



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

Document No.:

**ENTERPRISES RESOURCE  
PLANNING MANUAL**

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**ENTERPRISES RESOURCE  
PLANNING MANUAL**



**PHARMA DEVILS**  
(Oral Solid Dosage & Injectable Facility)



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### APPROVALS:

Approval of this ERP manual indicates agreement with the strategies and principles as outlined and commitment to support the handling of Enterprises Resource Planning System of the Solid oral dosage (Tablet, Capsule & dry syrup), Injectable (liquid & Dry) Facility at .....

Following signatures signify review and approval of this manual.

### PREPARED BY:

Functional Areas	Name	Signature	Date
Quality Assurance			

### REVIEWED BY:

Functional Areas	Name	Signature	Date
Production (Oral Solid Dosages)			
Production ( Injection)			
Quality Control			
Information Technology			
Quality Assurance			

### APPROVED BY:

Functional Areas	Name	Signature	Date
DGM Quality Assurance			

### AUTHORIZED BY:

Functional Areas	Name	Signature	Date
General Manager (QA/QC/DRA)			



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**1.0 INTRODUCTION:**

..... is a professionally engaged Pharmaceutical company, manufacturing various dosage forms and has emerged as a reputed pharmaceutical formulation manufacturer .The company using **Enterprises Resource Planning** system from year ..... This **Enterprises Resource Planning Manual** is related to handling of ERP System in manufacturing facility of ..... The site manufactures Tablets, Capsules, Liquid Injectable, Dry Syrup & Dry Injectable in General category.

**2.0 OBJECTIVE:**

The objective of the Enterprises Resource Planning manuals to summarize the philosophy, intentions and approach for handling of Enterprises Resource Planning system and maintaining the quality system in accordance with current good manufacturing practices (cGMP)/current good laboratory practices (cGLP).

**3.0 SCOPE:**

The scope of this document is for the Handling of Enterprises Resource Planning system and maintaining the quality system for the manufacturing products at .....

**4.0 RESPONSIBILITY:**

In order to achieve the objective for the collection of complete details of ERP System, following shall be the responsible.

Department	Responsibility
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Shall Prepare &amp; Review the manual.</li><li>• Collection and attachment of all required documents with manual.</li><li>• Handling of the Enterprises Resource Planning System by authorized person and make entry in the Enterprises Resource Planning.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Review the manual for correctness, completeness and technical excellence.</li><li>• Handling of the Enterprises Resource Planning System by authorized person and entry in the Enterprises Resource Planning.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review the manual for correctness, completeness and technical excellence.</li><li>• Handling of the Enterprises Resource Planning System by authorized person and entry in the Enterprises Resource Planning System at the time of manufacturing and packing process stage.</li></ul>
<b>Warehouse</b>	<ul style="list-style-type: none"><li>• Handling of the Enterprises Resource Planning System by authorized person and entry in the Enterprises Resource Planning System at the time of process and Dispatch.</li></ul>
<b>Human Resource &amp; Account</b>	<ul style="list-style-type: none"><li>• Handling of the Enterprises Resource Planning System by authorized person and entry in the Enterprises Resource Planning System at the time of material entry in company.</li></ul>

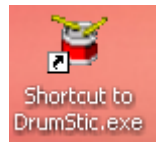


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<b>Information Technology</b>	<ul style="list-style-type: none"><li>• Review the manual for correctness, completeness and technical excellence.</li><li>• To Support all the department for handling of Enterprises Resource Planning System.</li><li>• Conduct the Enterprises Resource Planning System Validation as per define schedule.</li></ul>
<b>ERP Vendor</b>	<ul style="list-style-type: none"><li>• To change the Enterprises Resource Planning Software as per the company Requirement.</li></ul>

### 5.0 OPERATION OF ENTERPRISES RESOURCE PLANNING (ERP) SYSTEM:

5.1 The company is having Separate Enterprises Resource Planning system (Drum Stick) with latest version of the same. Each department user can use Enterprises Resource Planning system. The drum stic.exe icon display on the each user system.



5.2 The user person can open the ERP by the double click on the icon. The icon shows open file window, in this file RUN and CANCEL option display.



5.3 The User can click on the RUN option for the start of the ERP. Computer screen display Login Screen, Company name, User name and Password.



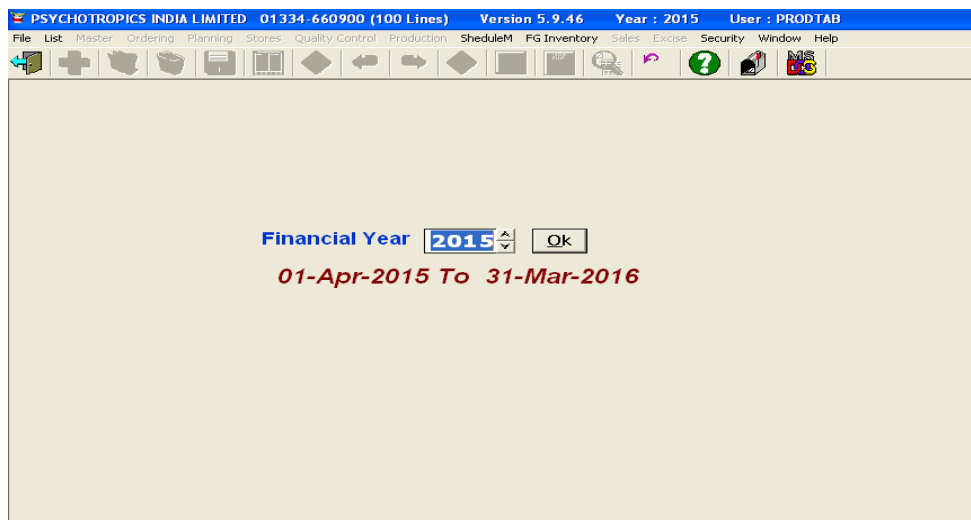
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5.4 The User can enter username and password as per the assigned by the Information Technology Department (IT)/Administrator, and click on the OK button, (Click on the CANCEL option if not want to use ERP) If user forget user and password contact to IT Department.



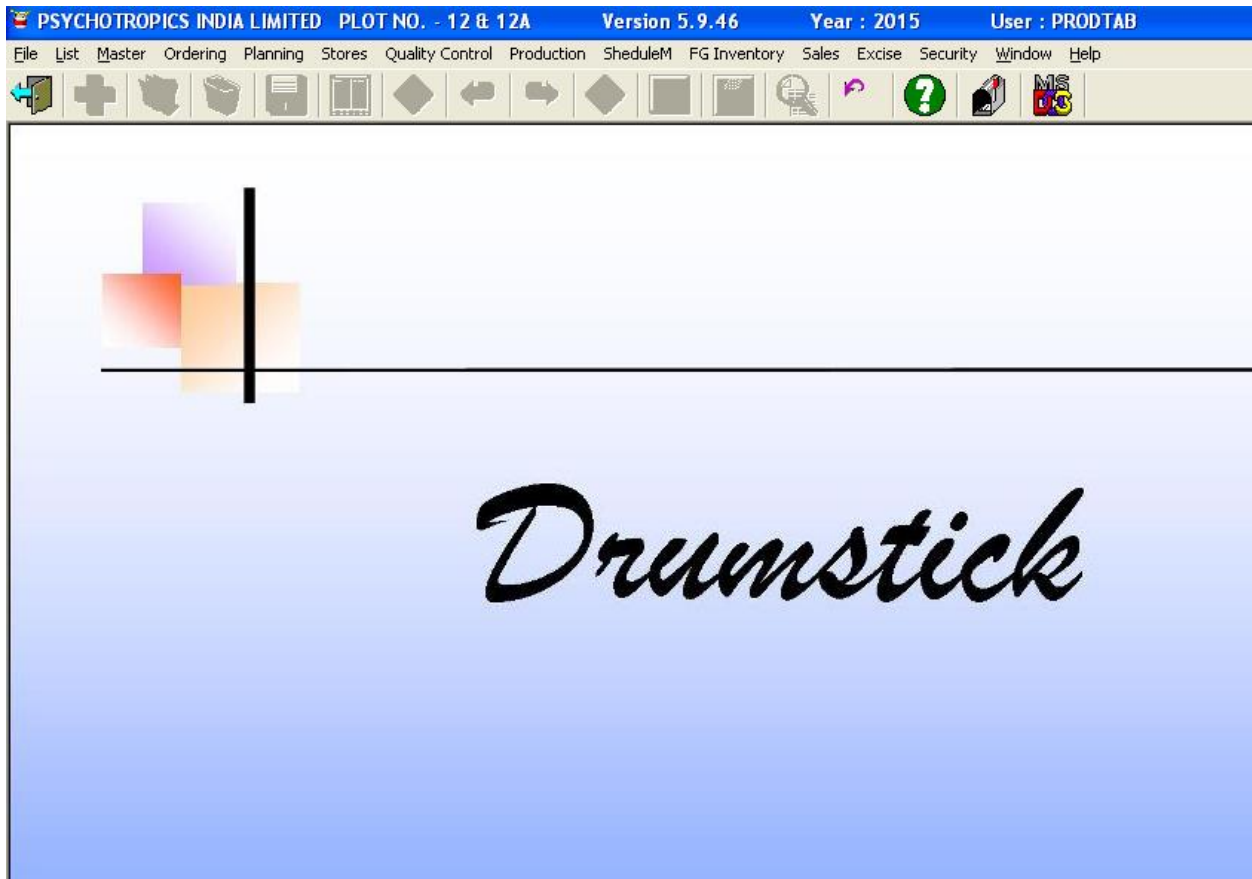
5.5 The ERP screen shows company name, company phone no., latest version No., Year ,user, Financial Year option with up and down key, OK, below of the screen display vendor address, Phone No. , Mail ID, Date and Time.





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5.6 The user can select the year as per the requirement, and click the OK option. The home page display Drum Stick and other option (File, List, Master ,Ordering , Planning, Store ,Quality Control, Production, Schedule M, FG Inventory, Sale , Excise, Security , Window and Help.



5.7 The user can change the financial year through Security Module in ERP System.



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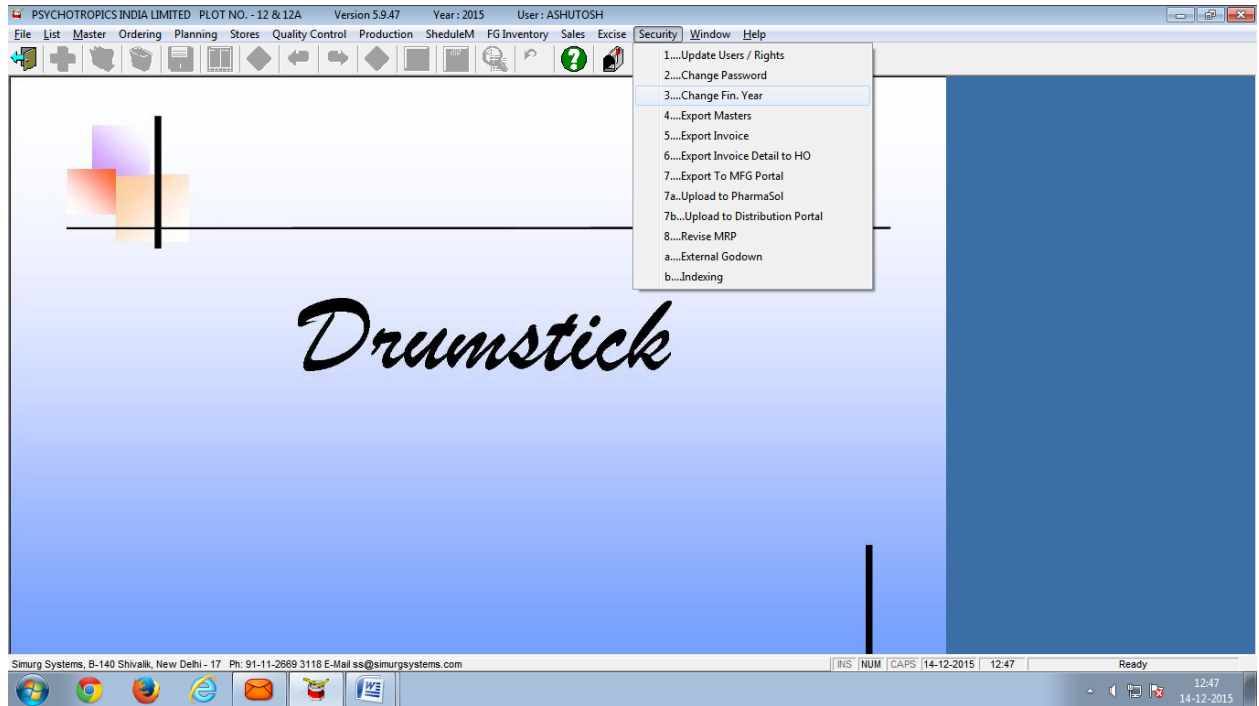
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## 6.0 ENTERPRISES RESOURCE PLANNING MANAGEMENT SYSTEM

- 6.1 The ERP System used by the authorized persons of the each department. Each department user can enter details in ERP System and start the ERP for daily use.
- 6.2 The Production Department informs to purchase department for new raw materials for manufacturing of new products.
- 6.3 The Purchase Department generates new Purchase Order (PO) in ERP by entry in Ordering Module generation option.





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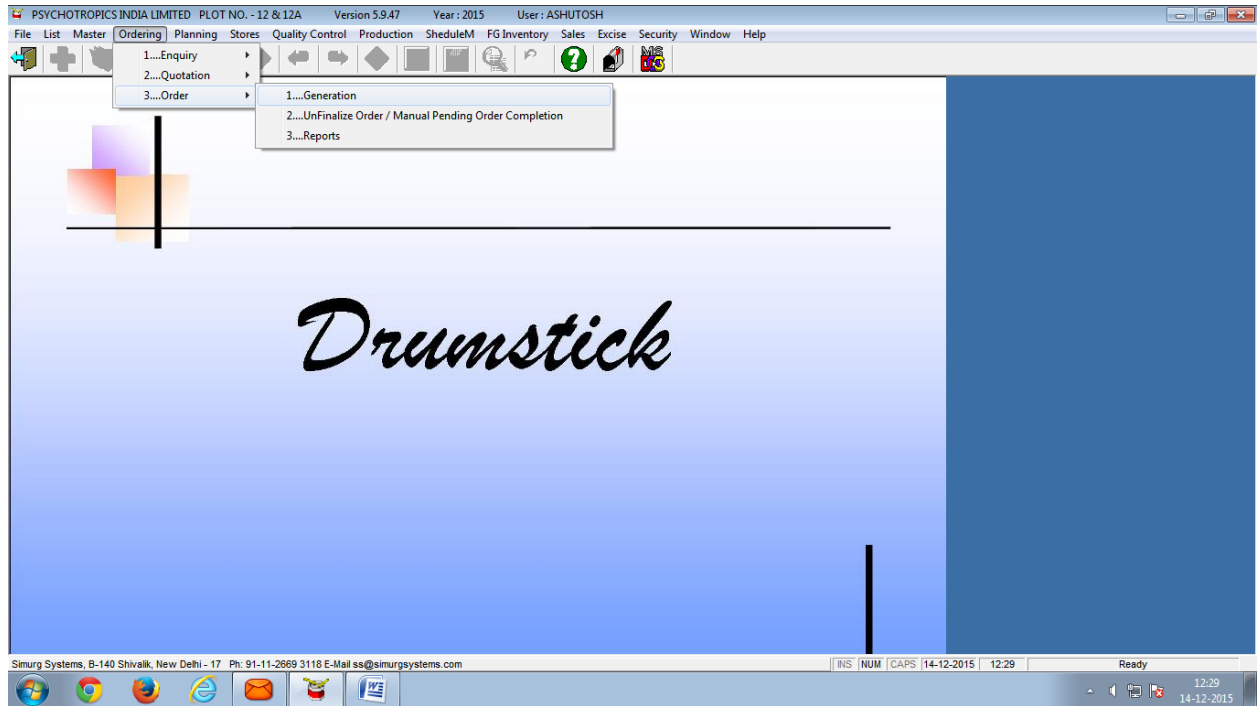
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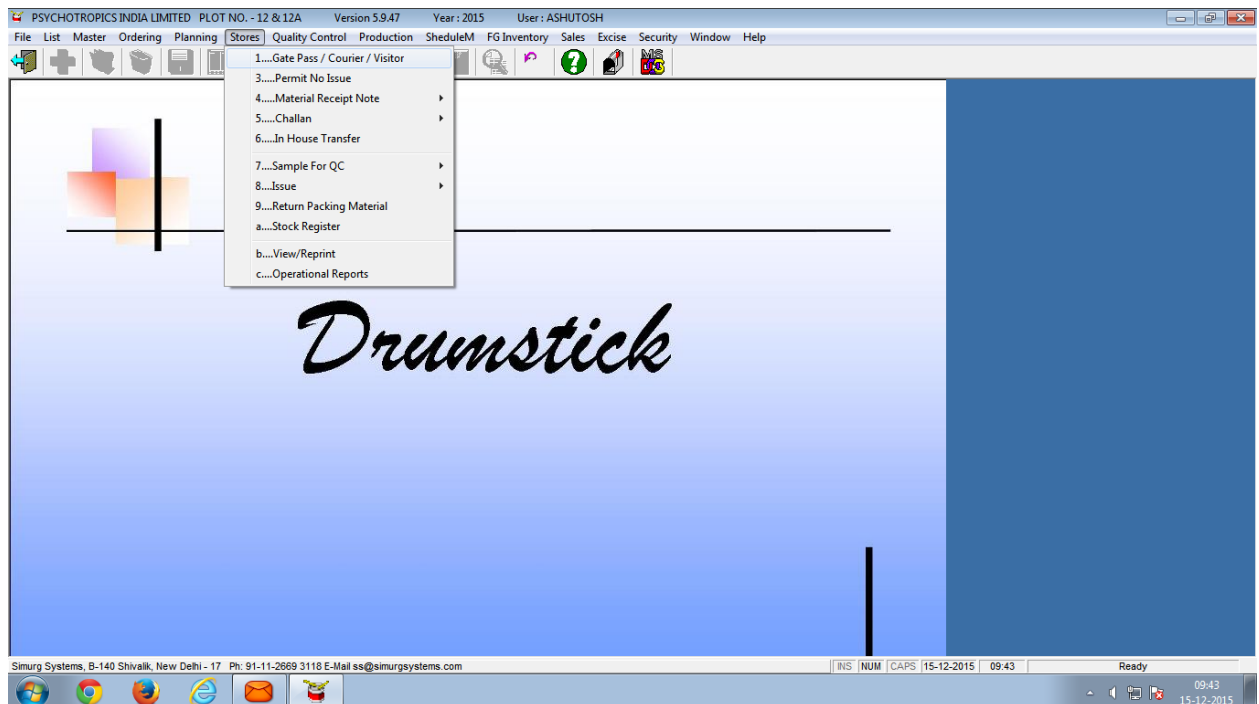
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6.4 On the basis of P.O. Vendor provide Materials to Company.

6.5 The Material reached in company gate Human Resources- Security persons make entry of all details in Store Module of the ERP System and hand over to copy of the same to Warehouse.



6.6 The warehouse person generates Material Receipt Note for new Materials in ERP System's Store Module.



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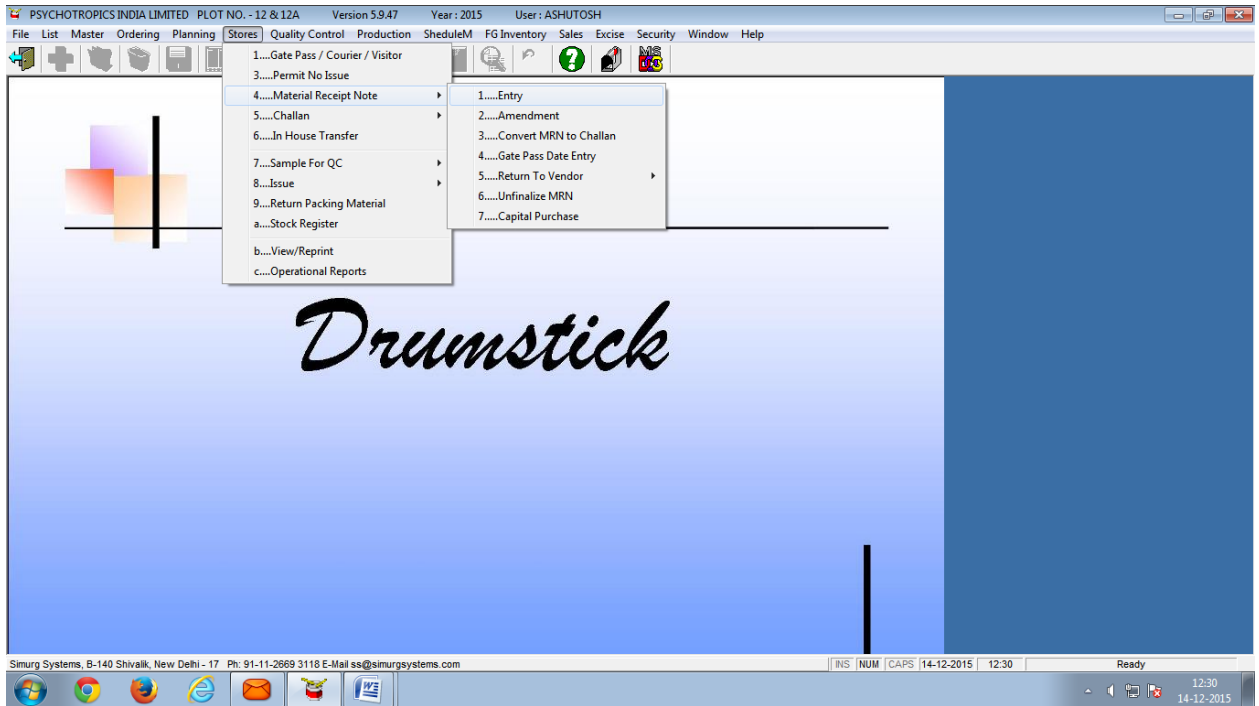
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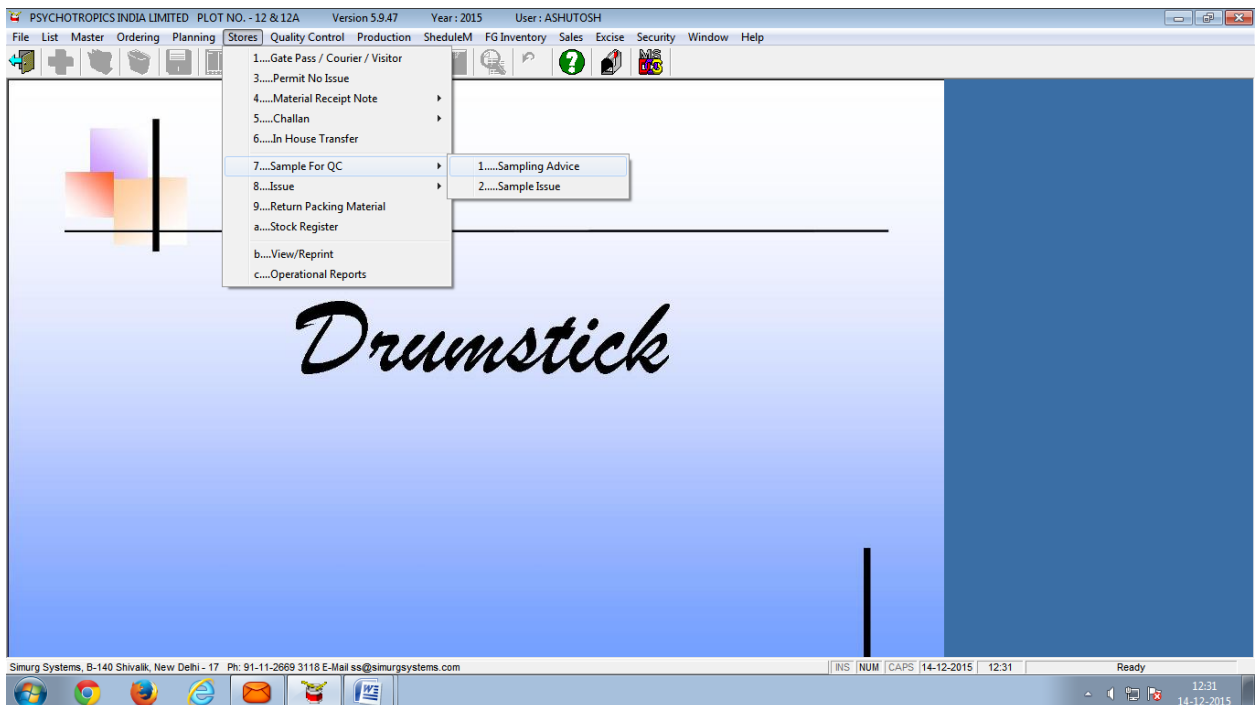
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6.7 After Entry in MRN option Account department verify the data and transfer the same in their Finance Software.

6.8 After MRN of new material Warehouse person make entry in sample for QC Sampling advice option for sampling purpose of QC and forward all the details to QC department, with this details take a final print out and signed on defines space and send to QC for the further action, simultaneously take print out of Quarantine labels through ERP and affixed on the materials, and transfer the material Quarantine area.





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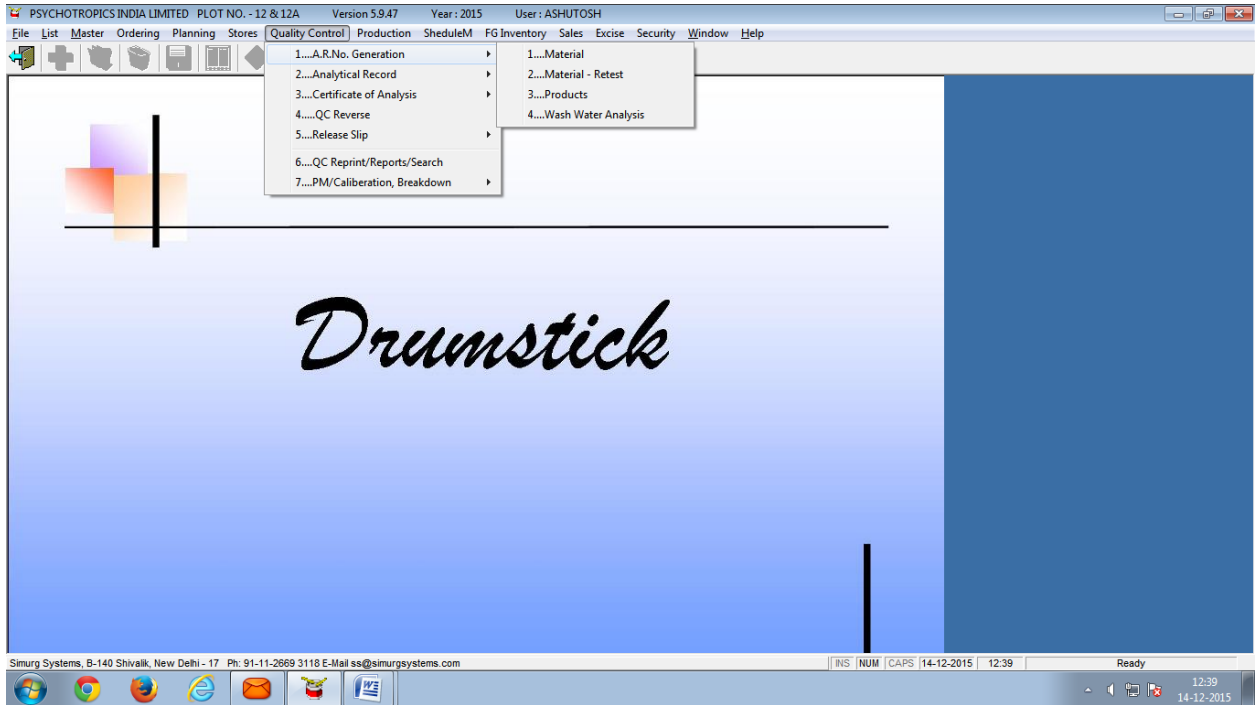
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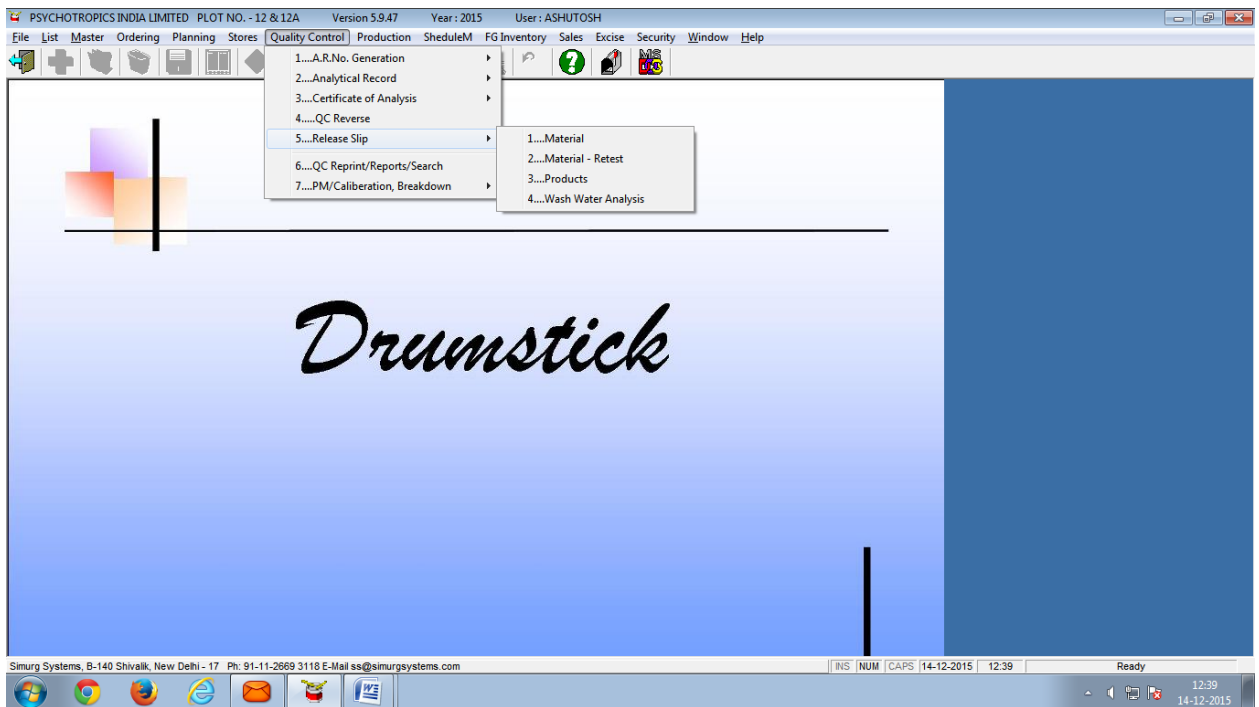
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6.9 After receiving of sampling advice, QC person generate new A.R. No. and analytical report for new material, after sampling the materials, transfer the material Quarantine to Under Test area.



6.10 QC person test the new materials and generate new Release slip.



6.11 The QC person also generates Certificate of analysis of the new materials and attached with documents.



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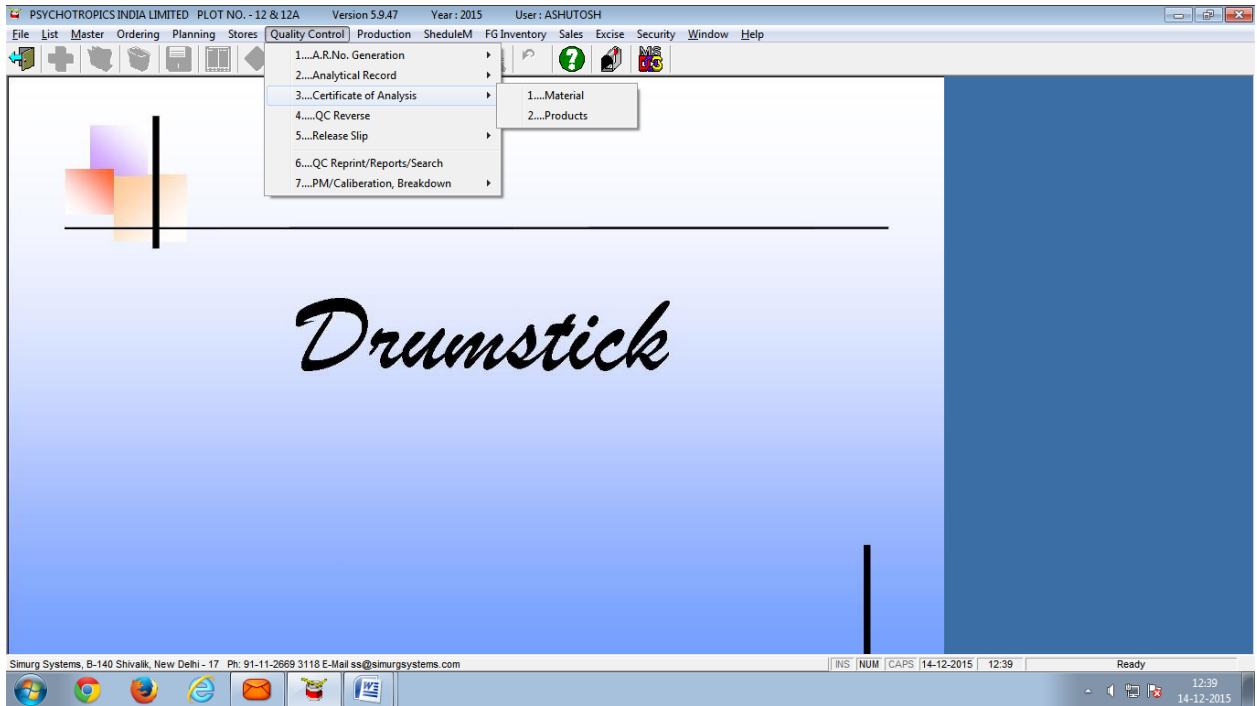
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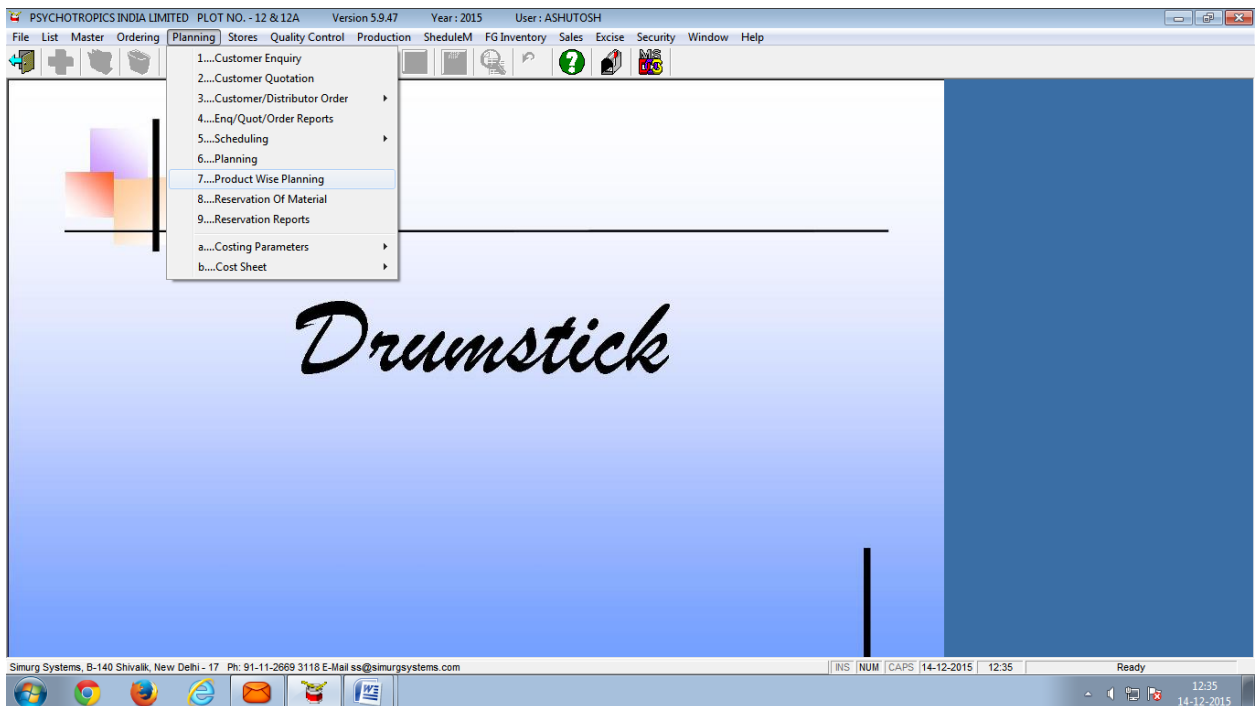
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- 6.12 The Warehouse persons checked the status of the material in ERP on daily basis if material is approved the material display in Stock list if material if reject the material display in Reject stock list, warehouse person transfer the material from Under test to Approved area.
- 6.13 If any material in Retest period the ERP system display the same. The warehouse person follows the point No. 6.6.1 to 6.6.5.
- 6.14 As per the materials availability Production Person Initiate the batches in ERP through Planning Module.





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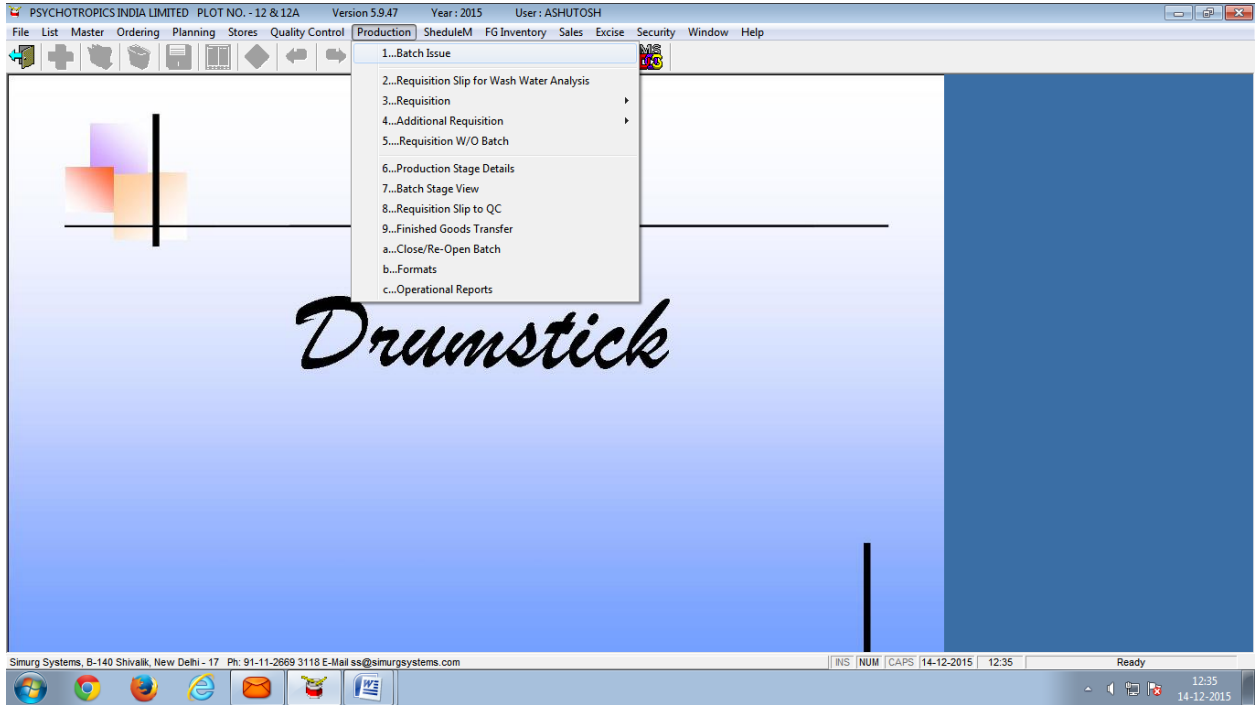
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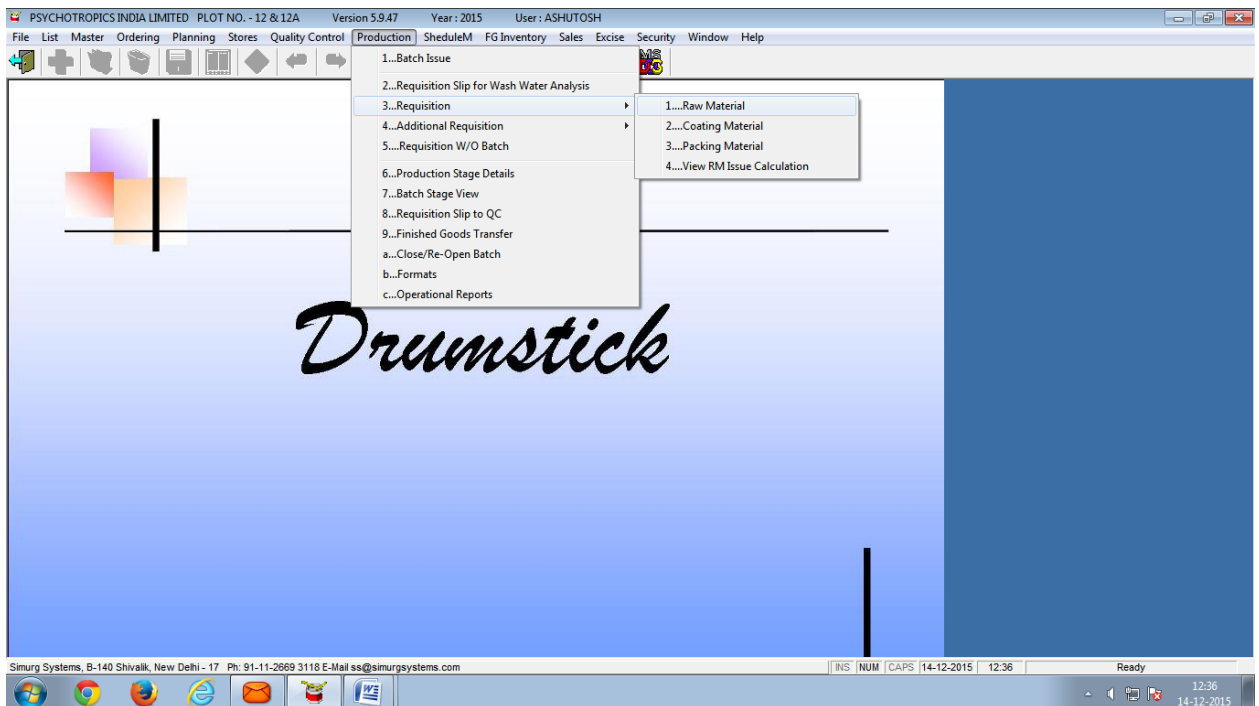
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6.15 After production planning production person generate Batches in ERP through Production Module.



6.16 On the basis of Production plan Production person generate the Raw Material Requisition Slip/ Packing Material Requisition Slip from ERP System, IPQA person verifies the raw /packing slip, Active material calculation and handover to store person.



6.17 On the basis of Production Requisition slip, Warehouse person generate the Raw Material Issue Slip/ Packing Material Issue Slip, the ERP system automatically deduct the Raw/ Packing materials.



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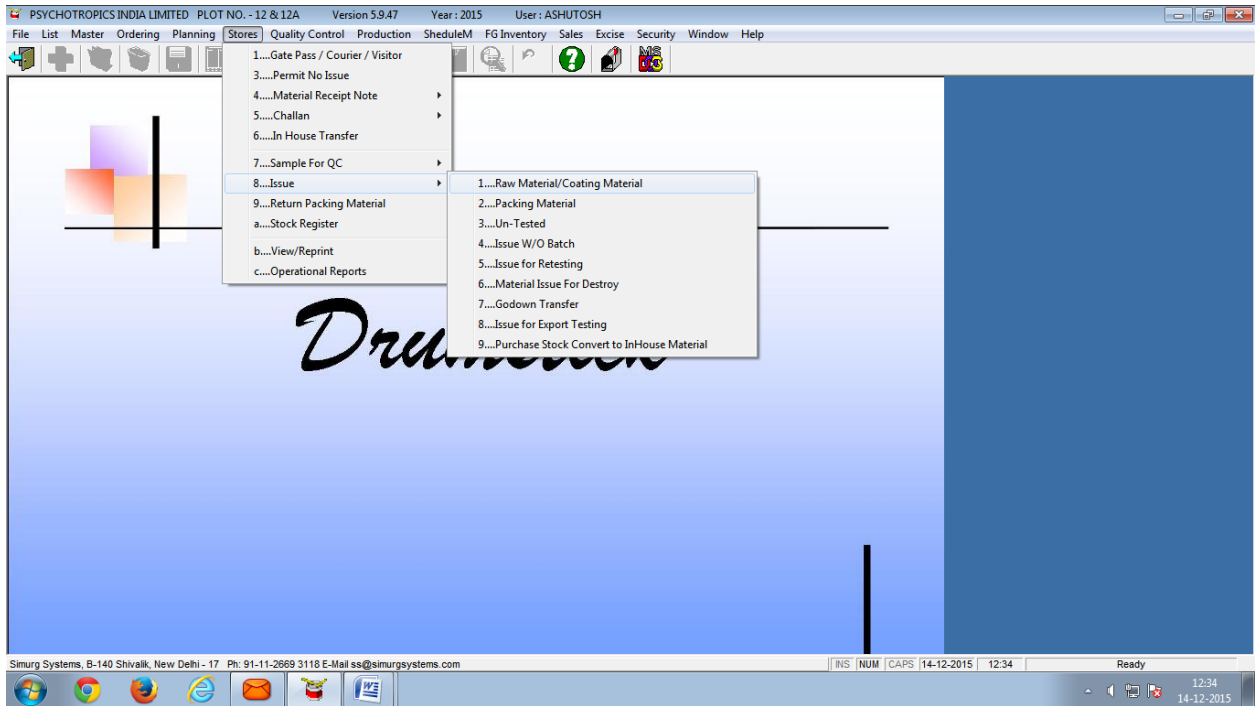
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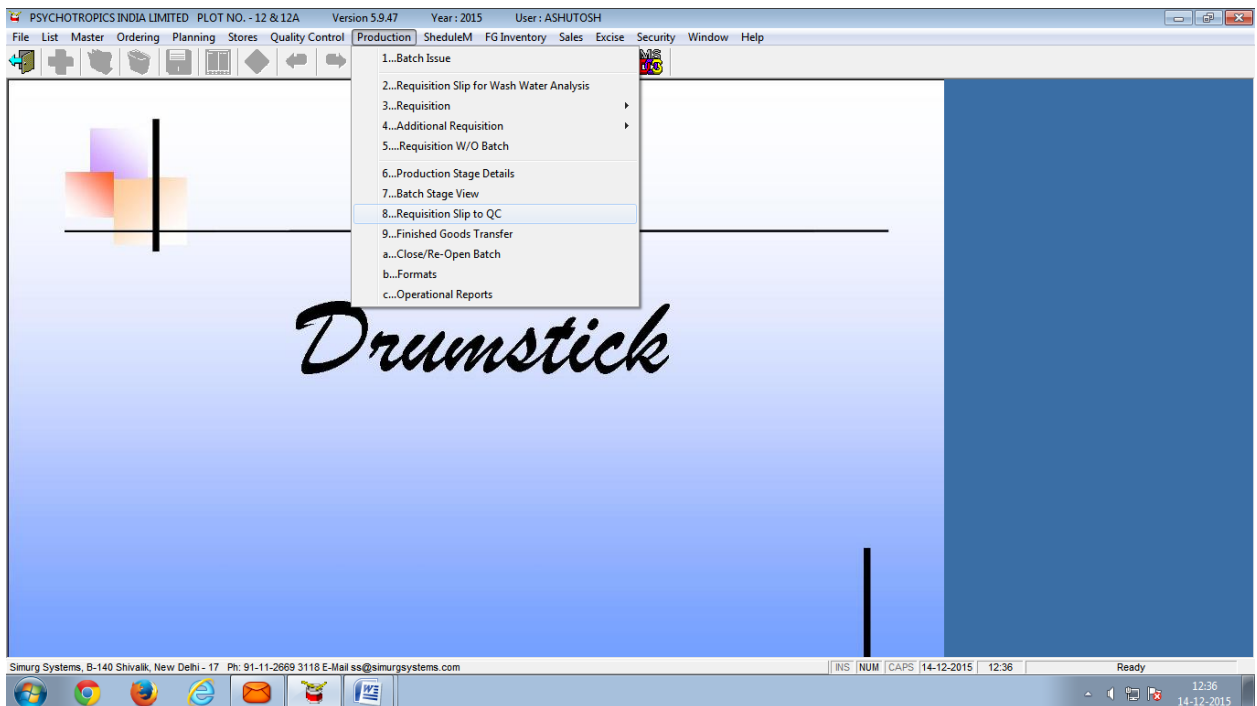
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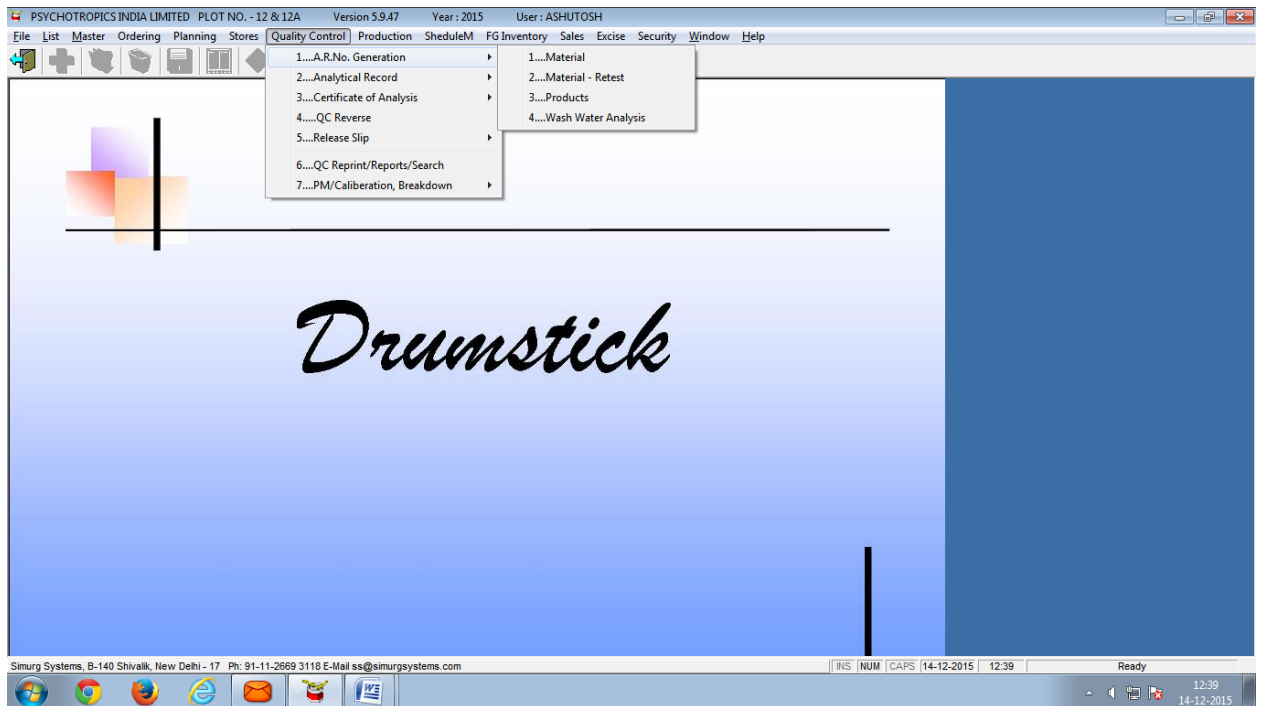
- 6.18 The Warehouse persons dispense the material on the basis of Material slip, and handover the material to Production.
- 6.19 After completion of different manufacturing process, Production department generate the Bulk Requisition slip for sample testing/Semi-Finished Requisition slip for sample testing/Finished Product Requisition slip for sample testing and forward to QC through ERP and take a print out of the same and hand over to IPQA.





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- 6.20 IPQA person collect the samples as per Bulk Requisition slip for sample testing/Semi-Finished Requisition slip for sample testing/Finished Product Requisition slip and send to QC Department with written Requisition.
- 6.21 QC person test the products of different manufacturing stages and generate test data sheet.
- 6.22 After receiving of Bulk Requisition slip for sample testing/Semi-Finished Requisition slip for sample testing/Finished Product Requisition slip , QC person generate new A.R. No. and analytical report for test material in ERP.



- 6.23 QC persons test the bulk/Semi Finished /finished material and release the products and generate the Bulk Release slip / Semi- Finished Release slip and forward to Production through ERP, QC person hand over the release copy to IPQA, same attached in BMR/BPR.





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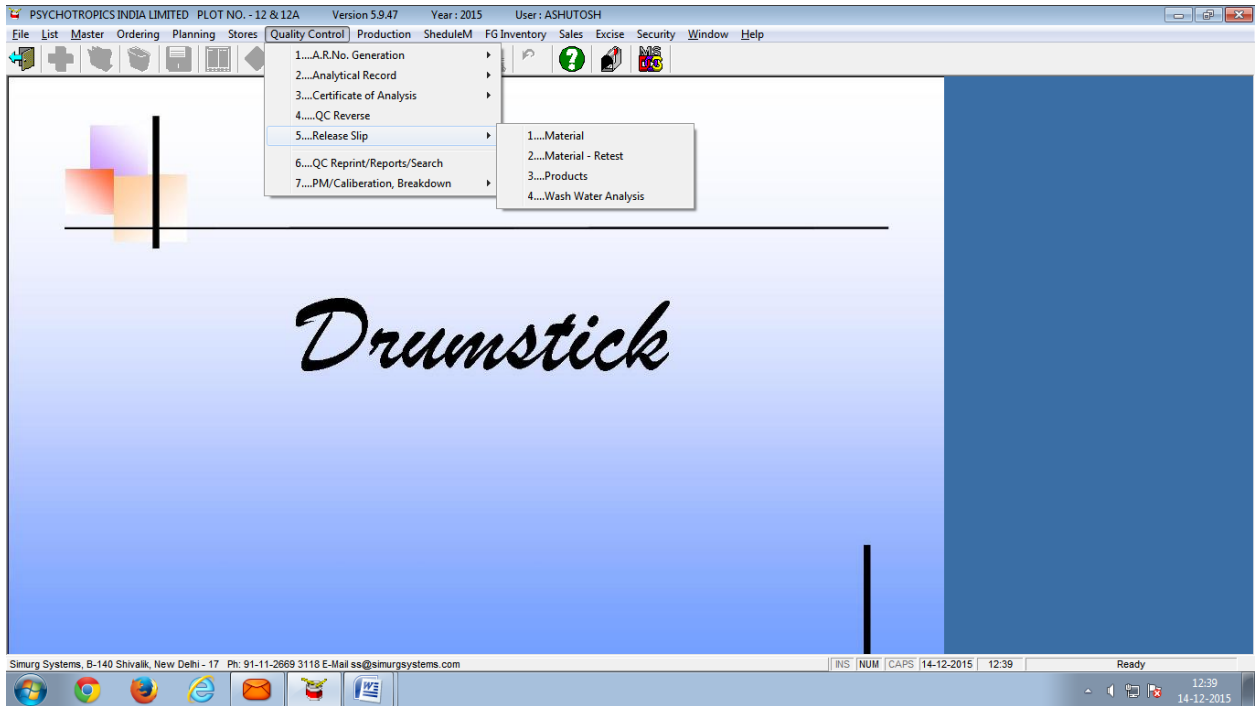
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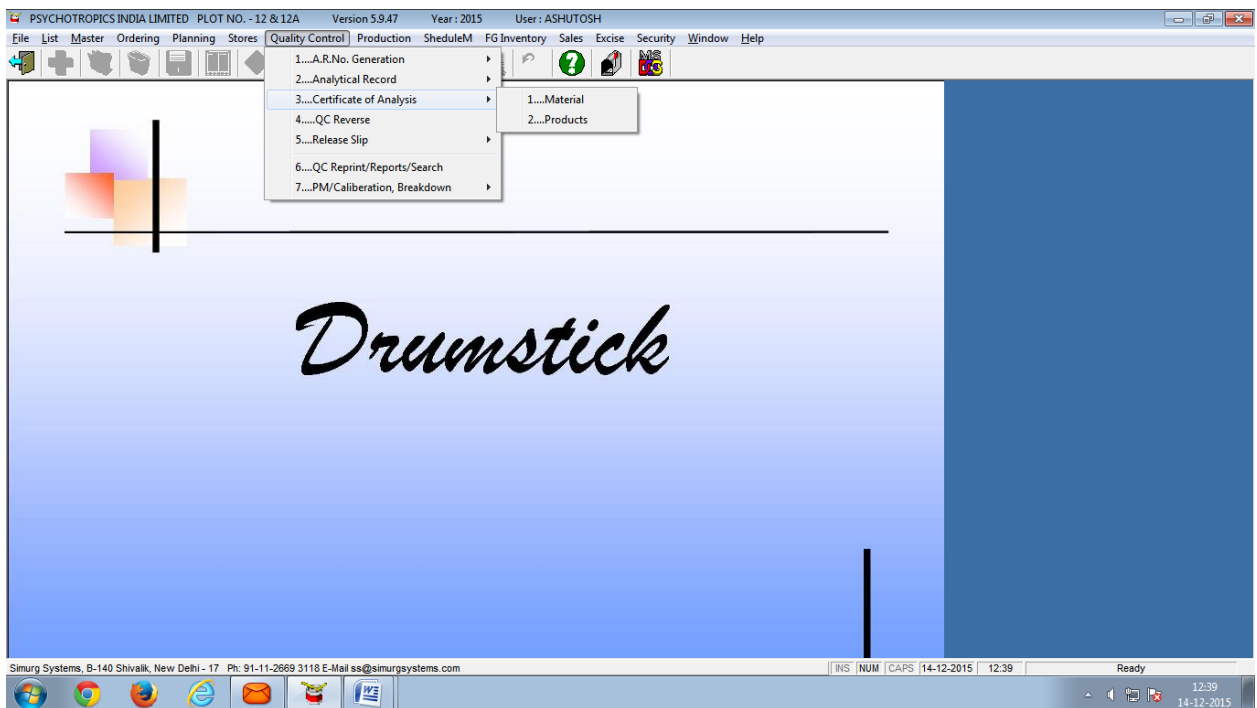
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6.24 QC persons test the finished Product and generate the Finished Product Certificate of analysis slip and forward to Production through ERP, QC person hand over the release copy to IPQA, same attached in BMR/BPR.



6.25 After completion of packing process and release from QC, Production person Transfer the QA in ERP through Finished Goods Transfer option (take print out).





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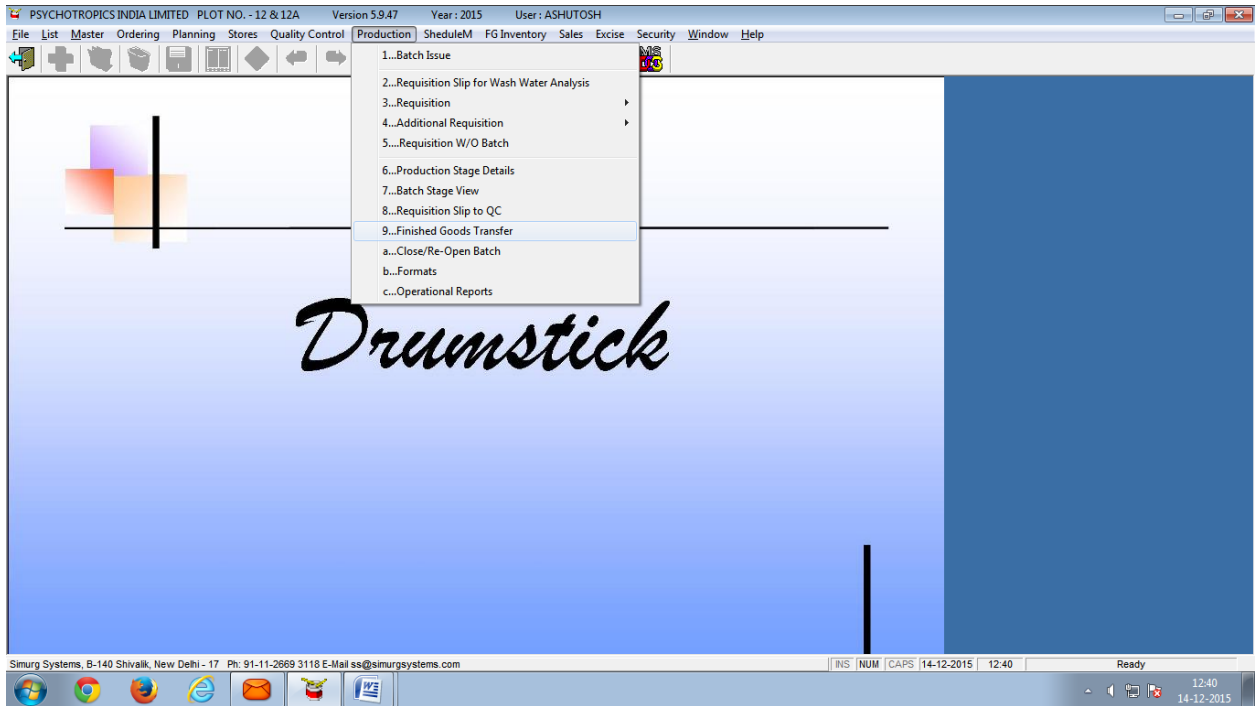
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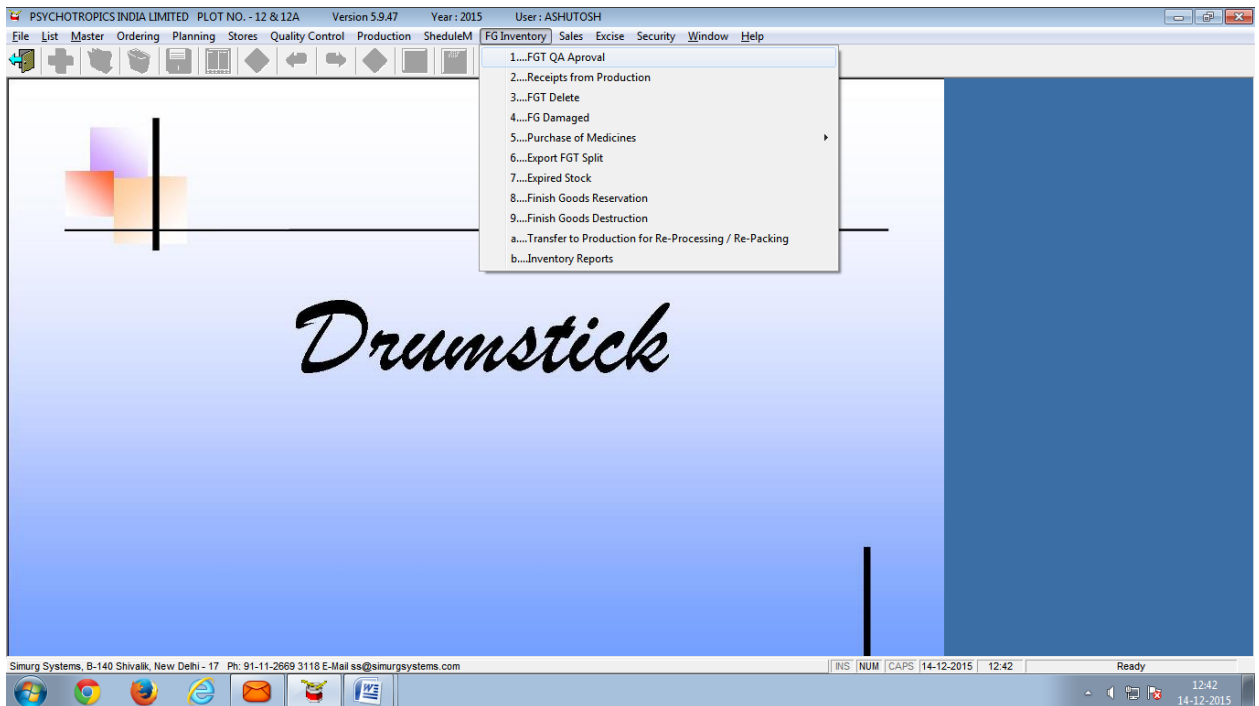
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6.26 After signature on FGT print out by IPQA, Head QA approved the Product Finished Goods Transfer Note in ERP and forward to FG Store, QA take final print out of the same for attachment in BMR/BPR and for FG Store.



6.27 After approval from QA, FG Person received the Finished Goods stock in ERP System and copy of the same attached in FG record.



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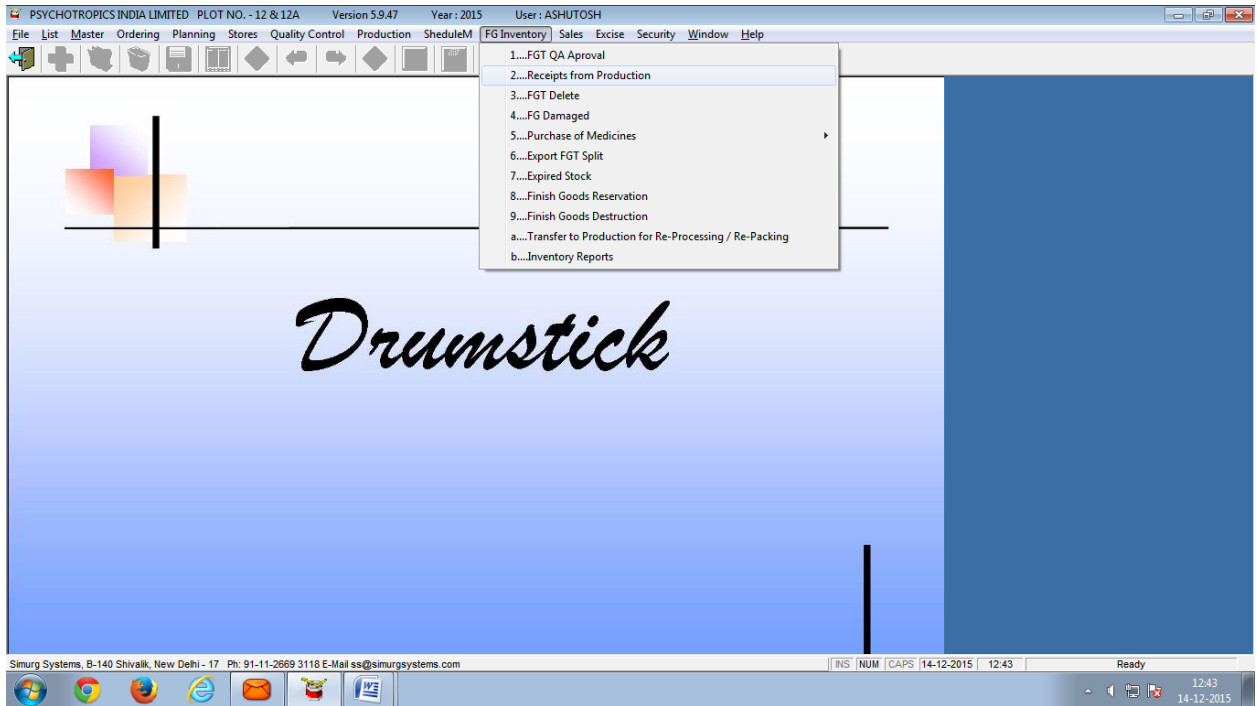
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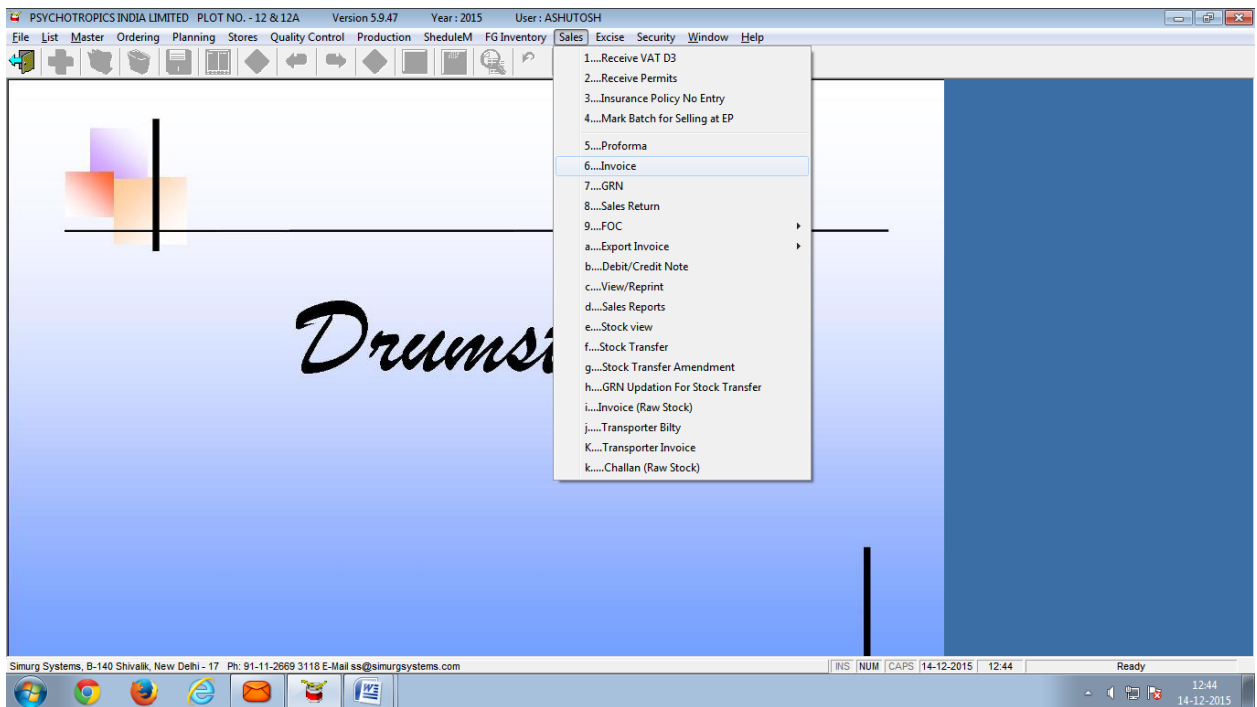
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6.28 FG Person Prepare Invoice copy in ERP System as per the party Requirement and transfer the stock to the party.





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## 7.0 UPDATION OF ERP SYSTEM

The updation (For any new option/facility implementation in ERP Software) in ERP System is the part of the IT Department. As per the requirement of changes in ERP, IT Department can be initiated for change in ERP through **Change control Policy**. After change in ERP by the Vendor, IT Department is responsible for the re- training of the same.

## 8.0 ERP SYSTEM TRAINING REQUIREMENT

The selection and training of competent personnel is an important consideration in establishing and maintaining an effective ERP system control program. Personnel having the necessary education, training, background, and experience shall perform operations. After opening a new account/login in ERP, Head IT shall give the proper training for handling of ERP.

For the detail procedure refer to the Training Procedure **SOP**.

## 9.0 QUALIFICATION/ REQUALIFICATION CRITERIA

Major or Critical changes, or refurbishments, should be accompanied by verification activities analogous to those used for the validation. These new versions would incorporate all changes to the system that were handled under change control from the time of the initial production release until the revalidation takes place and would supersede the previous versions.

Re-verification is recommended in these cases:

- Following updates/upgrades of system software or system hardware
- Following major changes, which also impact the structure (major-changes)
- Following major system faults
- Following changes to be environmental or operational conditions
- If any of the above conditions do not occur then any computerized system shall be revalidated **every five years from out side Agency**. This is to take care of general decay in performance of any electronic components/systems which has been used on regular basis in the period.