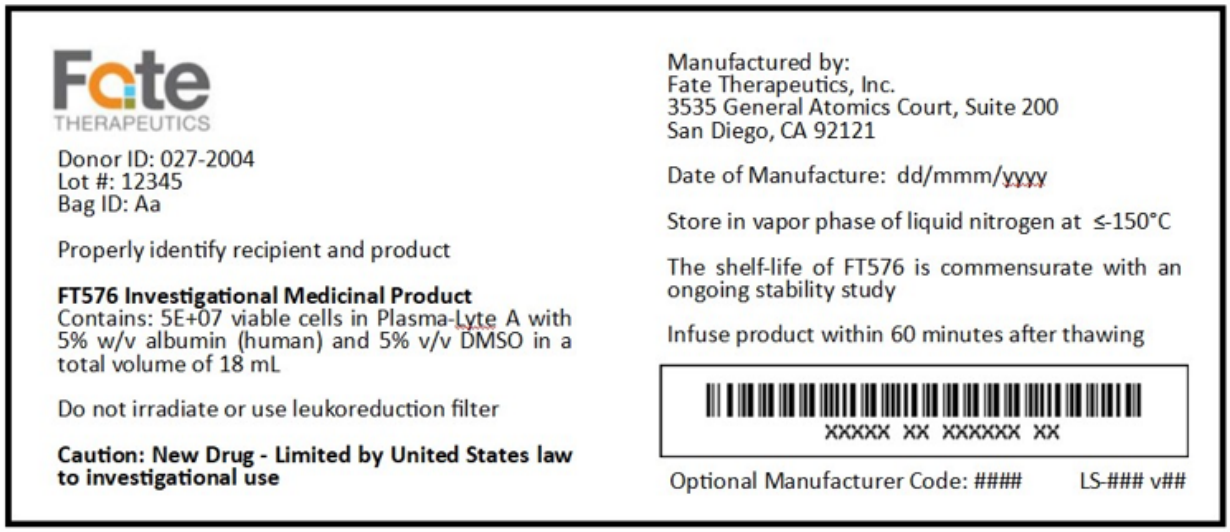
13. REVISION HISTORY

Version	Change Summary
2.0	The Pharmacy Manual has been updated to include instructions for Temporary Onsite Dewar Storage (TODS), to allow for variability with study sites that may or may not be using an Interactive Response Technology (IRT) and/or Contract Research Organization (CRO). Contact information for Clinical Drug Supply, formerly called Clinical Manufacturing, has also been added.
1.0	Original document

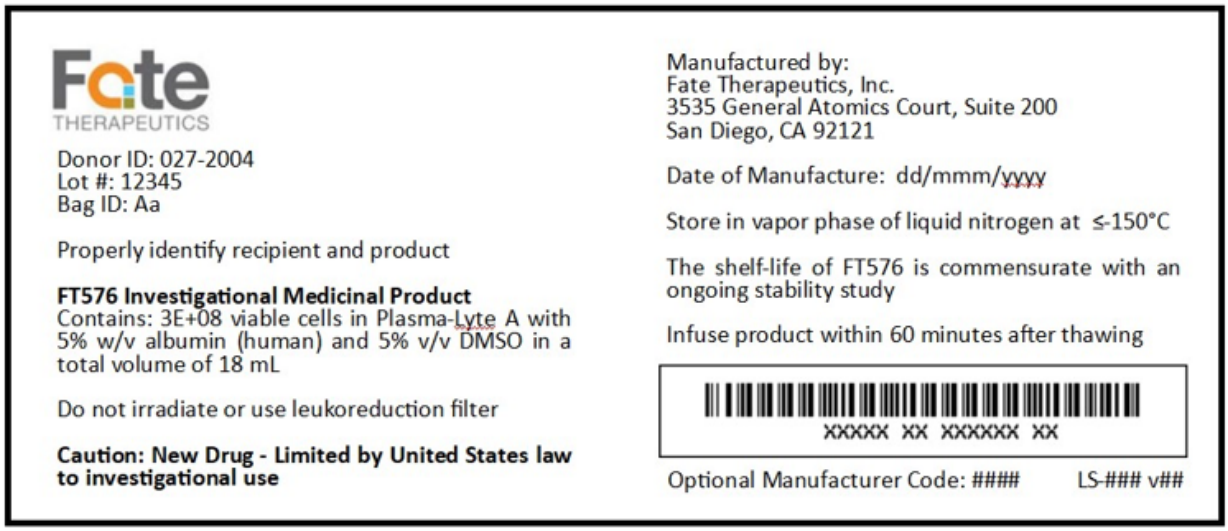
Appendix 1 Sample Images of FT576 Labeling and Cassette

Sample Labels for FT576

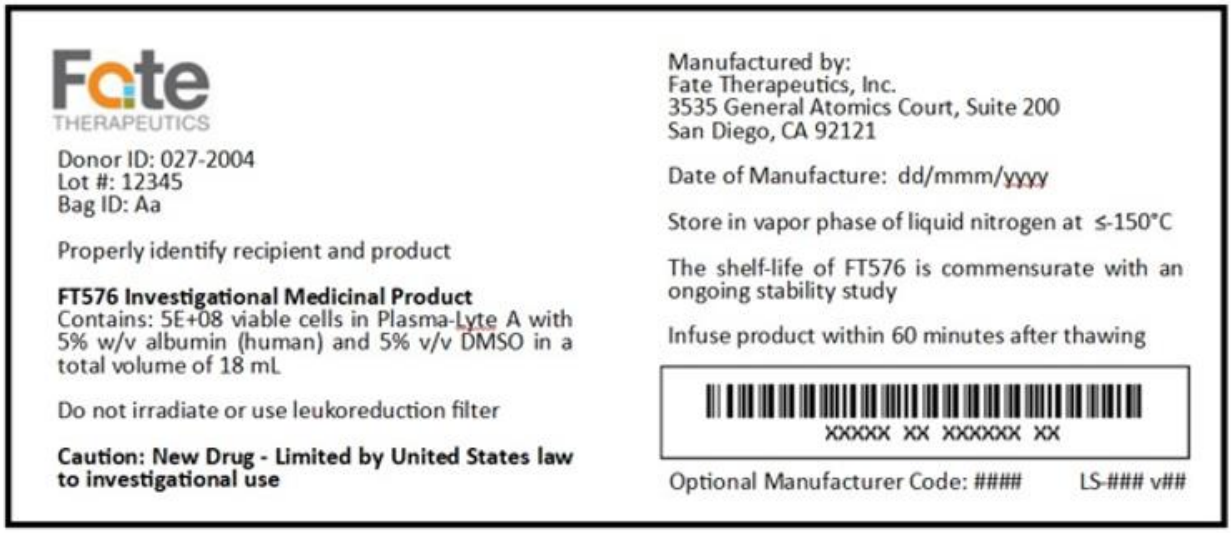
(A) Representative Label: 5E+07 viable cells in 18 mL



(B) Representative Label: 3E+08 viable cells in 18 mL



(C) Representative Label: 5E+08 viable cells in 18 mL



(D) Sample Cassette

Note: The cassette will also have the appropriate label affixed to it; refer to Appendix 1(A), 1(B), and 1(C) for representative labels.

Appendix 2 FATE Investigational Medicinal Product Accountability Log

FATE INVESTIGATIONAL MEDICINAL PRODUCT ACCOUNTABILITY LOG

Product: _____ **Protocol No.:** _____ **Principal Investigator:** _____

Site Name: _____ **Site No.:** _____

Product Lot #	Bag ID #	Date Product Received	Visual Inspection Passed (Yes/No) [a]	Product Received By	Product Issued (Yes/No) [b]	Date Product Issued to Subject	Study-Assigned Subject ID #	Product Issued By	Site Monitor Verification (initial and date)

[a] If the bag integrity is compromised, contact FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1 of the applicable Pharmacy Manual).
[b] If product has not been issued to subject, a written explanation is required (record below).

Product Lot #:	Bag ID #:	Reason Product Not Issued:
Product Lot #:	Bag ID #:	Reason Product Not Issued:
Product Lot #:	Bag ID #:	Reason Product Not Issued:

[Retain Sponsor template version number and date on site-specific version] Sponsor Template Version 5.0 (19 May 2021)

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Appendix 3 FATE Investigational Medicinal Product Administration Record

FATE INVESTIGATIONAL MEDICINAL PRODUCT ADMINISTRATION RECORD

Subject Information:

Subject ID	**Date of Infusion** (dd/mmm/yyyy)

Product Information:

FATE IMP ("Product")	**Protocol No.**

BAG _____ of _____

ISSUED PRODUCT:

Assigned dosage: _____ No. of bags required to meet dose: _____

Confirm number of bag(s) × dosage of bag(s) issued equals the total assigned dosage.

Product Lot #	Bag ID #	Bag Volume (mL)	Dose (viable cells per bag)

Issued by *(signature)*: _____ Date: _____

Verified by *(signature)*: _____ Date: _____

PRODUCT THAW:

Confirm subject and product identity prior to thawing of product.

Time into 37°C Thawing Device (24-hr. clock)	Time out of 37°C Thawing Device (24-hr. clock)	Visual Inspection Passed (Yes/No) *	Performed By (Initials/Date)

* If thawed and not administered or otherwise compromised, record observations in notes/comments section below. Contact FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1 of the applicable Pharmacy Manual).

Thaw Notes/Comments:

_____

_____

Performed by *(signature)*: _____ Date: _____

Verified by *(signature)*: _____ Date: _____

*[Retain Sponsor template version number and date on site-specific version]*Sponsor Template Version 6.0 (10 October 2022)
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FATE INVESTIGATIONAL MEDICINAL PRODUCT ADMINISTRATION RECORD

Subject Information:

Subject ID	**Date of Infusion** (dd/mmm/yyyy)

Product Information:

FATE IMP ("Product")	**Protocol No.**

BAG _____ of _____

PRODUCT ADMINISTRATION:

Start Time of Administration (24-hr. clock)	Stop Time of Administration (24-hr. clock) [a]	Infusion Interrupted (Yes/No) [b]	Full Bag Infused (Yes/No) [c]	Administration and Rinse Performed By (Initials/Date)

[a] The end of administration time (Stop Time) should be recorded after the rinse step has been completed.
[b] If Yes, record reason infusion was interrupted in notes/comments section below.
[c] If No, record volume infused, total nucleated cells (TNC) administered, volume discarded, and reason in notes/comments section below.

Administration Notes/Comments:

_____

_____

Performed by *(signature)*: _____ Date: _____

Verified by *(signature)*: _____ Date: _____

BAG LABEL RECORDING:

- For the infused bag, affix label below.
- For bag not infused, quarantine per institutional guidelines and contact FATE Quality Assurance and the FATE Clinical Trial Manager (see Section 1 of the applicable Pharmacy Manual).

Affix Bag Label for
Administered Product Here

Appendix 4 Complaint Report (QA-016-F01)

Fate THERAPEUTICS	Complaint Report	QA-016-F01

COMPLAINT NUMBER (ASSIGNED BY QA):

SECTION 1:

Complaint Received From (name, address, email, & phone #):

Complaint Received By/Date/Time:

How was complaint received?

Product and Lot #:

Patient ID # (N/A ☐):

Clinical Trial (IND, CTA) and Protocol #:

Detailed summary of the nature of the complaint, including the complaint's potential impact:

Suggested Actions/Follow Up:

Fate THERAPEUTICS	Complaint Report	QA-016-F01

SECTION 2 - TO BE COMPLETED BY QA:

Is a MRB necessary? ☐ NO ☐ YES (attach additional documentation)

Is notification of a regulatory authority necessary? (provide justification) ☐ NO ☐ YES

Name: Date:

If yes: Agency to be notified:

Agency contact:

Justification:

Is a recall necessary? ☐ NO ☐ YES, explain:

Initiate Deviation report? (if yes, record DR Number) ☐ NO ☐ YES, explain:

Was the complaint adequately resolved? ☐ YES ☐ NO, explain:

Approval of Complaint Report	Signature	Date
Author of Section 1		
Quality Assurance		

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Appendix 5 Abbreviations

Abbreviation	Term
BCMA	B-cell maturation antigen
C	Centigrade
CAR	Chimeric antigen receptor
CRO	Contract Research Organization
CVC	Central venous catheter
eTMF	Electronic trial master file
hnCD16	High-affinity, non-cleavable CD16 receptor
IL	Interleukin
IL-15RF	IL-15/IL-15 receptor fusion protein
IMP	Investigational medicinal product
IND	Investigational New Drug
IRB	Institutional Review Board
IRT	Interactive Response Technology
IV	Intravenous
mL	Milliliter
PI	Principal Investigator
PICC	Peripherally inserted central catheter
SOP	Standard Operating Procedure
TODS	Temporary Onsite Dewar Storage
USP	United States Pharmacopeia
VC	Viable cell(s)
VPLN	Vapor phase of liquid nitrogen