PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of Finished products, Semi-finished, In process, Validation and Swab Samples	**Effective Date:**
Supersedes: Nil	**Review Date:**
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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.

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4.9 The investigation shall be carried out as per SOP.

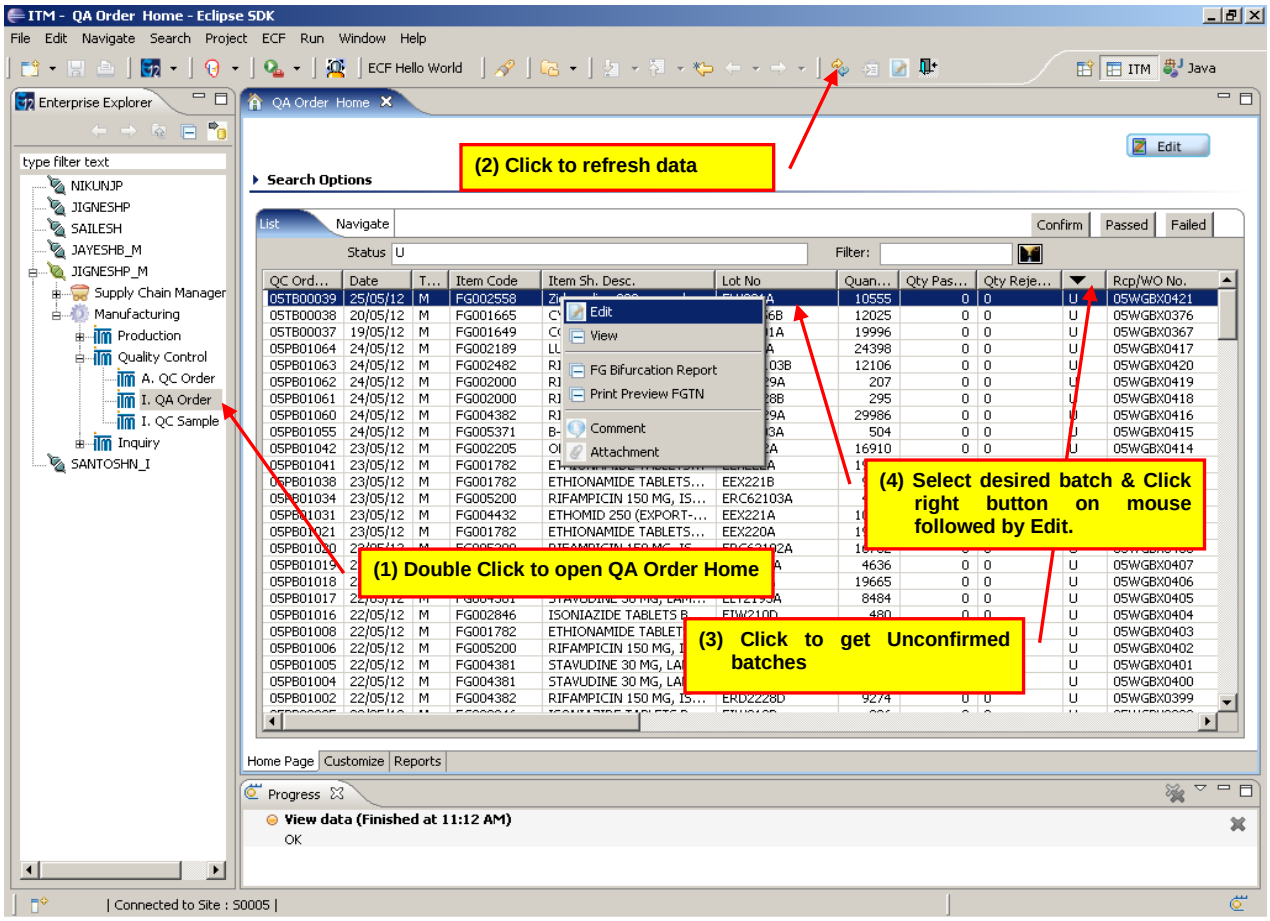
4.10 The COA of the sample shall be prepared as per respective specifications.

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.



1 Double click QA order t o 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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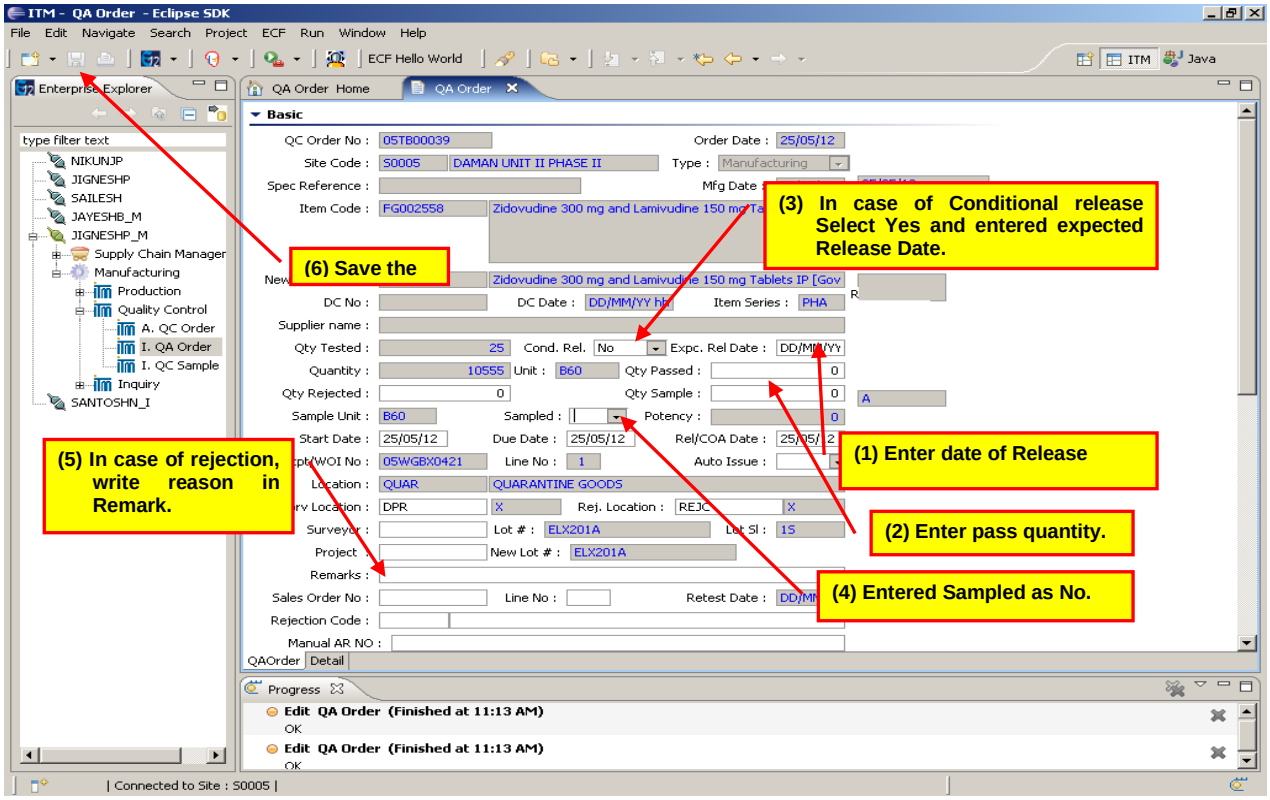

1 Enter the date of release.

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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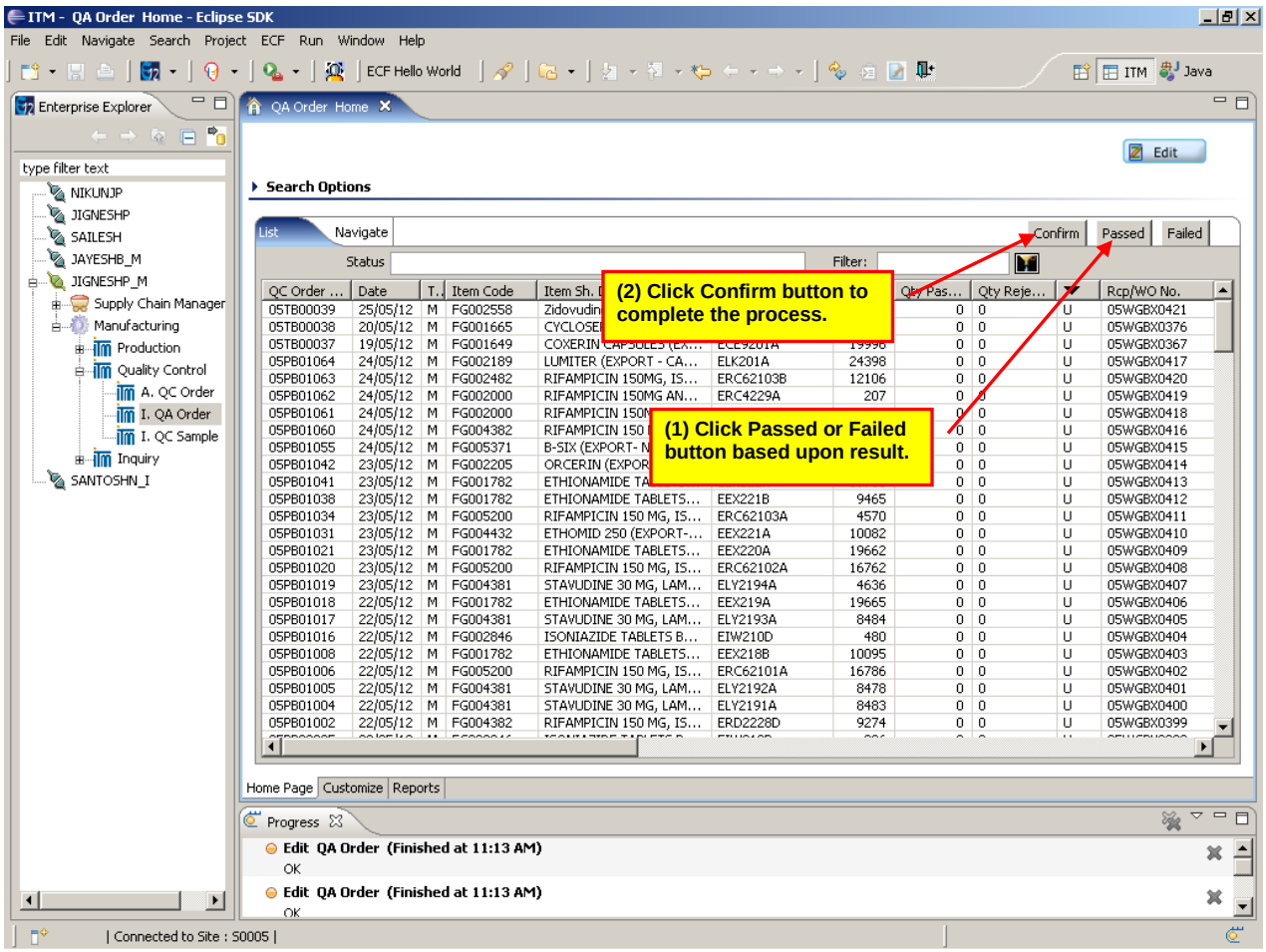

1 Click Passed or Failed button based upon COA.

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

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ANNEXURE I
FINISHED PRODUCT REGISTER

S. No.	Date of Intimation	Name of Product	B. No.	Mfg. Date	Exp. Date	Batch Size	A. R. No.	Date of analysis	Date of Release	Analyzed BY	Remarks

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ANNEXURE II
INPROCESS & SEMIFINISHED PRODUCT REGISTER

S. No	Date of Intimation	Product	B.No.	Mfg. Date	Exp. Date	Batch size/ Quantity	AR No.	Date of analysis	Date of Release	Analyzed by	Remarks

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ANNEXURE III
VALIDATION SAMPLE INWARD REGISTER

S.No.	Date of Intimation	Name of product	B. No.	Mfg. Date	Exp. Date	Batch size/ Quantity	Stage	AR No.	Date of analysis	Date of Release	Analyzed By	Remarks

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ANNEXURE IV
SWAB SAMPLE INWARD REGISTER

S. No.	Date of Intimation	Location Description	Previous product	Batch No.	Planned product	Analysis required for	A. R. No.	Date of analysis	Date of Release	Analyzed By	Remarks

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ANNEXURE V
MARKET SAMPLE REGISTER

S.No.	Date of Receipt	Name of the Product	B. No. / Lot No.	Mfg. Date	Exp. Date	Mfg. Name	Tests to be performed	A. R. No.	Date of Report	Remarks