



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Handling of Finished products, Semi-finished, In process, Validation and Swab Samples	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down a procedure for handling of Finished products, Semi-finished, In process, Validation and Swab samples.

**2.0 SCOPE:**

This procedure is applicable to handling of Finished products, Semi-finished In process, Validation and Swab samples in Quality Control Laboratory.

**3.0 RESPONSIBILITY:**

Executive, Officer – Quality Control  
Head – Quality Control

**4.0 PROCEDURE:**

- 4.1 After receipt of samples along with sample slip from IPQA, QC personnel shall enter the details in the respective inward register for finished product, semi-finished & In-process, Validation, Swab and Market samples as per annexure I, II, III, IV and V respectively.
- 4.2 QC In charge or designee shall allocate the samples along with analytical test data sheets to the respective analyst for analysis.
- 4.3 Analyst shall perform the analysis as per respective standard test procedures and specifications.
- 4.4 Analyst shall maintain all chromatographic data (if applicable) with the analytical raw data sheets along with signature.
- 4.5 The data sheets shall be filled online during analysis.
- 4.6 After completion of analysis, analyst shall submit the report along with all supporting documents to QC In charge or designee for review.
- 4.7 QC In charge or designee/reviewer shall review each of the test and supporting data according to respective standard test procedure and specification of the products for compliance.
- 4.8 During analysis of the sample if results are Out of specifications, Inform immediately to the respective QC In charge or designee for investigation.



# PHARMA DEVILS

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- 4.9 The investigation shall be carried out as per SOP.
- 4.10 The COA of the sample shall be prepared as per respective specifications.
- 4.11 A copy of COA shall be given to QA for review and to keep it with batch record.
- 4.12 After preparation of finished product COA, QC In charge or designee enter the details of the analyzed batch no. of the product in ERP system as per below procedure.
- 4.13 QC In charge or designee shall login in ERP as per SOP.
- 4.13.1 ERP Related Process for release of finished product.

The screenshot displays the ITM - QA Order Home - Eclipse SDK interface. The main window shows a table of QA orders with columns: QC Ord..., Date, T..., Item Code, Item Sh. Desc., Lot No, Quan..., Qty Pas..., Qty Reje..., and Rcp/WO No. The table contains multiple rows of data. A context menu is open over one of the rows, showing options like Edit, View, Comment, and Attachment. Red arrows and yellow callout boxes highlight the following steps:

- (1) Double Click to open QA Order Home (pointing to the 'I. QA Order' folder in the left tree).
- (2) Click to refresh data (pointing to the refresh icon in the toolbar).
- (3) Click to get Unconfirmed batches (pointing to the 'Unconfirmed' filter button).
- (4) Select desired batch & Click right button on mouse followed by Edit. (pointing to the right-click context menu on a row).

- 1 Double click QA order to Open QA Order Home Screen.
- 2 Click on refresh button.
- 3 Click to get unconfirmed batches.
- 4 Select desired batch & Click right button on mouse to select Edit with click.



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ITM - QA Order - Eclipse SDK

File Edit Navigate Search Project ECF Run Window Help

Enterprise Explorer

QA Order Home QA Order

**Basic**

QC Order No: 05TB00039 Order Date: 25/05/12

Site Code: S0005 DAMAN UNIT II PHASE II Type: Manufacturing

Spec Reference: Mfg Date:

Item Code: FG002558 Zidovudine 300 mg and Lamivudine 150 mg Tablets IP

(3) In case of Conditional release Select Yes and entered expected Release Date.

(6) Save the

DC No: DC Date: DD/MM/YY Item Series: PHA

Supplier name:

Qty Tested: 25 Cond. Rel. No Expc. Rel Date: DD/MM/YY

Quantity: 10555 Unit: B60 Qty Passed: 0

Qty Rejected: 0 Qty Sample: 0 A

Sample Unit: B60 Sampled: Potency: 0

Start Date: 25/05/12 Due Date: 25/05/12 Rel/COA Date: 25/05/12

pt/WOI No: 05WGBX0421 Line No: 1

(1) Enter date of Release

Location: QUAR QUARANTINE GOODS

rv Location: DPR X Rej. Location: REJC X

Surveyor: Lot #: ELX201A Lot SI: 15

Project: New Lot #: ELX201A

Remarks:

Sales Order No: Line No: Retest Date: DD/MM

Rejection Code:

Manual AR NO:

QAOrder Detail

Progress

Edit QA Order (Finished at 11:13 AM) OK

Edit QA Order (Finished at 11:13 AM) OK

Connected to Site : S0005

- 1 Enter the date of release.
- 2 Enter pass (release) quantity.
- 3 In case of Conditional release/Deviation, Select Yes and entered expected Release Date.
- 4 Enter sample as no.
- 5 In case of rejection/conditional release/deviation, write reason in Remark.
- 6 Click on save button to save the enter data.



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**(2) Click Confirm button to complete the process.**

**(1) Click Passed or Failed button based upon result.**

- 1 Click Passed or Failed button upon COA.
- 2 Click Confirm button to complete the process.

### 5.0 ANNEXURE (S):

- Annexure I : Finished product Register
- Annexure II : In-process & Semi-finished Product Register
- Annexure III : Validation sample inward Register
- Annexure IV : Swab sample inward Register
- Annexure V : Market Sample Register

### 6.0 REFERENCE (S):

SOP: Handling of Out of Specifications Results.



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SOP: Procedure for protecting password in ERP

SOP: QC Release of RM, PM & FG in ERP

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

### 7.0 ABBREVIATION (S)/DEFINITION (S):

COA : Certificate of Analysis

IPQA : In-process Quality Assurance

### REVISION CARD

S.N o.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---











