DCP/Ph1/016: Managing a pharmacy for storage of investigational products for clinical trials

Version 1.3

Effective date: 1st of January 2024

Revision due date: 31st of December 2024

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# DCP/Ph1/016: Managing a pharmacy for storage of investigational products for clinical trials

- **1. Purpose**: The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the proper management and storage of investigational products in a pharmacy for use in clinical trials.
- **2. Scope:** This SOP applies to the pharmacy department responsible for receiving, storing, and dispensing investigational products in a clinical trial setting.
- **3. Responsibilities:** The Principal investigator, Co-investigator, Pharmacist, Study Nurse, Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator for implementation of this SOP.

#### 4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR (2017)
- ICH E6 (R3) Integrated Addendum to ICH E6 (Rl), Current Step 4 version dated May 2023
- Medical Devices Rules, 2019
- New Drugs and Clinical Trials Rules, 2019

#### 5. References (to other SOPs)

 Ph1 SOP No. 17/45: Management of investigational products for a Phase I clinical trial

#### 6. Detailed instructions

S.No	Task	Person responsible
1	Instructions regarding receipt and placement of	

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esinilo	IPs in the refrigerator:	a parganala akokang libu.
enilsbine.	• Record temperature of the refrigerators twice every day (excluding Sunday and any public/bank holidays as per local policy)	Pharmacist, Study Nurse, study co-ordinator under the supervision of PI and CO-I
2,589 1	• Store study IPs in the main body of the refrigerator, allowing air to circulate around the packages and ensuring there is no obstruction to	a incomeganium respons cele pel
seni-totz'	the refrigerator fan.	2. Seenar This SOP applies
	• Do not keep the IPs in the door of the refrigerator or in the bottom drawers or adjacent	anoningtheorni gmanolpali Los
nate and hi	to the freezer plate.	(10 - con an antimident (1 - con)
	• Protect IPs from light.	
	<ul> <li>Place IPs in the refrigerator in such a way that the vent or fan meant for circulation of air is not blocked.</li> </ul>	Statement and a special section is
name Fi	• When 2 or more different IPs are simultaneously	e Edwiczi Coniconnes
	administered in a single study, place each IP on a separate rack and label it accordingly.	ST STAND, strengistrad strength (69) del HDL =
2	Maintenance of IP Refrigerators Required.	alusi mayati igadaald
	<ul><li>Defrost refrigerators once a week.</li><li>Keep the refrigerators away from radiator or</li></ul>	Pharmacist, Study Nurse under the supervision of PI and CO-I
	other heat source.	5. References (to other SOF)
chaical	• Cover the refrigerator plugs and sockets with tape which reads "DO NOT UNPLUG"	PHT SOP No DIES
	• Lock the refrigerators once used and use it exclusively for medicines.	enoitymment belleville a
	• Avoid unnecessarily opening of the door of the	30.00

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	refrigerator.	Kalifa iku sask
	• Arrange for back up facilities in the event of the	A Reconfigure the
	refrigerator failing or breaking down.	to explure the
	• Calibrate the refrigerator annually.	: Improvement
3	Instructions regarding the data logger or	ESCO ESTOTOGO O T
	temperature recording device	a (aldabasai mia
	Go through the operations manual for handling	noo barees a edal.
	of the data logger.	agmitted with Till and
	• If the instructions are not clear, then contact the	Standays or pass
	sponsor /CRO for the operational details.	galak istiven
	• Ensure that the data logger is calibrated and	and the second
	battery is not in a drained state at the time of	Pharmacist, Study Nurse under the supervision of PI
	receipt.	and CO-I
	• Position the probe of the data logger in the	IP with the help
	center of the storing device.	Titl (municipale)
	Allow the data logger to get conditioned by	com antighus the
	placing it in the refrigerator for at least 2 hours	ans all milat a
	before initiating the recording of the	eliminos eliminal si di e
	temperature.	Silv Staff Stonia - vi
4	Instructions regarding recording of temperature	Pharmacist, Study Nurse
	• Record the temperature of the refrigerator in <sup>O</sup> C/	under the supervision of PI and CO-I
	<sup>0</sup> F as per protocol requirements twice a day (in	
	the morning and evening or at times specified by	sunisansze
	the protocol) by the study pharmacist.	b to see at a
	• Record the minimum, maximum and actual	temperature rate
	temperature.	berneni fromo siy
	The recorded readings of the temperature log	· Download the d
	and should be signed and dated by allotted study	steb off vitinshi

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		identify the date and time at which the excursion	giz od Clumsta Lins
	•	Download the data from the data logger and	on hatnesses sell a
		via email immediately.	endlerenoisi
		temperature range, inform the PI and the sponsor	tion saft bresist +
	•	In case of deviation from the specified	r vid (Insoluting self.
	ex	cursions	and CO-I
5	In	structions regarding handling of temperature	Pharmacist, Study Nurse under the supervision of PI
-14-40	n ni	the protocol.	e Recent the temps
	14	Sponsor/CRO at regular intervals as specified in	danger anothermal
	•	Ensure that the temperature log is sent to the	- continuousi
		Investigator and the sponsor/CRO via email.	illainini stalist
	•	Inform the same immediately to the Principal	odr ni. tizaniosią
		can maintain the required temperature.	atab opi-wells
		temperature) to another room/ refrigerator that	tole said to some
		IP with the help of Cryobox (if IP requires low	v Position the per
		exceeds the given limit, immediately transfer the	delegan
	•	In case the temperature of the room/ refrigerator	ni ton si vestissi
		log.	all tails count in
		provided stating the reason in the temperature	0.093 mempe
		Sundays or public holidays, a comment must be	noimmani adrili a
	•	If the readings are not measured in case of	regard out to day to day to
		into a secure computer by the Pharmacist.	salt demonstrate w
		downloadable) at least once a week and saved	brosen erungsennisk
	•	Download data from the logger (if	Torrentiens regar
		temperature.	for an eliberic me refi
		to capture the true maximum and minimum	nillai companier
	•	Reconfigure the data logger at least once a week	land not supposed.
		staffs and reviewed by the PI.	and stone in the second

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017.317	occurred.	
	Notify the Institutional Ethics Committee (IEC)	
	at the earliest with the corrective measures taken	E 10031 Davoisson Ta
	• Identify the reason for the excursion and take	TOTAL RELEASE CONTROL
	appropriate measures to avoid a repeat of the	San Stationtific
	same.	STR YOU CHOOLING IN
6	Instructions to avoid temperature excursion	Pharmacist, Study Nurse
	Avoid opening the refrigerator frequently for the	under the supervision of PI and CO-I
	purpose of storing and retrieving the IPs.	
7	Ordering and Monitoring of Stock	Pharmacist, Study Nurse
	• Order IPs by the designated/delegated person(s)	under the supervision of PI and CO-I
	Avoid over ordering or stock piling IPs. No	and All harbeit a
	more than 2-4 weeks stock should be	
	maintained.	
	• Ensure IPs with shorter dates are used first, (i.e.	and the Glassia as
	stock rotate).	
	Check regular weekly or monthly for removal of	
	time expired IPs	
8	Disposal of Unused and Expired IP	Di Co i N
	• Use of all reconstituted IPs and opened single	Pharmacist, Study Nurse under the supervision of PI
	and multi-dose vials within the period	and CO-I
	recommended by the manufacturer and disposed	A STATE OF THE STA
	of at the end of a session	
	• Dispose the expired and partly used IPs in a bin	
	for incineration, together with used ampoules	A STATE OF THE STA
	and vials.	0 7 CORRESPONDED TO 0211
	• If site has no facility for proper destruction of	D Dollangingh oxid
	expired and partly used IPs then return the same	incomit telimold, as

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	for destruction to manufacturer or sponsor.	acamona finan
9	IP Removed from The Refrigerator For Use	Pharmacist, Study Nurse
	• Remove IPs from the refrigerator, only prior to immediate use	under the supervision of PI and CO-I
	Only one box should be removed at a time.	San Statedorage
	• All unused IPs which have been out of the	
	refrigerator must be marked with a cross and	tors of racinatibation
	dated and then replaced immediately in the	a granucio siona.
	refrigerator, or appropriately destroyed, if the IP	
	has been exposed to a higher-than-average room	
	temperature or a long clinic session.	
	• Marked IPs must be used at the session (if	010 1970 Hamb
	allowed) or appropriately destroyed.	
10	IP Spillage	Pharmacist, Study Nurse under the supervision of PI and CO-I
	Clear IP spillage up quickly.	
	Wear gloves, mop up with paper towels.	and CO-1
	Avoid skin puncture from glass or needles.	
	Discard soiled paper towels, gloves and vials in	
	a bin for incineration.	
	Clean surface with Lysol Disinfectant.	
	Wash with soap and water in case of splashes on	
	the skin.	
	• Wash eyes with copious amounts of 0.9%	
	sodium chloride and medical advice sought	
11	Use of Insulated Cool Boxes	Pharmacist, Study Nurse
	Use designated cool boxes	under the supervision of PI
	Monitor the cool boxes with a thermometer.	

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12		Pharmacist, Study Nurse
	Will be carried as per Departmental SOP 24     (Waste Management)	under the supervision of PI and CO-I.

#### 7. Abbreviations

Co-I	Co-investigator Co-investigator
ICH	International Council for Harmonisation of Technical Requirements for
	Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
ID	Identity number
SOP	Standard Operating Procedure
PI	Principal Investigator

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#### ANNEXURE 1: TEMPLATE OF TEMPERATURE LOG

TEN	/PER	ATUR	EI	OG
11 11/11	A	~ II U II N		I P Q II

**Protocol ID:** 

Protocol title:

**Investigational Product:** 

**Principal Investigator:** 

Person maintaining temperature log

Centre:

		Morning Temp <sup>0</sup> C			sauba	Evening Temp <sup>0</sup>		Standa		Monitor verification during site visit (Initials and date)	
Date	Time	Max	Min	Actual	Sign	Time	Max	Min	Actual	Sign	
						7,10310					
							- 10000010			/	
							1101	-62			
					-	208/12	4/1-				
							- yaiga	Nahiya 6	aG : ay	d beyon	In/A
							- bpold	& rozzá	549		
				1 60	5//	JU					

Signature of PI or designee: