

STANDARD OPERATING PROCEDURE			
SOP No.:	SOP-PD-011-04	Effective Date:	01.01.2018
Supersedes:	SOP-PD-011-03	Next Review Date:	31.12.2020
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TITLE: INPROCESS SAMPLING

1.0 **PURPOSE:**

This procedure describes the general sampling and testing of in-process materials in manufacturing process in Discovery.

2.0 **SCOPE**:

This procedure applies to all the in-process sampling done by the Production personnel.

3.0 **RESPONSIBILITY:**

It is the responsibility of the Production department to implement the procedure as written.

4.0 **DEFINITIONS:** Nil.

5.0 **PROCEDURE**:

- 5.1 Batch Production Records provide instructions for taking in-process samples for Quality Control checks at critical steps in the manufacturing process. The Batch Production Record also has accommodations for reporting laboratory results or further instructions based on the findings of these in-process tests.
- 5.2 Collect samples according to the following guidelines and submit to the laboratory for analysis:
 - 5.2.1 Follow the safety precautions while collecting the sample and wear the personal protective equipment as required.
 - 5.2.2 Collect samples of solid materials using a appropriate sampling equipment. Collect samples to ensure that each fraction of the total quantity is represented (for example, sample each centrifuge lot of a wet cake). Composite the material into a clean polyethylene bag or sample bottle.
 - 5.2.3 Collect samples of liquid materials from reactors by using clean SS or PP samplers as applicable (use SS samplers for SS reactors and PP samplers for Glass lined reactors) while stirring is stopped. Take about 50 ml of sample for all in process samples (for the samples that are not covered in the specific SOPs)

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- 5.3 Enter the batch no., name of the sample, name of the tests requested and sign on the A.T.R Request form of the practice and send it to the Quality Control laboratory along with the sample.
- 5.4 Attach the A.T.R Request returned by the Quality Control supervisor to the Batch Production Record.
- 5.5 In case of Receivers: Collect sample from Receiver bottom valve.
- 5.6 For an Aq. samples: Collect samples from upper side under settling.

6.0 **FORMATS / ANNEXURE(S):**

Nil.

7.0 **CHANGE HISTORY:**

Revision No.	Effective date	Details of Revision	Ref. CCF No.
00	01.01.2009	New SOP is introduced	
01	24.08.2010	SOP Procedure is updated	
02	01.06.2014	Revised as per current SOP No system & more clear and clarity	
03	01.01.2017	Procedure elaborated in this SOP.	PD-CRF-
03 01.01.2017		1 roccdure claborated in this 501.	024/16
04	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/ GEN/17035

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