Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-PD-043-06	Effective Date:	20.06.2019
	Supersedes:	SOP-PD-043-05	Next Review Date:	19.06.2022
	Department:	Production	Page:	1 of 4
TITLE: HANDLING AND USAGE OF RECOVERY SOLVENT				

1.0 PURPOSE:

To lay down the procedure for handling, recovery and usage of recovered solvents.

2.0 SCOPE:

This procedure applies to all solvents intended for recovery and usage of the same at appropriate stages at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility to production personnel to recover the solvent as per procedure. QC shall analyze the sample as per test procedures.

3.2 Production in charge is responsible to monitor the procedure and maintain the re-conciliation

4.0 DEFINITIONS: Nil.

5.0 PROCEDURE :

5.1 The Recovered solvents, which are meeting the specification requirements, shall be permitted to use in the same stage of next batch of the same product.

5.2 The reconciliation of solvent shall be maintained by using "Recovered Solvent Receipt & Issue Record" format PD043-FM016.

5.3 **Procedure for handling and usage of recovery solvents:-**

5.3.1 Solvents can be recovered through the following methods

5.3.1.1 In process distillation

5.3.1.2 Reactor distillation / Column distillation

5.3.1.3 Chemical treatment or followed by reactor / Column distillation.

5.4 **Handling and usage of recovered solvents through In process distillation:-**

5.4.1 Collect the In process solvent of the particular product into receiving tank or into dedicated containers and paste the Quarantine label.

5.4.2 Production person shall give the test requisition to QC for sample collection and analysis.

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Sk. Saleem Basha	K. V. Ramana Reddy	N. Sreedhar
Department	Production	Production	Quality

5.4.3 QC shall test and provide the approved / rejected label on yellow portion of Quarantine label.

5.4.4 Once QC approves the batch, the approved recovered solvents shall be permitted to use in the same stage of next batches of the same product.

5.5 **Handling and usage of solvents recovered through column distillation / reactor distillation / treatment :-**

5.5.1 The mother liquor and washings obtained during the process are stored in the dedicated storage tanks or drums.

5.5.2 If the solvent stored in the storage / holding tanks, fill the identification label with Name of the solvent, batch number, quantity etc…and paste the label current version of PD014-FM003.

5.5.3 Segregate the solvents as per product and stage wise.

5.5.4 The solvent to be recovered shall be transferred to reactor / column from the storage tank / drums

5.5.5 The solvent shall be recovered as per respective recovery BPR and shall collect the distilled / treated solvent into dedicated tank / containers and affix the Quarantine label.

5.5.6 Production person shall give the test requisition to QC for sample collection and analysis.

5.5.7 QC shall test and provide the approved / rejected label on yellow portion of Quarantine label.Once QC approves the batch, the approved recovered solvents shall be permitted to use in the same stage of next batches of the same product.

5.5.8 If the Receiving Tank / Storage / Holding Tanks are not sufficient, unload the solvent into dedicated drums.

5.5.9 The recovery process shall be validated like a process validation procedure to ensure that process gives consistent quality. The validation process shall be carried out through protocol.

5.5.10 The validation protocol shall describe the following but not limited to; Recovery procedure, Equipment details, collection of solvent, sampling plan like testing of individual fractions and composite sample for validation batches, specification and testing procedures.

5.6 The fresh solvent specification can be followed for testing and release of recovery solvent or if the specification is different, the specification for recovery solvent shall be prepared separately based on the process requirement defined in the technology development document.

5.7 If technology is transferred by customer, the specifications defined in the technology transfer shall be followed. In case the technology developed in-house the specifications shall be taken from development report.

5.8 Once the campaign of product is completed the left over recovered solvent can be stored and can be used in next campaign or it can be disposed.

5.9 The fresh solvent containers, which were emptied by consuming the solvent in previous batch can be used for collection of recovered solvent and the same shall be identified with proper labeling and/or also new drums can be procured for collection of recovery solvents and labeling shall be done.

5.10 If the recovered fails to meet the defined specification, QC shall reject and paste the rejected label.

5.11 The rejected solvent can be reprocessed to meet the specification or can be disposed /sale as spent and shall update the details in reconciliation record.

6.0 FORMATS / ANNEXURE(S):

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Sk. Saleem Basha	K. V. Ramana Reddy	N. Sreedhar
Department	Production	Production	Quality

6.1 Recovered Solvent Receipt & Issue Record : PD043-FM016

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.01.2011	New SOP is introduced.	------
01	01.01.2014	Recovered Solvent Receipt & Issue Record introduced Revised current SOP No system.	------
02	01.09.2014	SOP revised with more clarity, PD-F-009 & PD-F-010 Format removed.	------
03	05.03.2016	Revised as per better clarity	------
04	01.01.2017	Procedure elaborated and SOP format changed.	PD-CRF-024/16
05	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/ 17035
06	20.06.2019	The procedure for validation requirement, store and usage of containers, disposal of failed solvent and specification to be followed is incorporated.	CCF/GEN/ 19018