Owning Location:	Virtual Org - CAR-T
Document Type: Subtype	Technical Document:Investigational Product Preparation Procedure
Title:	Investigational Product Preparation and Administration Instructions for JNJ 68284528, a CAR-T Therapy Directed Against BCMA in Subjects with Multiple Myeloma

Investigational Product Preparation and Administration Instructions for JNJ-68284528 (Ciltacabtagene Autoleucel), a Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA in Subjects with Multiple Myeloma

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1. INTRODUCTION

This Investigational Product Preparation Instruction (IPPI) provides instructions for preparation and administration of JNJ-68284528 (ciltacabtagene autoleucel or "cilta-cel"), hereafter referred to as the investigational product (IP). The IPPI must be carefully reviewed and followed when preparing and administering the IP.

Deviations from the instructions, whether intentional or accidental, must be documented and reported to the Site Manager.

Staff Training and Delegation of Responsibilities

- Only qualified individuals identified in the Site Signature Log and Delegation Log are permitted to perform any activities described in this document.
- Any individual involved in the preparation and administration of the study drug must have appropriate training by the Sponsor/Sponsor Representative, documented proficiency of these activities by the site and must follow their local guidelines to perform his/her activities. If adherence to local guidelines requires deviation from the IPPI instructions, immediately report to the Site Manager.
- **Note:** This IPPI is formatted to include documentation of "Performed by" and "Checked by" for critical Preparation and Administration steps. All preparers must document "Performed by" as required in the IPPI. Sites that utilize a staff member to verify or check that the steps were performed should document "Checked by" per their site and local guidelines. Sites that do not utilize a second person verification per site and local guidelines must place "N/A" in the "Checked by" line.
- Sites may translate the worksheets provided in the attachments into their native language but must document all entries as specified on the provided Worksheets and follow the preparation and administration steps in the exact order.
- Sites may use site-prepared worksheets as an alternative but must complete all steps in the specified order and document all entries on the site generated worksheets as shown on the provided Sponsor worksheets. Site prepared worksheets should be reviewed by the SM prior to use.
- Sites that utilize Electronic Data Capture systems may add the preparation and/or administration directions and documentation directly in the system in lieu of paper copies of **Attachments 1 & 2**.

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2. DEFINITIONS AND ACRONYMS

DIN	Donation Identification Number
Dispensing	Delivering the IP to the subject/participant's bedside
Flush	Using 0.9% Sodium Chloride to clear the remaining drug product from the IP bag, administration set and through the IV access into the subject/participant, after the IP infusion is completed or the infusion bag is empty
IP	Investigational Product (JNJ-68284528; ciltacabtagene autoleucel or "cilta-cel")
IPPI	Investigational Product Preparation and Administration Instructions
Priming	Initial filling of or removal of air from the infusion set
Priming Volume	Volume of 0.9% Sodium Chloride solution flowing through the attached infusion set in order to fully displace the air in the infusion set
SEC-DIS	Single European Code Donation Identification Sequence
SM	Site Manager

3. PREPARATION OF THE INVESTIGATIONAL PRODUCT

3.1. IMPORTANT INFORMATION ABOUT JNJ-68284528

- The IP is considered a genetically modified autologous T-cell immunotherapy product and should be handled according to current safety guidance and local site procedures for cell therapy products.
- Do not deviate from the instructions in the IPPI.
- Do not pre-filter IP into a different container or wash/re-suspend in alternative media without consulting the sponsor.
- Do not use a leukocyte depleting in-line filter.
- The IP must be stored at temperatures ≤ -120°C, vapor phase of liquid nitrogen and protected from light prior to thawing and administration.
- Avoid exposure of IP to direct sun light.
- Do not shake the thawed IP. Do not **re-freeze** or **refrigerate** the thawed IP.

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- Each IP expires **150 minutes** after it has been thawed. IP administration (including the flush) must be completed within **150 minutes** after thawing. IP administration is to be performed at room/ambient temperature and light conditions.
- The IP must be used with **only 0.9% Sodium Chloride, USP/EP/JP** for Injection. **Do not use any other intravenous solution.**
- The IP should not be dispensed or administered if there is a concern about the quality of the IP. Refer to the Cellular Therapy Product Procedure Manual (CTPPM) for specific details for product quality concerns.

3.2. MATERIALS AND EQUIPMENT

Description of materials required for preparation of one IP is noted in **Table 1** below. If multiple IP bags are to be administered, the materials marked with an asterisk (*) under "Quantity for Unit Operation" require an additional unit for each IP bag.

The site should maintain an inventory log of Sponsor provided ancillary supplies for each JNJ-68284528 clinical trial, listing catalog numbers, lot numbers and expiry dates. If the site has a process that documents the materials that they have in their ancillary inventory, then the site may defer to their procedures.

The ancillary supplies as noted in **Table 1** are provided by the Sponsor or sourced locally by the site/pharmacy. Contact your SM at least 30 days in advance if additional Sponsor-provided supplies are needed based on stock or expiry date. Sites that are not able to provide the specified supplies can request the required supplies via the Site Manager.

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Table 1: Materials Specified for Preparation and Administration of JNJ-68284528

Category	Description	Quantity for Unit Operation	Provided by
IP	JNJ-68284528, 70 mL or 30 mL prefilled infusion bag(s) containing subject/participant specific dose	1*	Sponsor
IV Solution	0.9% Sodium Chloride Injection, USP/EP/JP, appropriately sized infusion bag (for priming and flushing)	1-2*	Site
Solution	Use appropriate solution as specified by site or equipment manufacturer for water bath thawing. It is recommended to use Sterile Water for Irrigation or Sterile 0.9% Sodium Chloride Solution, USP/EP/JP.	2-3 L (adjust as necessary for water bath capacity	Site
Equipment	Water Bath (approximately 5 L capacity) or dry thawing device capable of maintaining constant temperature of 37°C ± 2°C or equivalent (as agreed upon by Sponsor)	1	Site
Equipment	Portable Vapor phase nitrogen transport container, previously "charged" to ensure it is and will maintain ≤ -120^{0}C temperature	1	Site
Ancillary	A sealable plastic bag with a tight closure system (For thawing of IP Bag) It is recommended that a sterile bag be used	1*	Site
Ancillary	IV Administration set	1*	Site
Ancillary	A 170 µm or larger non-leukocyte binding in-line or add-on filter	Optional*	Site
Ancillary	Extension set, or site-determined equivalent, with needle-free connector to be used with peripheral IV catheter	1	Site
Ancillary	Central or Peripheral IV Catheter	1	Site
Equipment	Programmable IV pump	Optional	Site

***** For administration of multiple IP bags, additional units are needed per IP bag.

3.2.1. CLOSED SYSTEM TRANSFER DEVICES

Commercially available closed system transfer device must **NOT** be used in the administration of the IP.

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3.3. PREPARING DISPENSING LABELS

Each IP bag will be pre-labeled by the manufacturer in accordance with the manufacturing site procedures and local regulatory requirements. If multiple bags are to be administered, the label on the first IP bag may read "Container: A1 (or B1) of X" in which X is the total number of IP bags to be administered for each Subject. Subsequent IP bags would be labeled as "Container: A2 (or B2) of X" for a second bag or "Container: A3 (or B3) of X" for a third bag.

The site will be responsible for creating the expiry labels for each thawed IP bag that will be administered.

The site/sponsor generated expiry label for the thawed IP will include the following minimum information for the IP Infusion Bag post thaw.

1. Maintain thawed IP at room/ambient temperature and light conditions. Avoid direct sunlight exposure.
2. Route: Intravenous
3. Expiry*:
    a. Preferred format: DD / MMM / YYYY hh:mm

* Expiration time is 150 minutes after the IP infusion bag has been thawed.

3.4. CALCULATION OF APPROPRATE DOSE/DOSE TABLE

No dose calculations are required by clinical site personnel. The IP dose is subject specific. Refer to clinical protocol for details on dose calculations.

3.5. PREPARATION STEPS

- IP preparation must occur at the time of scheduled administration due to the 150-minute expiry of the post thawed IP.
- IP preparation must be performed by appropriately trained staff.
- It is recommended that IP preparation be performed at the subject/participant's bedside or in close proximity to the subject/participant due to the 150-minute expiry of thawed IP.
- If multiple IP bags are to be administered, prepare for only one IP administration at a time. Do not start the second IP preparation until receiving confirmation that the

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first IP administration is complete (including the flush). For each additional IP administration, use ancillary materials as denoted in **Table 1** by an asterisk (*).

- IP preparation and administration must be performed using aseptic techniques.

The preparation procedures should be provided as stand-alone pages in the document directly to the preparer for completion.

- The IP Preparation Instructions are provided in **Attachment 1**, for IP which is supplied as a 70 mL or 30 mL infusion bag(s). If multiple IP bags are to be administered, additional IP Preparation worksheets (**Attachment 1**) (or site-prepared worksheets) must be completed.

4. DISPENSING TO STUDY DOSE ADMINISTRATOR

The following components are transported from the laboratory or site-specific storage location to the subject/participant's bedside or within close proximity to the subject/participant for administration of IP:

1. One or more 70-mL or 30-mL infusion bags containing cryofrozen IP labeled as per section 3.3.

Transportation of the IP should occur from the site-specific storage location to the subject/participant using a liquid nitrogen vapor phase transport container to maintain the temperature at $\leq -120^{0}$C.

5. ADMINISTRATION

The Investigational Product Dose Administration Instructions are provided in **Attachment 2,** which is provided directly to the Dose Administrator as a stand-alone document.

If multiple IP bags are to be administered, an additional IP Administration worksheet (**Attachment 2** or site-prepared worksheet) must be completed for each additional IP bag.

Administration of IP infusion to subject/participant may be given via either peripheral or central catheter. Use of central venous catheter with a valve is not recommended for IP infusion via gravity infusion.

IP may be administered via gravity or IV pump at an infusion rate that is suitable for administration to the subject/participant in accordance with site/local procedure.

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ATTACHMENT 1: PREPARATION WORKSHEET FOR JNJ-68284528

PREPARATION STEPS FOR JNJ-68284528

(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID:_____ Date:** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ IP Lot No._____

Container: _____ (e.g., A1 of 1) IP Volume: _____

NOTE: Prior to beginning this section, confirm that administration line is in place. Verify that the DIN, Apheresis ID or SEC/DIS and subject/participant identification on the IP bag matches the subject/participant identification when removing from long term storage unit. Document verification according to current site procedures.

IP PREPARATION	RECORD
1. Adjust the temperature of thawing device to 37°C ± 2°C.	
2. When the temperature of the thawing device has reached 37°C ± 2°C remove the IP Infusion Bag from the portable liquid nitrogen container and verify that the DIN/ Apheresis ID or SEC-DIS and subject/participant identification on the IP bag matches subject/participant and documents. Document performed by & checked by.	☐ Subject ID Verified Performed by: _____ Checked by: _____
3. Inspect the IP bag for cracks/fractures prior to thawing. Once the IP bag integrity is verified, place IP bag inside of the sealable plastic bag and seal (it is recommended to use a sterile bag). Immediately place into thawing device. • If a water bath will be used, ensure that the top of the sterile sealable plastic bag remains above the water. Record start time of thaw. **Total time required to thaw the IP must remain within 15 minutes from start of thaw until end of thawing.**	Thawing Start Time: hh_____: mm_____

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PREPARATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID:_____ Date:** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ IP Lot No._____

Container: _____ (e.g., A1 of 1) IP Volume: _____

PREPARATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID: _____ Date** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ IP Lot No._____

Container: _____ (e.g., A1 of 1) IP Volume: _____

IP PREPARATION	RECORD
4. Allow the IP Infusion Bag to thaw in the thawing device (water bath or dry bath). If a water bath is used, gently invert the contents of the bag while thawing in water bath Monitor the thawing process and when there are only one or two small cell clumps (approximately 18 mm in diameter or smaller) of frozen product left remove the bag from the thawing device and record the end of thaw time. **Total time required to thaw the IP must remain within 15 minutes from start of thaw until end of thawing.**	Thawing End Time: hh_____: mm_____

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PREPARATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID:_____ Date:** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ IP Lot No._____

Container: _____ (e.g., A1 of 1) IP Volume: _____

5. Remove the IP bag from the sealable plastic bag and wipe dry. Gently invert the bag **five** times to mix. Inspect the thawed IP infusion bag for presence of cell clumps. If present, use a gentle squeezing motion to disperse the clumps until no visible clumps remain. Confirm and document that IP is thawed, free of ice crystals and cell clumps. **Note**: IP will be administered with or without 170 micron or larger non-leukocyte reducing filter even if small (approximately 18 mm in diameter or smaller) clumps are present.	IP is thawed and free of ice/cell clumps **(Circle one) Yes No**

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PREPARATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID: _____** **Date** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ ____ **IP Lot No._____**

Container: _____ (e.g., A1 of 1) **IP Volume: _____**

IP PREPARATION	RECORD
6. Document expiration time of thawed IP Infusion Bag as: **Thawing End Time (Step 4) + 150 minutes** Document on the site generated IP post-thaw label the expiration date/time and apply the expiry label to the IP Infusion Bag.	Expiration Time: hh_____: mm_____
7. For multiple bags, repeat steps 1-6 for each bag as requested by administrator. Complete a new Preparation Worksheet for each bag of IP.	
_____ / DD_____ / MMM_____ / YYYY Performed by:	_____ / DD_____ / MMM_____ / YYYY Checked by*:

*Sites that do not utilize a second person verification per site and local guidelines must place "N/A" in the "Checked by" line
** Mark as "N/A" if not applicable

Please print this worksheet, complete, sign, and file in the appropriate site research file/binder if not documented electronically.

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ATTACHMENT 2: ADMINISTRATION WORKSHEET FOR JNJ-68284528

ADMINISTRATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID: _____** **Date** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ _____ **IP Lot No._____**

Container: _____ (e.g., A1 of 1) **IP Volume: _____**

NOTE: Ensure subject/participant has a patent IV catheter started before contacting pharmacy/cell lab to thaw IP. Prior to beginning the administration of IP, verify that the DIN, Apheresis ID or SEC/DIS and subject/participant identification on the IP bag matches the subject/participant. Document verification according to current site procedures. All used IV bags and any material remaining in an IV bag after administration should be discarded per local site procedures.

IP ADMINISTRATION WORKSHEET	RECORD
1. Prime the IV administration set with 0.9% Sodium Chloride Injection, USP/EP/JP, per site procedure. A 170 micron or larger non-leukocyte reducing filter in-line or add-on filter is optional. If used, ensure filter is primed. **Note:** Administer IP with or without the optional filter, even if small (approximately 18 mm in diameter or smaller) clumps are present. **Document filter usage.**	Was a filter used? ☐Yes ☐No
2. Connect the distal end of the primed IV administration set (with optional filter) to the peripheral IV extension set or central IV catheter.	
3. Connect proximal end of the administration set to the IP bag. **Note:** If site practice is to perform **Step 3 before Step 2**, this is acceptable provided the administrator ensures clamp is closed to prevent IP spillage during connection procedure.	

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ADMINISTRATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID: _____** **Date** _____ / DD_____ / MMM_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ **IP Lot No._____**

Container: _____ (e.g., A1 of 1) **IP Volume: _____**

IP ADMINISTRATION WORKSHEET	RECORD
4. Begin IP infusion by administering via gravity or IV pump at an infusion rate that is suitable for administration to the subject/participant in accordance with site/local procedure. If needed, gently agitate the IP bag during infusion to prevent any cell clumps. **Record IP Infusion Start Time.**	IP Infusion Start Time: hh_____: mm_____
5. When infusion bag is empty, flush administration set with 0.9% Sodium Chloride using a minimum volume to ensure the total length of the primary administration set inclusive of the drip tube is flushed, per site procedure. Ensure that no IP or flush solution remains in the drip tube or filter if used, and that all IP/Flush solution is administered.	

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ADMINISTRATION STEPS FOR JNJ-68284528
(COMPLETE A SEPARATE WORKSHEET FOR EACH BAG OF IP)

****DIN, Apheresis ID: _____** **Date** _____ / DD_____ / MON_____ / YYYY

****SEC/DIS: _____**

Subject No. _____ _____ **IP Lot No._____**

Container: _____ (e.g., A1 of 1) **IP Volume: _____**

IP ADMINISTRATION WORKSHEET	RECORD
6. Post completion of the flush, **record end of infusion time and total volume infused**. The total infusion time for the IP and the flush must be within 150 minutes after thawing the IP. **Notify Site Manager immediately if:** • **The IP infusion and flush is infusing slowly and likely to exceed 150 minutes from thaw until end of infusion.** • **The IP infusion and flush exceeded expiration time (150 minutes from completion of thaw until end of infusion).**	IP Infusion End Time: hh_____: mm_____ Total Volume Infused: _____ mL
7. For multiple bags, contact pharmacy/cell lab to thaw each additional bag as needed. Then repeat steps 1-6 to administer each additional bag with new supplies. Complete a new Administration Worksheet for each bag of IP administered	
_____ / DD_____ / MON_____ / YYYY Performed by:	_____ / DD_____ / MON_____ / YYYY Checked by*:

*Sites that do not utilize a second person verification per site and local guidelines must place "N/A" in the "Checked by" line
** Mark as "N/A" if not applicable

Please print this worksheet, complete, sign, and file in the appropriate site research file/binder if not documented electronically.

*****END OF DOCUMENT*****

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6. REVISION HISTORY

Document Revision History			
Version Number	**Section**	**Description of Change**	**Justification of Change**
10.0	All	Manual approval	Manual approval form TV-REF-166014
	Attachment 2	Directions and recording sections updated	Align with v10 updates related to ancillaries and administration procedure
		Additional data capture added to capture filter usage	Track usage
	Attachments 1 & 2	IP volume added to headers added as an additional data capture	To capture the actual volume of preparation and administration worksheets
		Added “Please print this worksheet, complete, sign, and file in the appropriate site research file/binder if not documented electronically.”	Clarification
		Step 7 recording section removed	Align with Step 7 directions
		Added “ Note: Administer IP with or without the optional filter, even if small (approximately 18 mm in diameter or smaller) clumps are present.”	Clarification
		Step 2, & Step 5 include directions to document what should be recorded	Align with current writing standards
	5, Attachment 2	Gravity and IV pump added as administration methods. Direction for rate added	Align with current practice; additional clarification
	3.3	Route added to label	Industry standard
	3.2, Attachment 2	170 micron or larger non-leukocyte reducing filter made optional	Align with current practice
	3.2, Attachment 2	Administration technique restrictions removed.	Align with current practice
	3.2, Attachment 2	Saline replaced with 0.9% Sodium Chloride	Align with current writing standards
	3.2.1	Closed System Transfer Device section added	Clarification
	3.2	Material of construction restrictions removed	Align with current practice; TV-TEC-196618
	2	SIPPM replaced with Cellular Therapy Product Procedure Manual (CTPPM)	Document change

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Document Revision History

Version Number	Section	Description of Change	Justification of Change
	2	Definitions and Acronyms updated	Align with language within the document
	1	Added use of Electronic Data Systems for preparation and administration directions and documentation in lieu of Attachment 1 and 2 hardcopies.	Align with current practice
	1, 3.1 3.2, 3.3, 3.4, 3.5, Attachment 1 & Attachment 2)	Language and formatting adjusted	Align with v2 template language for clarity
	All	Expiry extended to 150 minutes	TV-TEC-196618
	All	Participant nomenclature added	Align with protocol naming convention
	All	Date and time abbreviations updated	Align with current writing standards
9.0	All	Manual approval	Manual approval form TV-REF-166014
	All	Added Ciltacabtagene Autoleucel to IP name	Updated IP name
	All	Substitute patient to subject	Keep consistency of the IPPI
	Front page	Added IPPI version number	Format update
	Introduction	Added the worksheet translation and allowing site- worksheet from section 3.5 to Introduction	Format change
	Definition and Acronyms	Deleted Administration, EDC, IV, and DOM	Not referenced in the IPPI
	Material and Equipment	Removed syringe and needle from this section	Post IP Bag infusion flush procedure is replaced by reverse flush
	Table 1	Removed saline solution for IP bag flush, bag access spike, syringe, needle, and tip cap. Removed picture of sealable bag and extension line. Added wording Flushing to saline bag	
	3.4	Remove saline flush syringe label preparation	

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Document Revision History

Version Number	Section	Description of Change	Justification of Change
	3.5	Removed saline flush syringe label preparation. Removed pre-infusion requirement	
	4.1	Removed Electronic Data Capture systems requirement. Added gravity to CVC valve is not recommended for IP infusion	Wording update
	Attachment 1	Remove this attachment. Update Attachments numbering due to this removal	Post IP Bag infusion flush procedure is replaced by reverse flush
	Preparation Worksheet Attachment	New wording for Note. Deleted Step 1 thawing device cleaning procedure	To align with attachment update
	Preparation Worksheet Attachment	Removed DIN/Apheresis ID and SEC/DIS recording	Subject ID verification recording update
	Preparation Worksheet Attachment	Added Step 7 for multi bag infusion	Clarify procedure for multi-bag administration
	Administration Worksheet Attachment	New wording for Note section	To align with attachment update
	Administration Worksheet Attachment	Added two steps at beginning of this section describing infusion line priming procedure	To align with IPPI template
	Administration Worksheet Attachment	Removed attach one infusion line spike to bag port sentence in step 3	Post IP Bag infusion flush procedure is replaced by reverse flush
	Administration Worksheet Attachment	Replace IP bag flush procedure with reverse flush procedure	
	Administration Worksheet Attachment	Added multi-bag administration	Clarify procedure for multi-bag administration
	Administration Worksheet Attachment	Change IP bag picture in step 3	Switch to a more representative IP bag picture

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Document Revision History

Version Number	Section	Description of Change	Justification of Change
8.0	All	Manual Approvals	Manual Approval Form TV-REF-166014
	3.1	Updated IP definition from blood derived product to a genetically modified autologous T-cell immunotherapy product and also inserted that it should be handled according to current safety guidance and local site procedures for “cell therapy products”	To align with correct product definitions during use in the clinic.
	3.2	Deleted plasmatherm from dry thawing equipment to indicate all dry thawing options to be acceptable	Study data support all dry thawing options
	Attachment 2	Step 5: Added maximum allowed thawing time to be 15 mins. from start of thawing until end of thawing.	Additional data available to support up to 30 mins. thawing time. This will provide an upper limit for clinical sites to implement and adhere.
7.0	All	Manual approval	Manual Approval Form DS-FRM-4260 for DS-TEC-131164
	3.1	Added requirement about strictly following IPPI	To prevent sites from deviating from the administration procedure
	3.1, 3.4, 3.5, 4.1 , Attachment 2, and Attachment 3	Extended the post thaw IP hold time to 90 minutes	Based on study data and scientific justification
	4.1	Added wording of not recommending using of central venous catheter with a valve	Added additional clarification on central venous catheter use
	Attachment 1	Delete Step 2	Priming of the administration set step is already included in Step 4
	Attachment 2 Step 6	Added a note about how to handle IP with cell clumps observed	Added clarification on IP with cell clumps handling

Owning Location:	Virtual Org - CAR-T
Document Type: Subtype	Technical Document:Investigational Product Preparation Procedure
Title:	Investigational Product Preparation and Administration Instructions for JNJ 68284528, a CAR-T Therapy Directed Against BCMA in Subjects with Multiple Myeloma

Document Revision History

Version Number	Section	Description of Change	Justification of Change
	Attachment 3 Step 3	Added a sentence "Gently agitate the IP bag during infusion to prevent any cell clumps"	Added instruction on how to prevent cell clumps generation during infusion
6.0	All	Manual approval	Manual Approval Form DS-FRM-4260 for DS-TEC-131164
	3.5	Replaced "30-minute" with "45-minute"	Correction of error
5.0	Table 1,Table 2, and attachment 2	Added dry thawing device for IP thawing	Dry Bath option was not included previously and will be implemented as an option for IP thawing
	Table 1	Change water bath thawing solution to follow site or equipment manufacture instruction	Follow site or equipment manufacture instruction
	Table 1	Change IP thawing bag to a sealable plastic bag with a tight closure system	Multiple bag type is acceptable for use
	3.2	Specify the material construction requirement for ancillaries only applies to the ancillaries in contact with IP	Clarification of ancillary MOC requirement
	3.1, 3.4, 3.5, 4.1, attachment 2, attachment 3	Change the IP post thaw expiry to 45 minutes	Based on study data and scientific justification
	3.4	Extend 50mL saline in syringe hold time to "Must begin to use within 4 hours after the flush volume has been drawn up into the syringe"	Follow USP 797
	3.4	Update the provider for IP labels and saline flush syringe labels to site/sponsor	Sponsor may also provide labels when necessary
	Table 1 and Table 2	Delete Luer lock from saline syringe tip cap. Added "Sterile"	Multiple syringe tip cap is acceptable for use
	Table 1	Update the Bag Access Spike picture to BD 2300E	To reflect ancillary update
	Table 1	Delete the needle size requirement	Follow site instruction

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	Attachment 3	Added wording “Notify Janssen Site Manager immediately if: • The IP infusion and saline flush is infusing slowly and likely to exceed 45 minutes from thaw until end of infusion. • The IP infusion and saline flush exceeded expiration time (45 minutes from completion of thaw until end of infusion).”	In time communication from site to sponsor is required when IP post thaw expiry is or will be exceeded.
4.0	Title	Removed trial number and specific trial name. Replaced with generic IPPI title for product.	Generic title to enable same IPPI document to be updated for various clinical trials across different sites.
	2	Added "DIS," "SEC," "SIPPM" abbreviations and removed "PP," “IV,” and “IWRS”	Updated table to reflect abbreviations used in document and removed common terms
		Updated definition of flushing volume by removing "at a controlled rate"	Infusion via gravity so rate is not controlled as with the use of a pump
		Updated IPPI definition to include "Investigational Product Preparation and Administration Instructions"	Administration was not included previously
	3.1	Replaced " all flushings" with "the flush"	Only a single flush to be administered (removed second saline flush).
	3.2	Removed entire section titled "Important Information About Catheter Preparation"	Memo in place to accept all CVC. No requirement around MOC for Centration Venous catheters
	3.2 (new)	Replaced trial number "68284528MMY2001" with "each JNJ-68284528 clinical trial"	Removed reference to specific trial number to make document generic across trials for product

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		Added the word “acceptable.” Added sentence: "PVC, PU, silicone, and/or titanium are acceptable materials of construction for ancillaries used (including administration sets, extension sets, and bag access spikes)."	Word added for clarity to the sentence. List of acceptable materials of construction for ancillaries to be used
	Table 1	Updated 0.9% Sodium Chloride Injection infusion bag description to "0.9% Sodium Chloride Injection, USP/EP/JP, minimum 100 mL infusion bag (for priming)"	Added EP/JP designation. Only single flush to be administered so reduced minimum volume of saline bag to 100 mL instead of 250 mL and removed "and post-infusion flush"
		Removed equipment information for IV infusion pump	IP infusion will be via gravity only
		Updated sterile sealable plastic bag ancillary information by removing OriGen example and adding "with a tight closure system." Updated to be provided by either Sponsor or site.	No mandate on sealable bag used
		Removed materials of construction information for IV administration set. Updated image of administration set. Added asterisk to quantity of administration set. Updated administration set to be provided by either Sponsor or site.	Multiple MOC acceptable for use as listed in text in Section 3.2. The IV administration set can be supplied by Sponsor or site. IP infusion will be via gravity only, so administration set for gravity is displayed. Multiple units needed for delivery of multiple IP bags, so asterisk was added.

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		Removed materials of construction information for extension set. Added clarification that extension set is "to be used with peripheral IV catheter." Updated extension set to be provided by either Sponsor or site.	Multiple MOC acceptable for use as listed in text in Section 3.2. The extension set can be supplied by Sponsor or site. Administration can be done with either peripheral IV catheter or central venous catheter, but the extension set is to be used only in the case of the peripheral IV catheter.
		Updated catheter ancillary information by removing materials of construction information and specific catheter examples. Added "(sponsor approval not required)." Updated catheter to be provided by either Sponsor or site.	Memo in place to accept all CVC. No requirement around MOC for Centration Venous catheters or peripheral catheter. The catheter can be provided by either the Sponsor or site, and in the case that the site is providing the catheter, sponsor approval is not needed.
		Updated wording to "Bag Access Spike." Removed reference #MY3004. Replaced image of BD reference #MY3004 with image of BD reference #2300E-0500. Added additional parentheses.	Updated wording for consistency. BD reference #MY3004 is discontinued product so image of other bag access spike listed used as an example. Added missing parentheses.
	3.4	Removed sentence: "Examples of the labels are included in Attachment 3."	Label examples not shown due to variability in labels/language used across countries/sites
		Updated to "USP/EP/JP" for 0.9% Sodium Chloride Injection designation	Missing EP/JP
		Removed specific protocol number "68284528MMY2001" and replace with a blank to be filled in	Generic IPPI document to be used/updated for multiple trials

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	3.5	Replaced " all flushings" with "the flush"	Only a single flush to be administered (removed second saline flush)
		Updated "Worksheet" to "Worksheets"	Typo
	4	Removed "labeled as per Attachment 4"	Attachment 4 removed from document
	4.1	Updated "subject" to "subject's"	Typo
	Attachments 1, 2, and 3	Added ":" to title	Formatting
	Attachment 1	Removed "infusion pump"	Infusion via gravity, not by pump
		Updated "cyro" to "cryo"	Typo
		Removed first step to "Verify subject's IV administration catheter meets the specified materials of construction. If not either replace or utilize alternate IV site using Sponsor provided Catheter (See Table 1 in Section 3.3"	No MOC requirement around catheter
	Attachment 1, Step 2	Updated to prime the "IV infusion line and the extension set (if applicable)"	Clarification that the infusion line is to be primed. Clarification that extension set is to be used if using peripheral catheter (not applicable if using central venous catheter).
		Remove "IV" designation for catheter	Either peripheral IV or central venous catheter allowed to be used
	Attachment 1, Step 3	Moved sentence: "Ensure the clamps are closed" so that it is before attaching the spike to the saline bag.	Align text with order that steps should be taken.
		Removed "Sponsor provided administration set" and replaced with "IV infusion line"	Administration set can be provided by either Sponsor or site

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		Updated 0.9% Sodium Chloride Injection bag size to "minimum 100 mL" from "250 mL or larger"	Only single flush to be administered so lower volume necessary. Wording adjusted to be consistent with description in Table 1.
	Attachment 1, Step 3	Updated to Step 3	Adjustment in numbering due to removal of Step 1 from previous version
	Attachment 1, Step 6	Removed Step 6 "Connect the administration line to the infusion pump according to the pump vendor instructions"	Infusion via gravity; pump no longer to be used
	Attachments 2 and 3	Added separate line for “SEC/DIS" (throughout Attachment 2 and 3) for use when applicable	Different IDs used depending on country of trial
	Attachment 2, Step 1	Added that water bath is to be prepared "with sterile water or sterile saline"	Added clarification
	Attachment 2, Step 3	Divided Step 3 (from old version) into two separate sections. Step 3 (new): "When the temperature of the water bath has reached 37°C ± 2°C remove the IP Infusion Bag from the portable liquid nitrogen container and verify that the DIN, Apheresis ID or SEC/DIS and subject identification on the IP bag matches subject. "	Divided for separate documentation steps
	Attachment 2, Step 4	Divided Step 3 (from old version) into two separate sections and added inspection of the IP bag prior to thaw. Step 4 (new): "Inspect the IP bag for cracks/ or fractures prior to thawing. Once the IP bag integrity is verified, place IP bag inside of the sterile sealable plastic bag and seal. Immediately place into the water bath ensuring that the top of the sterile sealable plastic bag remains above the water. Record start time of thaw."	Divided for separate documentation steps. Bag inspection added as a check of the IP bag to ensure that quality of bag is not compromised prior to thawing.

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	Attachment 2, Step 5	Clarified clumps are “cell clumps.” Replaced "the size of a dime or less" with “approximately 18 mm in diameter or smaller.”	Word added for clarification of sentence. Removed US-specific reference for document to be used across multiple countries.
	Attachment 2, Step 5	Clarified clumps are “cell clumps.” Added to disperse the clumps “until no visible clumps remain.”	Clarification
	Attachment 2, Step 7	Updated to Step 5	Adjustment in numbering due to change in steps from previous version
	Attachment 2, Footnote	Added “Mark ‘N/A’ if not applicable	Some fields may not be applicable at each site (i.e. DIN/Apheresis ID or SEC/DIS)
	Attachment 3, Step 1	Updated Step 1 from "Ensure the clamps on the administration line and Bag Access Spike Set are closed. Connect the administration line to the IP Infusion Bag using the center port (A) on the bag. Attach the Bag Access Spike Set to the IP Infusion Bag using the end port (B) on the bag" to "Ensure the clamps on the administration line are closed. Connect the administration line to the IP Infusion Bag via one of the ports on the bag. Attach the Bag Access Spike Set to the IP Infusion Bag via the other port on the bag." Updated image of the IP bag to remove labeling of the ports.	Bag Access Spike to be used does not have clamps (previous version of document had spike with clamps that is now discontinued). Ports on the IP bag are no longer designated for ease of preparation.
	Attachment 3, Step 2	Added that administration line can be connected to either extension set "or catheter."	Extension set not mandatory to be used (and cannot be used in case of a central venous catheter)
		Removed sentence: "Turn on the infusion pump and program pump to deliver IP infusion at 600 ml/hr."	Infusion via gravity; no pump to be used

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	Attachment 3, Step 3	Added to "completely open" the clamp of the "IP" administration line	Clarification
	Attachment 3, Step 4	Replaced "pump from alarming" with "air bubbles forming in the line"	Infusion via gravity; no pump to be used
	Attachment 3, Step 5	Removed “port”	Clarification
	Attachment 3, Step 6	Added to "completely open" the clamp	Clarification
		Removed "at the same rate as the IP (600 ml/hr)"	Infusion via gravity; no pump to be used
	Attachment 3, Step 7	Updated Step 7 from "Stop infusion when infusion bag is empty but and drip tube chamber remains full to prevent pump from alarming. Close the clamp to the IP infusion bag" to "Stop the flush when infusion bag containing the 50 mL flush volume and drip tube chamber and administration line are empty. Close the clamp to the IP infusion bag."	Infusion via gravity. Since there is no pump the drip chamber can be emptied to administer more flush volume. Replaced "infusion" with "the flush" and added "containing the 50 mL flush volume" for further clarification.
	Attachment 3, Step 8	Remove Step 8 (of previous version): "Program the pump to deliver 40 ml of saline flush at the same rate as the IP (600 ml/hr). Open the clamps on the 250 ml bag of 0.9% Sodium Chloride Injection, USP/EP/JP and the administration line and begin to infuse the administration line flush."	Infusion via gravity; no pump to be used. Removed second saline flush step.
		Updated Step 8 from "When all of the 40 ml flush volume is infused, record end of infusion time" to "Post completion of the flush volume, record end of infusion time. The total infusion time for the IP and the saline flush must be within 30 minutes of IP post thaw."	Removed second saline flush step of 40 mL. Added infusion time for further clarification of IP infusion time/IP expiry.
		Added “Mark ‘N/A’ if not applicable	Some fields may not be applicable at each site (i.e. DIN/Apheresis ID or SEC/DIS)

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	Attachment 3, Footnote	Removed entire section "Attachment 4 - IP Infusion Bag Label Examples"	Label examples not shown due to variability in labels/language used across countries/sites
	Attachment 4	Removed “PES – Polyether Sulfone” and “PSF-Polysulfone” from list	PES and PSF are no longer part of the document
3.0	2	For Priming - deleted “after connection of the infusion set to the IV infusion bag containing the IP”	To make the priming instruction clearer
		For Priming Volume - replaced “IP” with “saline solution” and deleted “from the IV infusion bag”	To make the priming instruction clearer To clarify materials of construction
		For Ancillary: IV administration (blood) set - added “tubing” after “PVC” and deleted “PES or PSF”	
	Table 1	For Ancillary: Extension set - changed “Extension set with SmartSite Needle-free Connector made of PVC with or without silicone” to “Extension set made of PVC tubing with needle-free connector”	To clarify materials of construction Typo correction
		For Ancillary: - Changed “used if the it is” to “used if it is”	
		For Ancillary: Bag Access Spike Set, added “or 2300E-0500”	Add additional example for ancillary item
		At top of each worksheets, changed entry for container label from: “ (Circle one) A1 A2 A3 B1 B2 B3” to a blank fill-in “_____ (e.g., A1 of 1)”	To broaden options for container label
	Attachments 1, 2, 3	For second page of each attachment, removed header section starting with “Prior to beginning this section”	To clarify instructions
	Attachments 1 and 2	Changed “Close the clamped” to “Close the clamp”	Typo correction
	Attachment 1, Step 5	Changed “Luer Loc” to “Luer Lock”	Typo correction To clarify instructions
	Attachment 1, Step 8	Added “NOTE:” to section header on first page	

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	Attachment 2	Changed “thawed IP bag matches subject” to “IP bag matches subject”	Typo correction
	Attachment 2, Step 3	After “Allow the IP Infusion Bag to thaw in the water bath”, added “Gently mix the contents of the bag while thawing.”	To make the bag preparation instruction clearer
	Attachment 2, Step 4	Moved instruction to “Gently invert the bag five times to mix” to occur immediately after the thaw and before inspecting the bag.	To make the bag preparation instruction clearer Typo correction
	Attachment 2, Step 5	Changed “using” to “use”	
		Changed “Thawing End Time (Step3) + 30 minutes” to “Thawing End Time (Step 4) + 30 minutes”	Typo correction
3.0	Attachment 2, Step 6	Added to section header on first page “NOTE: Prior to beginning this section, verify that the DIN (Apheresis ID) and subject identification on the IP bag matches the subject. Document verification according to current site procedures.”	To clarify instructions
	Attachment 3	Changed “adminstration" to “administration” throughout the attachment.	Typo correction
		Added DOM at DEFINITIONS AND ACRONYMS	Additional acronyms added
2.0	2	Typo corrected for 68284528MMY2001	Typo correction
	3.3	Changed The bag to Each bag.	To accommodate multi bag infusion
	3.1	Change the IP to the first IP bag	To accommodate multi bag infusion To accommodate multi bag infusion
	3.2	Added a sentence “If multiple IP bags are to be administered, the materials marked with an asterisk (*) under “Quantity for Unit Operation” require an additional unit for each IP bag.”	

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	3.3	In IV solution added * next to bag 1 and footnote "* For administration of multiple IP bags, additional units are needed per IP bag." In solution added sterile saline. In ancillary deleted PP from 60 mL Luer-Lok Tip PP single-use syringe, and deleted PP from luer lock tip cap. In IP deleted "as agreed upon by sponsor" for 60mL syringe, needles and tip cap. In IP deleted words "target dose" and "de-escalation dose" In Ancillary deleted the Sterile sealable bag catalog # In Ancillary bag access spike set deleted PVC from the requirement Deleted "PVC" from bag access spike	
	Table 1	Paragraph 1: Changed "The IP infusion" to "Each IP bag". Added a sentence "If multiple bags are to be administered, the label on the first IP bag may read "Container: A1 (or B1) of X" in which X is the total number of IP bags to be administered for each patient. Subsequent IP bags would be labeled as "Container: A2 (or B2) of X" for a second bag or "Container: A3 (or B3) of X" for a third bag." Paragraph 2: Added "for each IP bag that will be administered" to "The site will be responsible for creating two labels" And changed timing of label preparation to "before initiating thawing of the first IP bag".	

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	3.5	Added a paragraph "If multiple IP bags are to be administered, prepare for only one IP administration at a time. Do not start the second IP preparation until receiving confirmation that the first IP administration is complete (including all flushings). For each additional IP administration, use ancillary new materials as denoted in Table 1 by an asterisk (*)." Added a sentence to Pre infusion IP instruction "If multiple IP bags are to be administered, additional Pre-Infusion (Attachment 1) and IP Preparation worksheets (Attachment 2) (or site-prepared worksheets) must be completed for each additional IP bag"	
2.0	3.6	Changed the wording to "One or more 70-mL or 30-mL infusion bags" from "One 70-mL or 30-mL infusion bag"	To accommodate multi bag infusion To make the bag preparation instruction clearer
	4	Added a sentence "If multiple IP bags are to be administered, an additional IP Administration worksheet (Attachment 3) (or site-prepared worksheet) must be completed for each additional IP bag."	
	4.1	Added "Preparation for Container (Circle one) A1 A2 A3 B1 B2 B3"under "subject number". Added date to header.	
	Attachment 1	Added "container (Circle one) A1 A2 A3 B1 B2 B3" under "IP Lot No". Added date to header.	
	Attachment 2 and 3	Added COMPLETE 1 WORKSHEET FOR EACH BAG OF IP at the top of each attachment	
	Attachment 1, 2, and 3	Added sentence "Gently invert the bag five times to mix."	
	Attachment 2 step 5	Added Apheresis ID next to DIN	Explain DIN

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Version Number	**Section**	**Description of Change**	**Justification of Change**
	Attachment 2	New document. This document was manually approved by Loreta Marquez	New document
1.0	All		

Document Approvals

Approved Date:

Mandatory Approval Task Verdict: Approve	Xinran Li, (sli175@its.jnj.com) Document Management Approval 27-Oct-2021 19:11:42 GMT+0000

Mandatory Approval Task Verdict: Approve	Devon Zimmerman, (dzimmer8@its.jnj.com) Department Approval 27-Oct-2021 19:16:31 GMT+0000