



Pharmacy Information System (PhIS) and Clinic Pharmacy System (CPS)

User Manual Pharmacy Inventory - Product Complaint

Version	: 4th Edition
Document ID	: FB_U.MANUAL_INV_PRODUCT COMPLAINT



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1.0 Introduction

1.1 Overview of PhIS

Pharmacy Information System or better known as PhIS, is a complete and comprehensive system that integrates pharmacy related services that geared toward pharmacy excellence. PhIS implementation would transform most of current manual process to electronic system would benefit facility end user in the health care sector.

There are 12 modules to assist services delivery by the health care sector which comprises of:

1. Order Management
2. Inpatient Pharmacy
3. Outpatient Pharmacy
4. Medication Counselling
5. Ward Pharmacy
6. Pharmacy Inventory
7. Manufacturing of Cytotoxic Drug Reconstitution, Parenteral Nutrition, IV Admixture & Eye Drop, Radiopharmaceuticals and Extemporaneous
8. Adverse Drug Reaction & Drug Allergic (ADR & DAC)
9. Clinical Pharmacokinetics Services (TDM)
10. Drug Information & Consumer Education (DICE)
11. Medication Therapy Adherence Clinic (MTAC)
12. Data Mining (PhARM)

1.2 Purpose and Objectives

This user manual outlines the Product Complaints sub-module and its key features and functionalities. The primary objective is to guide user through the process of completing PhIS application process.

User will understand the following activities in details:

- Create New Product Complaints Record
- Product Complaint Investigation

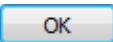
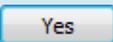
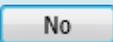
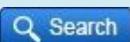
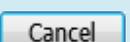
1.3 Organised Sections

These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Product Complaints
- Section 4 : Acronyms

2.0 Application Standard Features

2.1 PhIS Legend

Standard Legend			
	Login to PhIS		Logout from PhIS
	Close All Open Tabs		Refresh Screen
	Expand Menu		Collapse Menu
	Expand Module		Collapse Module
	Add/Create New Record		Save
	Close Window		Calendar Icon
	Save Transaction		Delete Record
	Export Report From PDF file to Excel file		OK Button
	Yes Button		No Button
	Radio Button		Checkbox
	System Automatic Generate Record No.		Automatically Display/Retrieve Box
	Reset Login Screen		Show Help
	Display Home Tab		Search Record
	Cancel		Dropdown Box
	Search Icon	*	Mandatory Field
	Edit Record		Empty Text Box
	Cancel Button		

Note

- To learn more about Login Information, kindly click [Login Information](#) Modules for descriptive step.

3.0 Product Complaints

Overview

The Product Complaint module allows any user to lodge their complaints online about a product and the complaint form will be sent to the Drug Information Services Unit set by the facility. Pharmacist in charge will receive the product complaint as a message in the Task List and perform internal investigation.

User Group

This module is intended for storekeeper and pharmacists at the Pharmacy Store, Pharmacist and Assistant Pharmacist at the Sub Store; Sister and Nurse at the unit/ward. (subject to user assign by the facility)

Functional Diagram

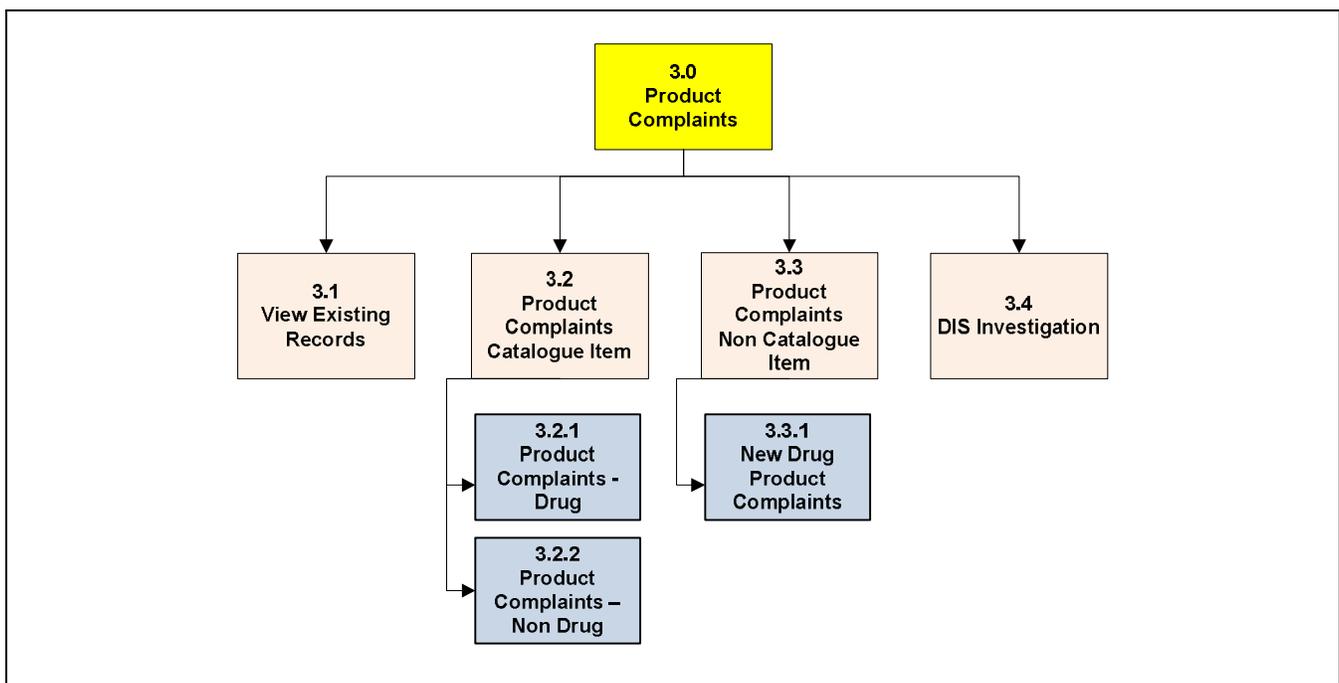


Figure 3.1

Functional Description

Product complaints comprises of four (4) main functions:

- **Product Complaints**
This function allows user to view all existing transactions
- **Product Complaints Catalogue Item**
This function is used to create new product complaints that are listed in the drug catalogue item
- **Product Complaints Non Catalogue Item**
This function is used to create new product complaints that are listed in the non drug catalogue item
- **Product Complaint Investigation**
This function allows user to receive and investigate the validity of a complaints received on a product

3.1 View Existing Product Complaints Record

To view existing Product Complaints record, perform the steps below:

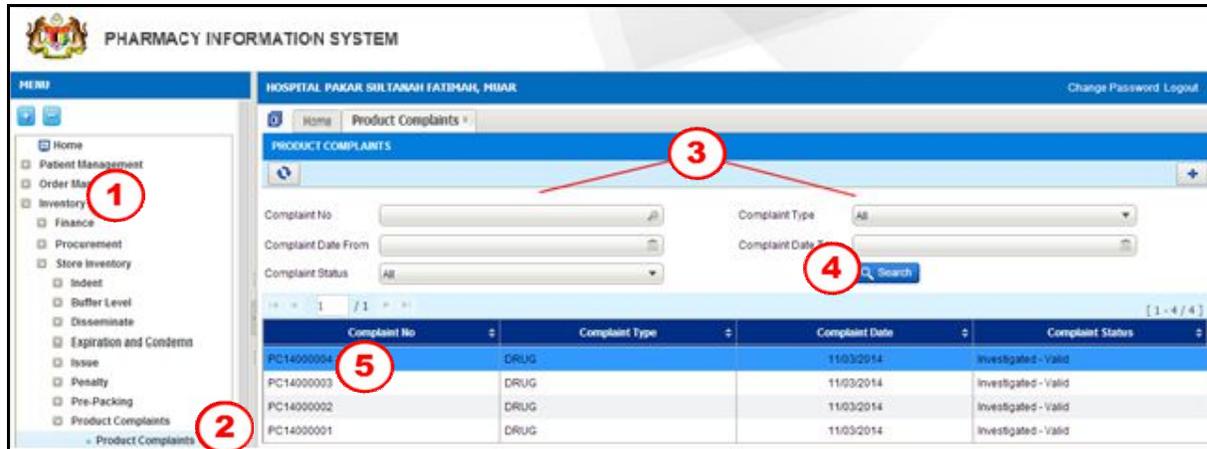


Figure 3.1-1 Create New Product Complaints

STEP 1

Click on 'Inventory menu' and click on 'Store Inventory' Sub-Menu

STEP 2

Click on 'Product Complaints'

STEP 3

To search for existing Product Complaints record(s), search by criteria as follow:

No	Field	Description	Remarks
a	Complaints No.	Product complaints Number	Display all existing Product complaints No. belongs to the requester unit
b	Complaints Type	Search by : All Drug Non Drug	Able to filter and search record(s)
c	Complaints Status	Search by: All Investigated – Invalid Investigated – Valid Investigation – Pending Open	Able to filter and search record(s)
d	Complaints Date From	Start date for the product complaints transaction	Format field (dd/mm/yy)
e	Complaints Date To	End date for the product complaints transaction	Format field (dd/mm/yy)

Table 3.1-1

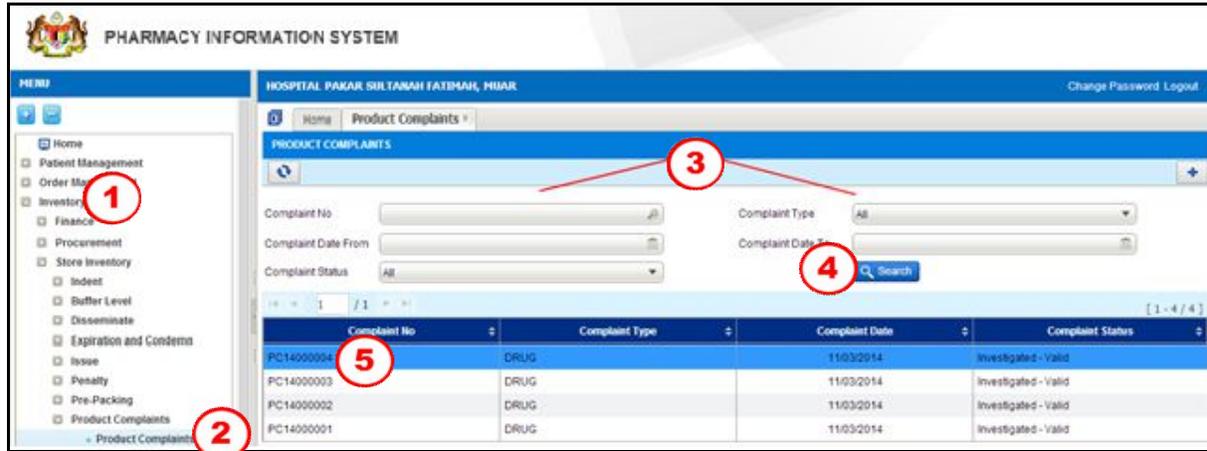


Figure 3.1-2 Create New Product Complaints

STEP 4

Click on the  button

Note

The result display will be based on the entered criteria as shown in Figure 3.1-2.

STEP 5

Double click on the selected record and the details will be displayed in Figure 3.1-3

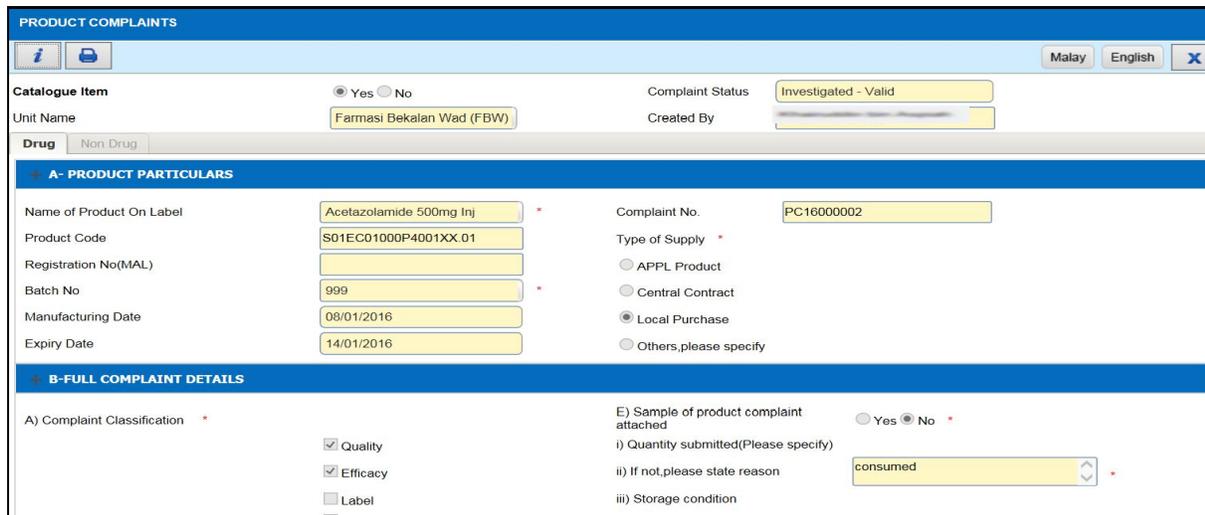


Figure 3.1-3 Products Complaints

3.2 Product Complaints Catalogue Item

Catalogue Items are items that are available in the facility's Catalogue. Product Complaints on Drug and Non Drug item can be logged by any user of PhIS. Pharmacist at the DIS Unit will then decide the Complaints' validity.

3.2.1 Product Complaint – Drug

To create a new Drug Product Complaints – Catalogue Item, perform the steps below:

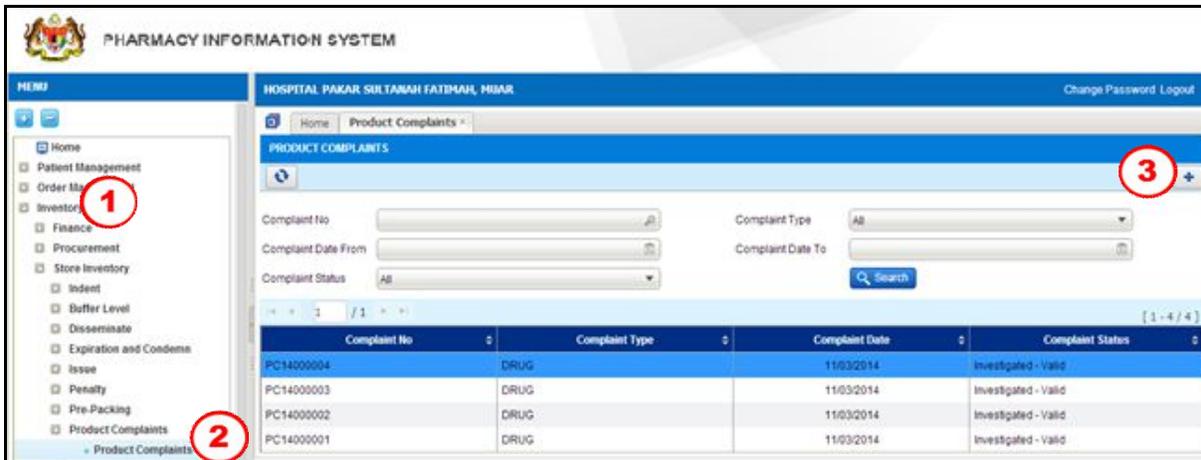


Figure 3.2.1-1 Product Complaints

STEP 1

Click on 'Inventory menu' and click on 'Store Inventory' Sub-Menu

STEP 2

Click on 'Product Complaints'

STEP 3

Click on the  button to record new complaints

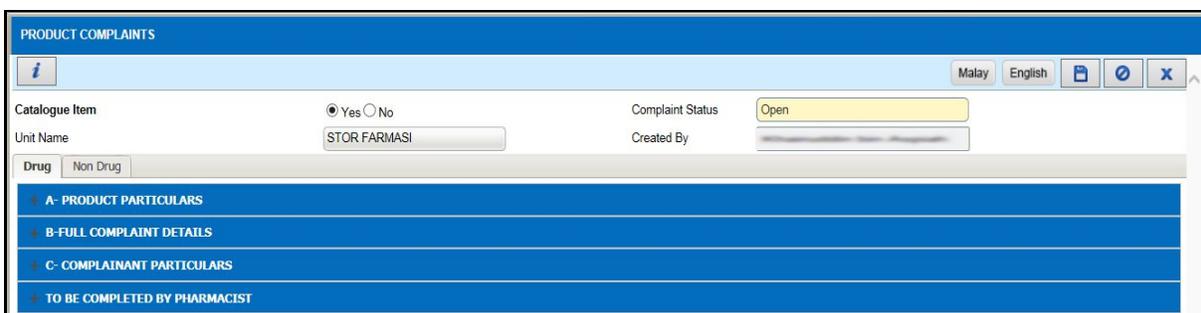
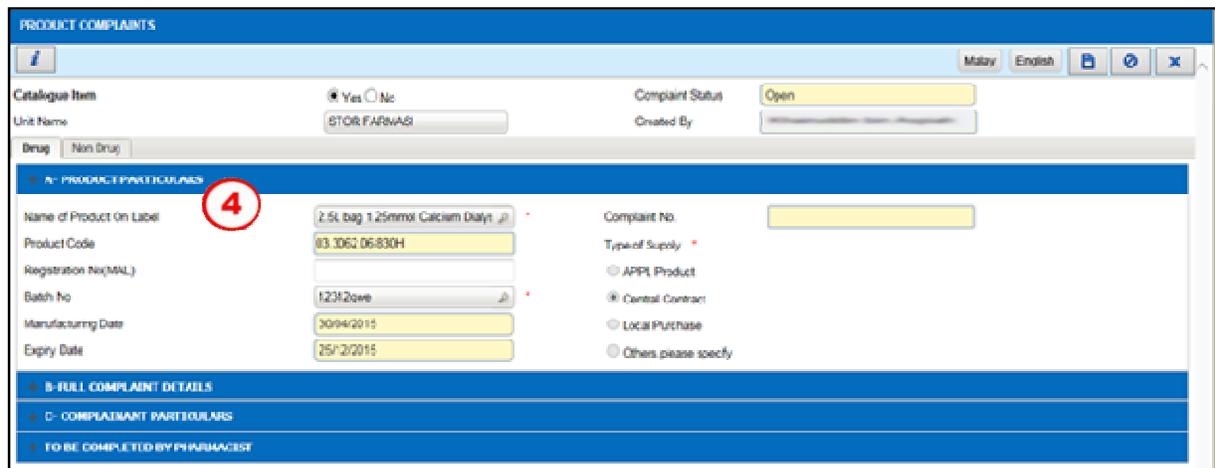


Figure 3.2.1-2 New Drug Product Complaints – Catalogue Item

Note

- Product Complaints screen will be displayed in Figure 3.2.1-2
- Default language is English; however, it is changeable to Malay language by clicking on the  button.
- The **Catalogue Item** radio button is default to 'Yes'. Change to 'No' if the Product Complaints item is not a catalogue item from the facility.
- Complaints on Drug and Non Drug item will have a different type of form. Select Non Drug tab if would like to lodge a Product Complaints on a Non Drug Item.
- These are the three (3) sections in a New Product Complaints form required to be filled:
 - A. Product Particulars
 - B. Full Complaints Details
 - C. Complainant Particulars
- The sections can be maximized or minimized by clicking on the Header.

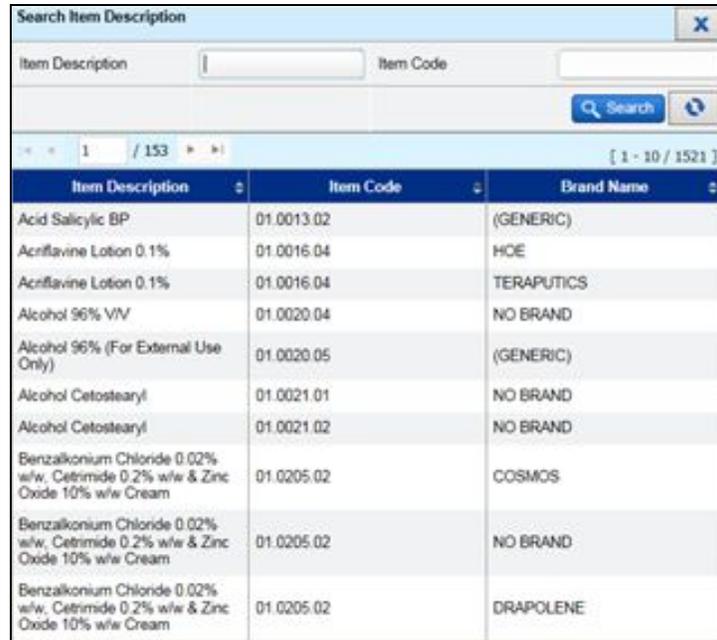


The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top right, there are buttons for 'Malay' and 'English'. Below that, there are fields for 'Catalogue Item' (Yes/No), 'Complaint Status' (Open), and 'Unit Name' (STOR FARMASI). There are also 'Drug' and 'Non Drug' tabs. The main section is divided into four parts: 'A- PRODUCT PARTICULARS', 'B- FULL COMPLAINT DETAILS', 'C- COMPLAINANT PARTICULARS', and 'D- TO BE COMPLETED BY PHARMACEUT'. In section A, there are fields for 'Name of Product On Label' (with a red circle and number 4), 'Product Code', 'Registration No(MAL)', 'Batch No', 'Manufacturing Date', and 'Expiry Date'. There are also radio buttons for 'Type of Supply' with options: 'APPI Product', 'Central Contract', 'LOCAL PURCHASE', and 'Others, please specify'.

Figure 3.2.1-3 Product Particulars

STEP 4

Click on the **Name of Product On Label**  button and 'Search Item Description' window will be displayed as Figure 3.2.1-4



Item Description	Item Code	Brand Name
Acid Salicylic BP	01.0013.02	(GENERIC)
Acriflavine Lotion 0.1%	01.0016.04	HCE
Acriflavine Lotion 0.1%	01.0016.04	TERAPUTICS
Alcohol 96% V/V	01.0020.04	NO BRAND
Alcohol 96% (For External Use Only)	01.0020.05	(GENERIC)
Alcohol Cetostearyl	01.0021.01	NO BRAND
Alcohol Cetostearyl	01.0021.02	NO BRAND
Benzalkonium Chloride 0.02% w/w, Cetrimide 0.2% w/w & Zinc Oxide 10% w/w Cream	01.0205.02	COSMOS
Benzalkonium Chloride 0.02% w/w, Cetrimide 0.2% w/w & Zinc Oxide 10% w/w Cream	01.0205.02	NO BRAND
Benzalkonium Chloride 0.02% w/w, Cetrimide 0.2% w/w & Zinc Oxide 10% w/w Cream	01.0205.02	DRAPOLENE

Figure 3.2.1-4 Search Item Description and/or Item Code

Note

Item Description and/or Item Code allows to do random search based on criteria entered regardless partially and/or fully.

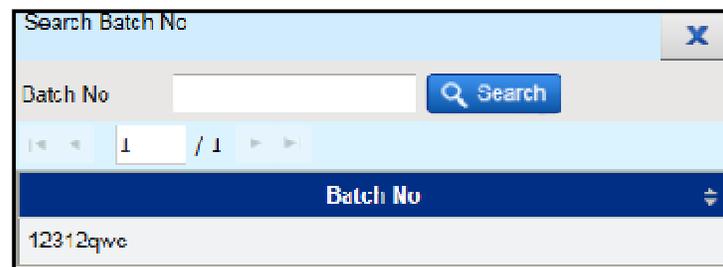
Click on the  button.

Type of Supply will be automatically selected based on the Name of Product on Label selected.

Product Code will be automatically displayed based on the Name of Product on Label selected.

STEP 5

Click on the **Batch No**  button and 'Search Batch No' window will be displayed as Figure 3.2.1-5



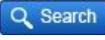
Batch No
12312qwe

Figure 3.2.1-5 Search Batch No

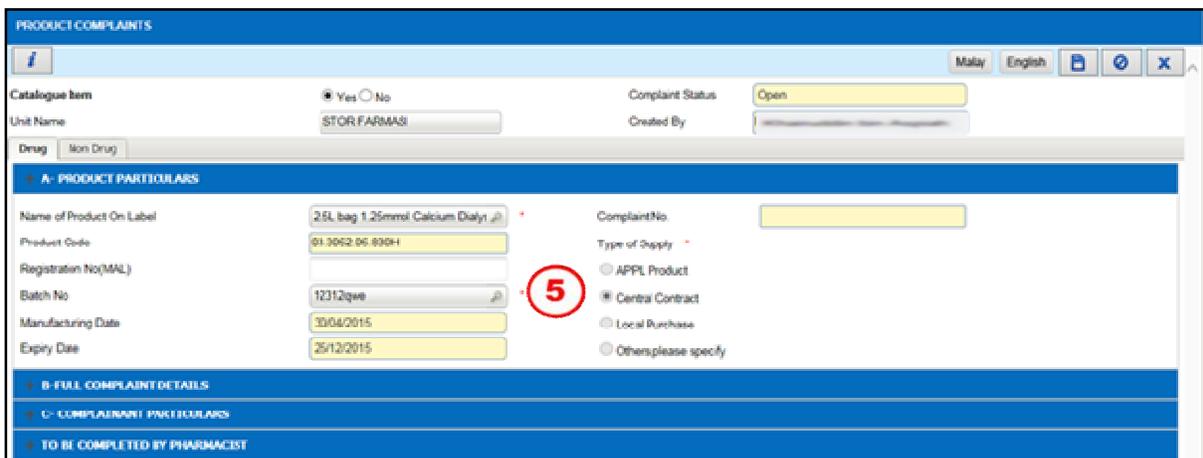
Note

Only **Batch No** available in the user's department will be displayed.

Batch No. allows to do random search based on criteria entered regardless partially and/or fully.

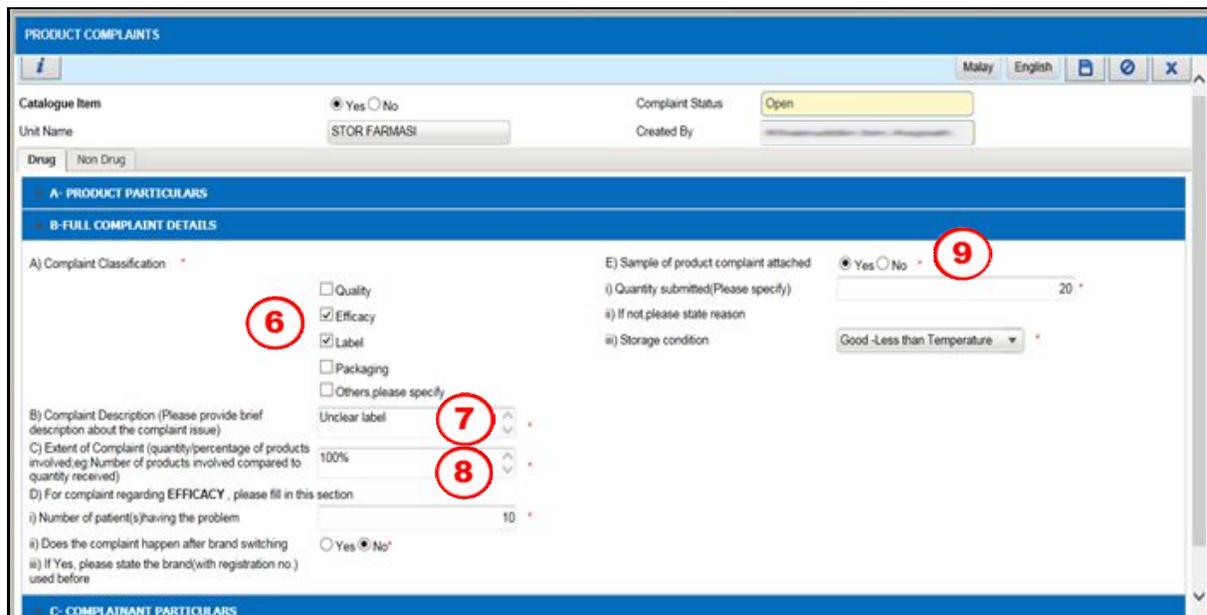
Click on the  button.

Registration No. (MAL), Manufacturing Date and Expiry Date will be auto displayed based on the **Batch No** selected.



The screenshot shows a web application interface for 'PRODUCT COMPLAINTS'. At the top, there are language options for 'Malay' and 'English', and window control buttons. Below this, there are input fields for 'Catalogue Item' (with 'Yes' and 'No' radio buttons), 'Complaint Status' (set to 'Open'), 'Unit Name' (set to 'STOR FARMASI'), and 'Created By'. A 'Drug' / 'Non Drug' toggle is also present. The main section is titled 'A- PRODUCT PARTICULARS' and contains several fields: 'Name of Product On Label' (25L bag 1.25mmol Calcium Dialy), 'Product Code' (01-3062-06-830H), 'Registration No(MAL)', 'Batch No' (12312qee), 'Manufacturing Date' (30/04/2015), and 'Expiry Date' (25/12/2015). To the right of these fields are 'Complaint No.' and 'Type of Supply' (with radio buttons for 'APPL Product', 'Central Contract', 'Local Purchase', and 'Others, please specify'). A red circle with the number '5' is drawn around the 'Batch No' field. Below this section are three more sections: 'B- FULL COMPLAINT DETAILS', 'C- COMPLAINT PARTICULARS', and 'TO BE COMPLETED BY PHARMACIST'.

Figure 3.2.1-6 Product Particulars



The screenshot shows the 'PRODUCT COMPLAINTS' form with the following details:

- 6**: A) Complaint Classification. Checkboxes for Quality, Efficacy, Label, Packaging, and Others please specify. 'Efficacy' and 'Label' are checked.
- 7**: B) Complaint Description (Please provide brief description about the complaint issue). Text input field containing 'Unclear label'.
- 8**: C) Extent of Complaint (quantity/percentage of products involved, eg. Number of products involved compared to quantity received). Text input field containing '100%'.
- 9**: E) Sample of product complaint attached. Radio buttons for Yes/No. 'Yes' is selected.

Figure 3.2.1-7 Full Complaints Details

STEP 6

Select the **Complaints Classification** checkbox as appropriate and user can select more than one.

- Quality
- Efficacy
- Label
- Packaging
- Others

Note

If the user selects the Complaints Classification as Others, Please Specify Field will be displayed.

STEP 7

Enter **Complaints Description**

STEP 8

Enter **Extent of Complaints** (quantity/percentage of products involved compared to the quantity received)

Note

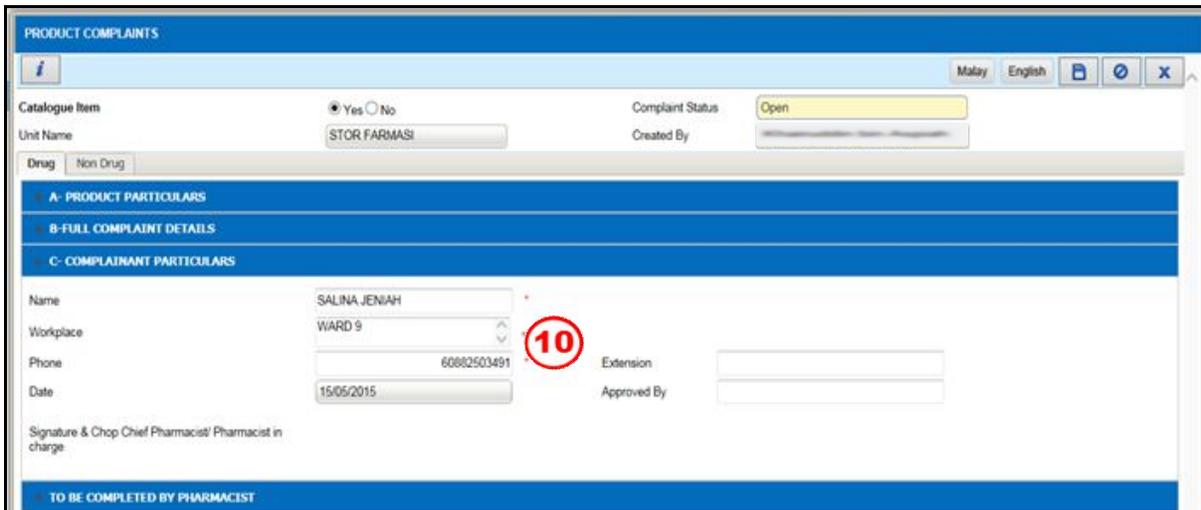
- If the **Complaints Classification** is selected as Efficacy, these fields will be enabled for the user to enter/select:
 - i. Number of Patient(s) having the problem.
 - ii. Does the Complaints happen after Brand switching?
- If 'Yes' radio button is selected for 'Does the Complaints happen after brand switching', User has to state the iii) brand (with Registration No.) used before.

STEP 9

Select from the Yes/No radio button for **Sample of product Complaints attached**

Note

- If 'Yes' radio button is selected, user has to state the i) Quantity submitted and the ii) Storage Condition.
- If 'No' radio button is selected, user has to state only the ii) Reason



The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top, there are language options for Malay and English, and window control buttons. Below this, there are fields for 'Catalogue Item' (Yes/No), 'Complaint Status' (Open), 'Unit Name' (STOR FARMASI), and 'Created By'. A tabbed interface shows 'Drug' and 'Non Drug' tabs. The main content area is divided into three sections: 'A- PRODUCT PARTICULARS', 'B- FULL COMPLAINT DETAILS', and 'C- COMPLAINANT PARTICULARS'. Section C contains the following fields: Name (SALINA JENIAH), Workplace (WARD 9), Phone (6082503491), Date (15/05/2015), Extension, and Approved By. A red circle with the number 10 is drawn around the Phone field. At the bottom of the form, there is a blue bar that reads 'TO BE COMPLETED BY PHARMACIST'.

Figure 3.2.1-8 Complainant Particulars

STEP 10

Enter the **Complainant's Name, Workplace, Phone No, Phone Extension** (if any)

Note

The date is defaulted to the current Date.



This screenshot is identical to Figure 3.2.1-8, showing the 'PRODUCT COMPLAINTS' form with the 'COMPLAINANT PARTICULARS' section. A red circle with the number 11 is drawn around the 'Save' button (a floppy disk icon) located in the top right corner of the form's header area.

Figure 3.2.1-9 Save record

STEP 11

Click on the  button to save the record

Note

After clicking on  button, alert message will be displayed in Figure 3.2.1-10 and Figure 3.2.1-11

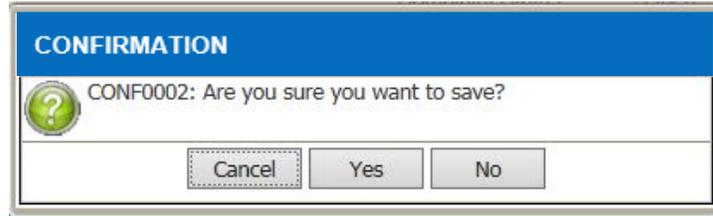
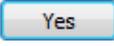


Figure 3.2.1-10 Save Record

- Click on the  button.

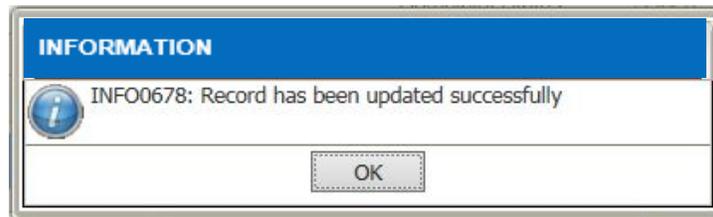


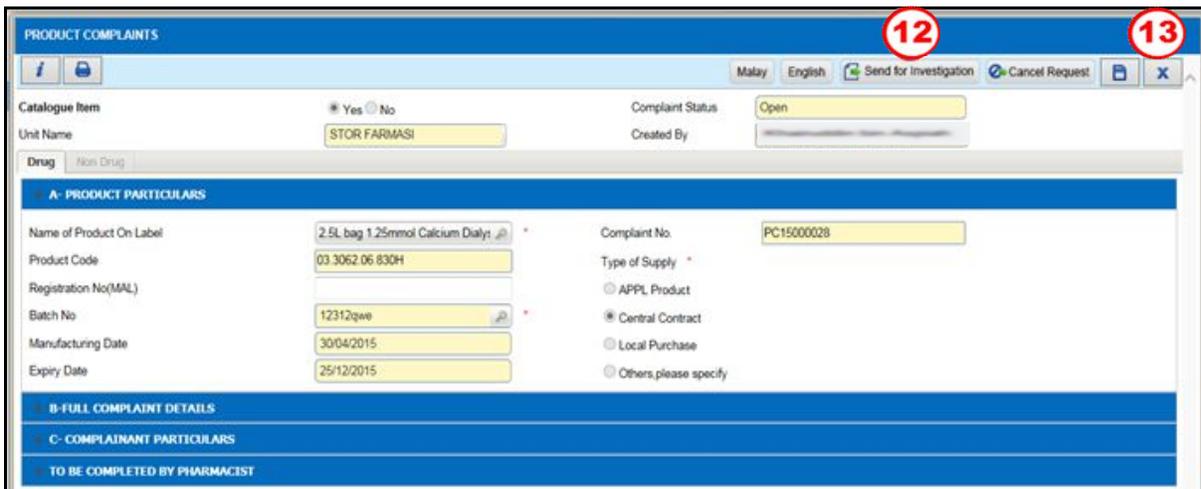
Figure 3.2.1-11 Message Information

- Click on the  button.
- **Complaints No** will be automatically generated for future reference.

Character	Description	Value
1-2	Refer to complaint drug item	'PC'
3-4	Current Year in YY format	12
5-10	Running No	Starting from 000001. This running number will be reset to start from 000001 at the beginning of every calendar year.

Table 3.2.1-1

- Send for Investigation  button will be enabled once user saves the Product Complaints record.

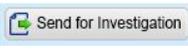


The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top right, there are two buttons: 'Send for Investigation' (highlighted with a red circle labeled 12) and 'Cancel Request'. At the bottom right, there is a 'Close' button (highlighted with a red circle labeled 13). The form contains the following fields:

Catalogue Item	<input checked="" type="radio"/> Yes <input type="radio"/> No	Complaint Status	Open
Unit Name	STOR FARMASI	Created By	
Drug	<input type="checkbox"/> Drug <input type="checkbox"/> Non Drug		
A- PRODUCT PARTICULARS			
Name of Product On Label	2.5L bag 1.25mmol Calcium Dialys	Complaint No.	PC15000028
Product Code	03 3062 06 830H	Type of Supply	
Registration No(MAL)		<input type="radio"/> APPL Product	
Batch No	12312qwe	<input checked="" type="radio"/> Central Contract	
Manufacturing Date	30/04/2015	<input type="radio"/> Local Purchase	
Expiry Date	25/12/2015	<input type="radio"/> Others, please specify	
B- FULL COMPLAINT DETAILS			
C- COMPLAINANT PARTICULARS			
TO BE COMPLETED BY PHARMACIST			

Figure 3.2.1-12 Send for Investigation

STEP 12

Click on the  button to send the Product Complaints record to the DIS Pharmacy for Investigation

Note

- The Status of the Product Complaints record will be changed to Investigation – Pending.
- DIS Pharmacist will receive the Investigation – Pending Product Complaints record in the Task List.

STEP 13

Click on the  button to close the Product Complaints screen

3.2.2 Product Complaint Investigation

The pharmacist at store Pharmacy will receive notification for Investigation - Pending records to investigate the validity of a Product Complaints.

Note

The Pharmacist will receive the 'Investigation – Pending' transaction in the Task List.

TASK LIST					
Transaction Type	Transaction No.	Date/Time	Task Status	From Unit/Department	From User
Product Complaint	PC15000022	22/04/2015 03:14 PM	Investigation - Pending	WAD 12	Wahamuddin bin Asyraf
Product Complaint	PC15000023	23/04/2015 11:09 AM	Investigation - Pending	WAD 12	Wahamuddin bin Asyraf
Product Complaint	PC15000024	27/04/2015 04:48 PM	Investigation - Pending	WAD 12	Wahamuddin bin Asyraf
Product Complaint	PC15000025	27/04/2015 04:57 PM	Investigation - Pending	UNIT FARMASI KLINIK PAKAR	Wahamuddin bin Asyraf
Product Complaint	PC15000026	30/04/2015 06:13 AM	Investigation - Pending	STOR FARMASI	Wahamuddin bin Asyraf
Product Complaint	PC15000027	30/04/2015 09:51 PM	Investigation - Pending	STOR FARMASI	Wahamuddin bin Asyraf
RCL Transaction type	RC15000016	11/05/2015 03:58 PM	Pending for Approval	STOR FARMASI	Wahamuddin bin Asyraf
Slow Moving Item	SM15000001	15/05/2015 10:02 AM	Pending For Approval	STOR FARMASI	Wahamuddin bin Asyraf
Product Complaint	PC15000028 1	15/05/2015 05:10 PM	Investigation - Pending	STOR FARMASI	Wahamuddin bin Asyraf

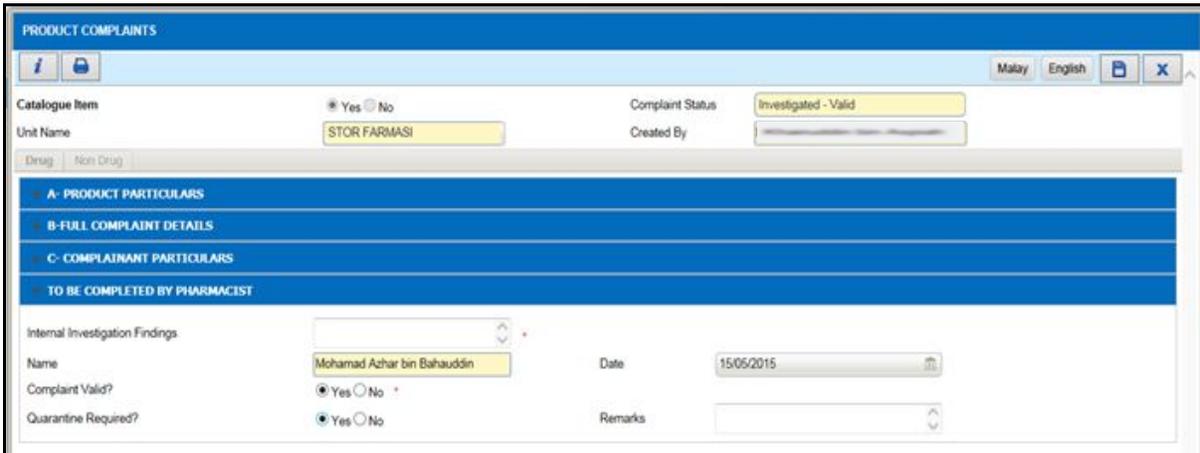
Figure 3.2.2-1 Task List

STEP 1

Click on the Transaction No. hyperlink and the Product Complaints screen will be displayed as shown in the Figure 3.2.2-1

Note

The pharmacist is also able to refer to section 3.1. Product Complaints Listing Page to search for the 'Investigation - Pending' Product Complaints record.



The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top, there are language options for Malay and English. The form includes fields for 'Catalogue Item' (with Yes/No radio buttons), 'Complaint Status' (set to 'Investigated - Valid'), 'Unit Name' (set to 'STOR FARMASI'), and 'Created By'. Below these are four expandable sections: 'A- PRODUCT PARTICULARS', 'B- FULL COMPLAINT DETAILS', 'C- COMPLAINANT PARTICULARS', and 'TO BE COMPLETED BY PHARMACIST'. The 'TO BE COMPLETED BY PHARMACIST' section is expanded, showing fields for 'Internal Investigation Findings' (with a dropdown menu), 'Name' (set to 'Mohamad Azhar bin Bahaudin'), 'Date' (set to '15/05/2015'), 'Complaint Valid?' (with Yes/No radio buttons), 'Quarantine Required?' (with Yes/No radio buttons), and 'Remarks'.

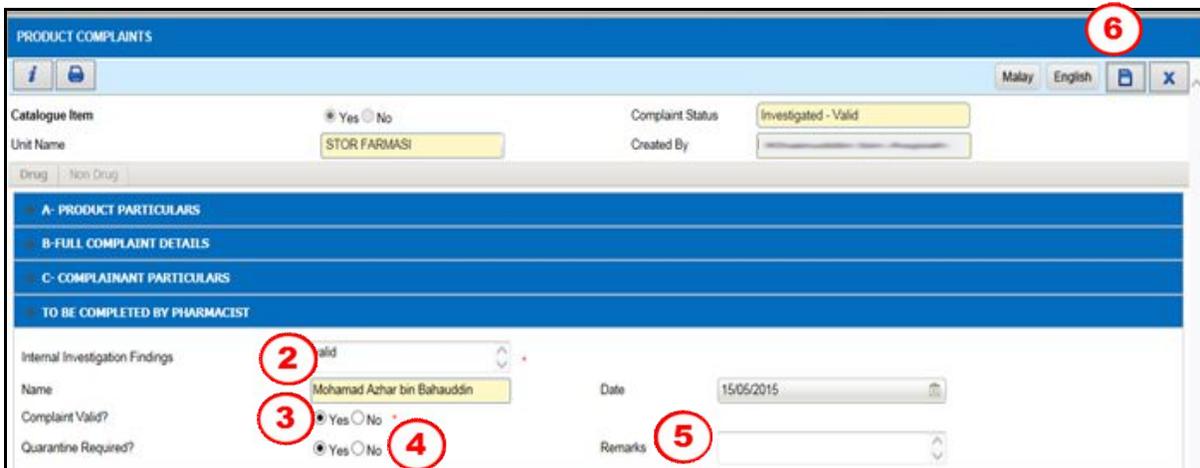
Figure 3.2.2-2 Product Complaints

Note

These four (4) panels can be maximized / minimized in the Investigation - Pending Product Complaints form :

- Product Particulars
- Full Complaints Details
- Complainant Particulars
- To Be Completed by Pharmacist

DIS pharmacist needs to fill in the To Be Completed by Pharmacist section as shown in Figure 3.2.2-3.



This screenshot is identical to Figure 3.2.2-2 but highlights specific fields with red circles: '6' is at the top right corner; '2' is on the 'Internal Investigation Findings' dropdown; '3' is on the 'Complaint Valid?' radio buttons; '4' is on the 'Quarantine Required?' radio buttons; '5' is on the 'Remarks' text field; and '6' is on the window control buttons.

Figure 3.2.2-3 Investigation – Valid Product Complaints record

STEP 2

Enter **Internal Investigation Findings**

STEP 3

Select from the 'Yes' radio button for **Complaints Valid?**

Note

If 'Yes' is selected, **Quarantine Required?** 'Yes' or 'No' radio button will be enabled.

STEP 4

Select from the 'Yes' or 'No' for Quarantine Required? radio button

Note

- If 'Yes' is selected, this Product Complaints No will be available in the Quarantine Module.
- If 'No' is selected, this Product Complaints No will not be available in the Quarantine Module.

STEP 5

Enter Remarks if applicable

STEP 6

Click on the Save  button to save the record

Note

After clicking on  button, alert message will be displayed as per Figure 3.2.2-4 & Figure 3.2.2-5.

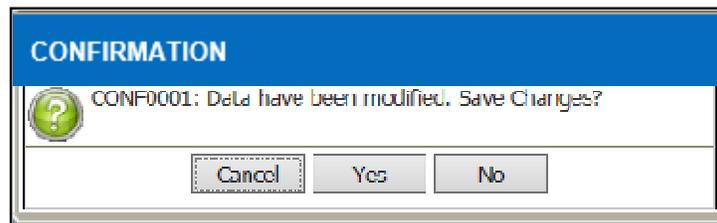
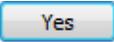


Figure 3.2.2-4 Confirmation message

- Click on the  button to confirm save.

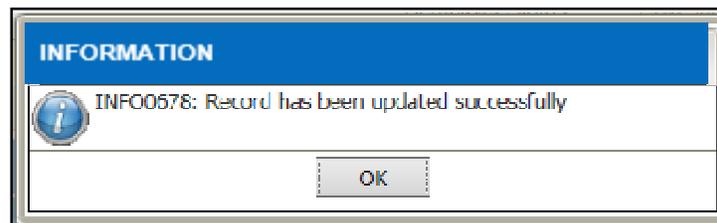
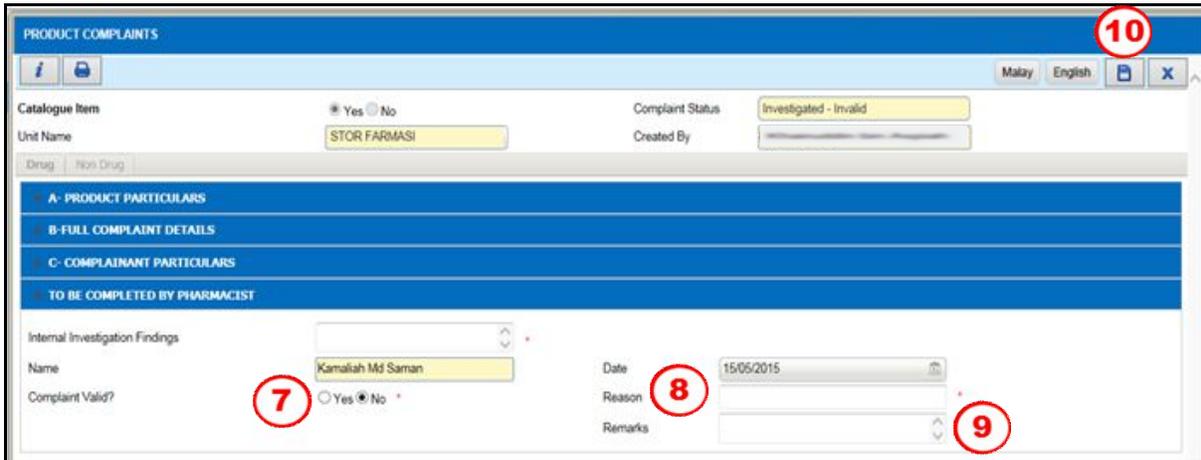


Figure 3.2.2-5 Message Information

- Click on the  button.
- The Status of the Product Complaints record will be changed to Investigated – Valid



The screenshot shows a web application window titled 'PRODUCT COMPLAINTS'. At the top right, there is a language selector with 'Malay' and 'English' options, and a close button. Below this, there are fields for 'Catalogue Item' (Yes/No), 'Complaint Status' (Investigated - Invalid), 'Unit Name' (STOR FARMASI), and 'Created By'. A navigation menu includes 'A- PRODUCT PARTICULARS', 'B- FULL COMPLAINT DETAILS', 'C- COMPLAINANT PARTICULARS', and 'TO BE COMPLETED BY PHARMACIST'. The 'Internal Investigation Findings' section contains a 'Name' field with 'Kamaliah Md Saman', a 'Date' field with '15/05/2015', a 'Complaint Valid?' section with 'Yes' and 'No' radio buttons (where 'No' is selected), a 'Reason' field, and a 'Remarks' field. Red circles 7, 8, 9, and 10 are overlaid on the form to highlight the 'Complaints Valid?' radio buttons, the 'Reason' field, the 'Remarks' field, and the top right corner of the window, respectively.

Figure 3.2.2-6 Internal Investigation Findings

STEP 7

Enter **Internal Investigation Findings** and select the 'No' radio button for 'Complaints Valid?'

Note

- If 'No' is selected, **Reason** field will be enabled
- If 'No' is selected, **Quarantine Required?** 'Yes' or 'No' radio button will not be enabled.

STEP 8

Enter **Reason**

STEP 9

Enter **Remarks** if required

STEP 10

Click on the Save  button to save the record

Note

After clicking on  button, alert message will be displayed as per Figure 3.2.2-7 & Figure 3.2.2-8.

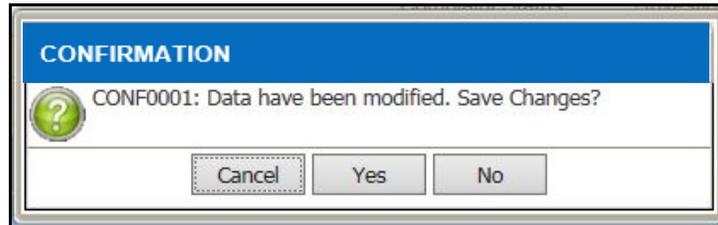
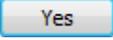


Figure 3.2.2-7 Save Record

- Click on the  button to confirm save.

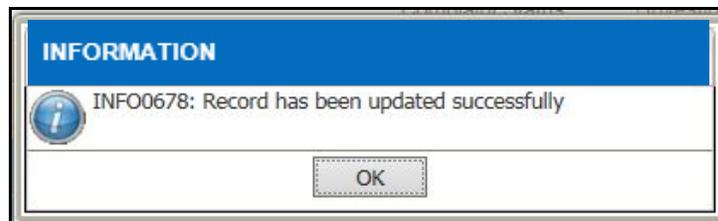
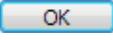


Figure 3.2.2-8 Message Information

- Click on the  button.
- The status of the Product Complaints record will be changed to Investigated – Invalid.

3.2.3 Product Complaints – Non Drug

To create a new Non Drug Product Complaints – Catalogue Item, perform the steps below:

Note

Catalogue Items are items that are available in the facility's Unit Catalogue. Pharmacist at the Pharmacy Store will then decide the Complaints' validity.

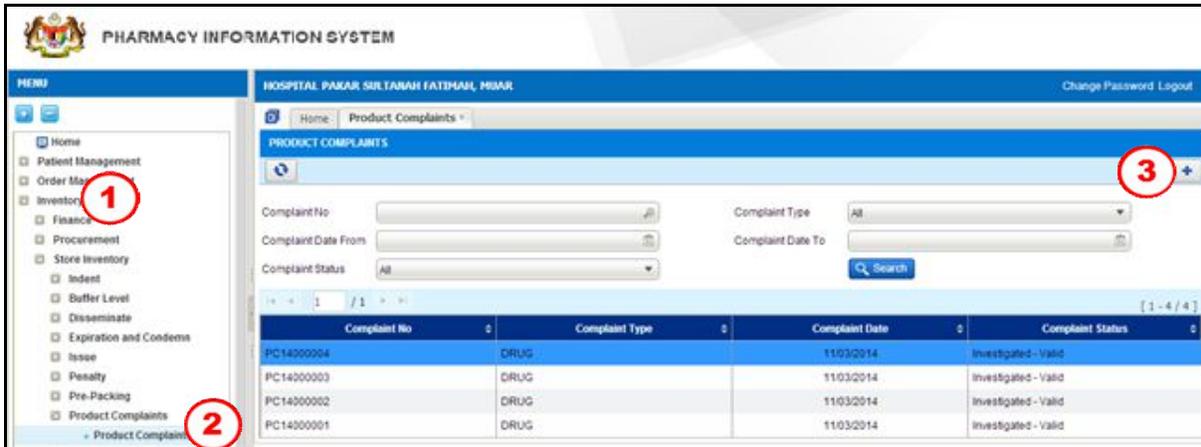


Figure 3.2.3-1 Create New Product Complaints

STEP 1

Click on 'Inventory' menu and click on 'Store Inventory' Sub-Menu

STEP 2

Click on 'Product Complaints'

STEP 3

Click on the  button

Note

Product Complaints screen will be displayed in Figure 3.2.3-2

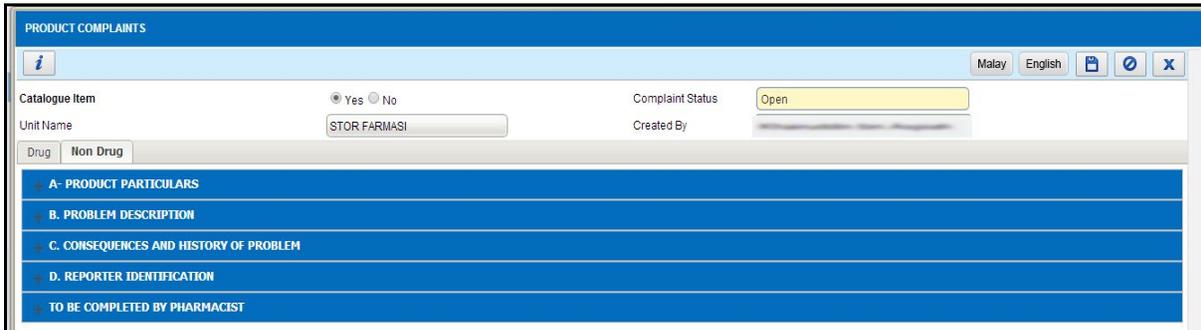


Figure 3.2.3-2 New Non Drug Product Complaints – Catalogue Item

Note

Default language is English; however, it is changeable to Malay language by clicking on the **Malay** button.

- The Catalogue Item radio button is default to 'Yes'. Change to 'No' if the Product Complaints item is not a catalogue item from the facility.
- Complaints on Drug and Non Drug item will have a different type of form. Select Non Drug tab if would like to lodge a Product Complaints on a Non Drug Item.
- These four (4) panels in a New Product Complaints form are required to be filled:
 - I. Product Particulars
 - II. Problem Description
 - III. Consequences and History of Problem
 - IV. Reporter Identification
- The sections can be maximized or minimized by clicking on its Header

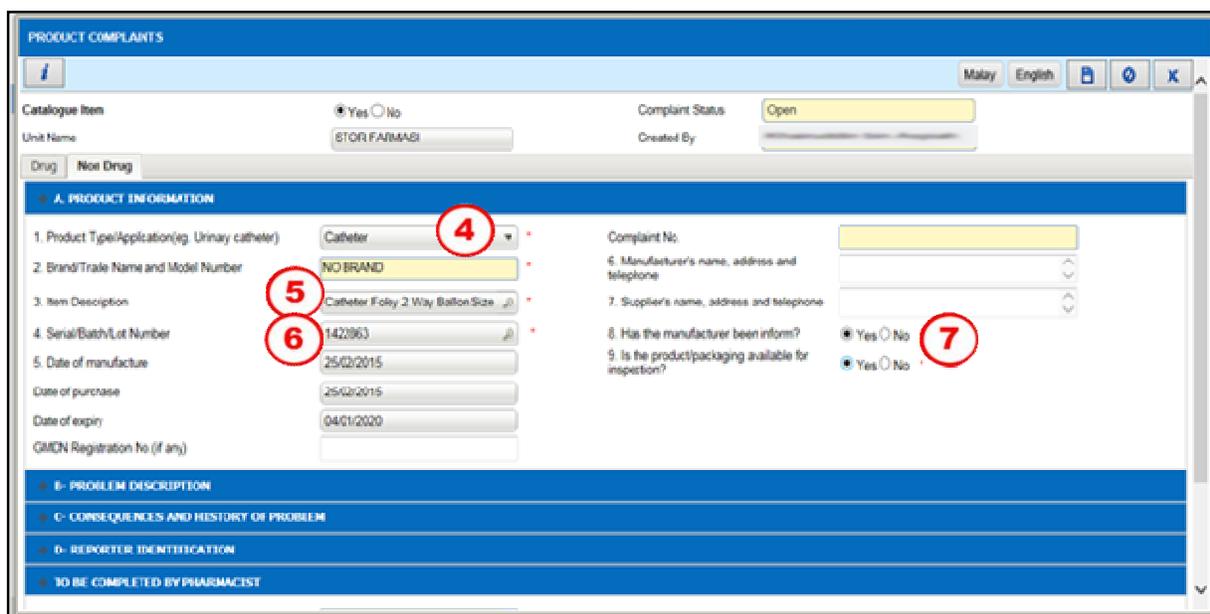


Figure 3.2.3-3 Product Particulars

STEP 4

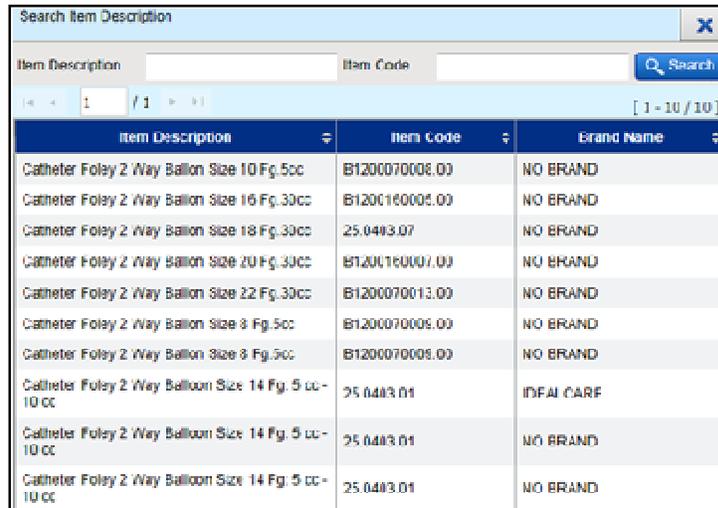
Enter the **Product Type/Application (e.g. Urinary catheter)**

STEP 5

Enter **Item Description**

Note

- System will display as Figure 3.2.3-4.



Item Description	Item Code	Brand Name
Catheter Foley 2 Way Balloon Size 10 Fg.5cc	B1200070008.00	NO BRAND
Catheter Foley 2 Way Balloon Size 16 Fg.30cc	B1200160005.00	NO BRAND
Catheter Foley 2 Way Balloon Size 18 Fg.30cc	25.0403.07	NO BRAND
Catheter Foley 2 Way Balloon Size 20 Fg.30CC	B1200160007.00	NO BRAND
Catheter Foley 2 Way Balloon Size 22 Fg.30cc	B1200070013.00	NO BRAND
Catheter Foley 2 Way Balloon Size 8 Fg.5cc	B1200070005.00	NO BRAND
Catheter Foley 2 Way Balloon Size 8 Fg.5cc	B1200070005.00	NO BRAND
Catheter Foley 2 Way Balloon Size 14 Fg. 5 cc-10 cc	25.0403.01	IDFAI CARF
Catheter Foley 2 Way Balloon Size 14 Fg. 5 cc-10 cc	25.0403.01	NO BRAND
Catheter Foley 2 Way Balloon Size 14 Fg. 5 cc-10 cc	25.0403.01	NO BRAND

Figure 3.2.3-4 Search Item Description and/or Item Code

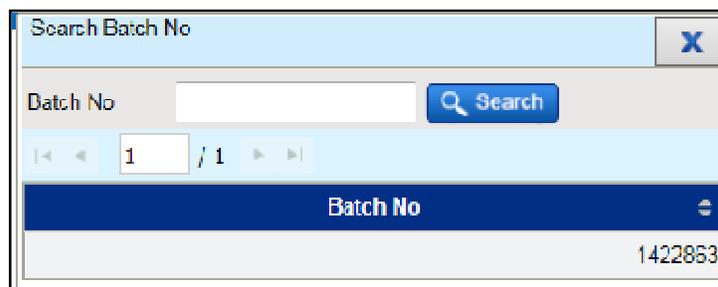
- Enter a partially or fully search criteria of Item Description and/or Item Code and click the  button.
- Click on the  button to close the Search Item Code text box.

STEP 6

Select the **Serial/Batch/Lot Number**

Note

- System will display as Figure 3.2.3-5.



Batch No
1422853

Figure 3.2.3-5 Search Batch No.

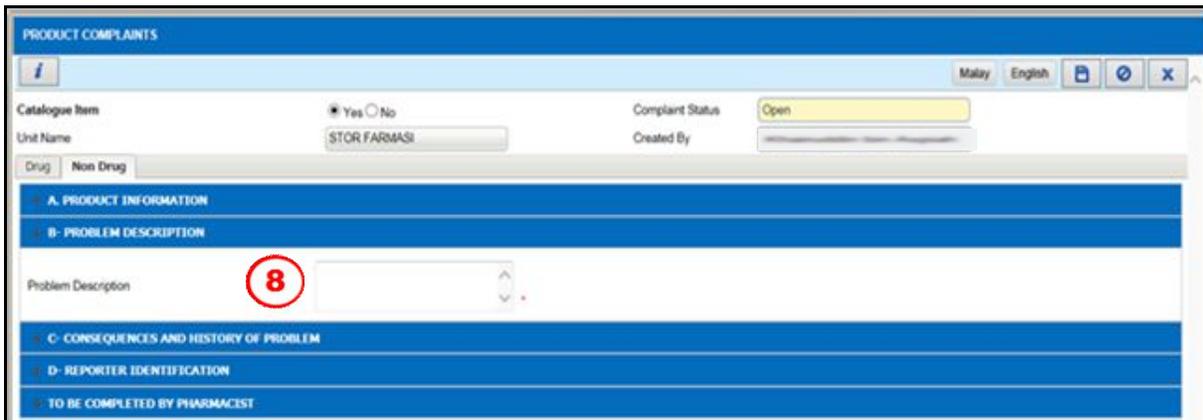
- Only available **Batch No** in the unit will be listed in the Batch No list.
- Click on the button to close the Search Batch No text box.
- **Date of Manufacture, Date of Purchase and Date of Expiry** will be automatically displayed based on the **Serial/Batch/Lot Number** selected.

STEP 7

Select the button for question 8 & 9

STEP 8

Enter the **Problem Description**

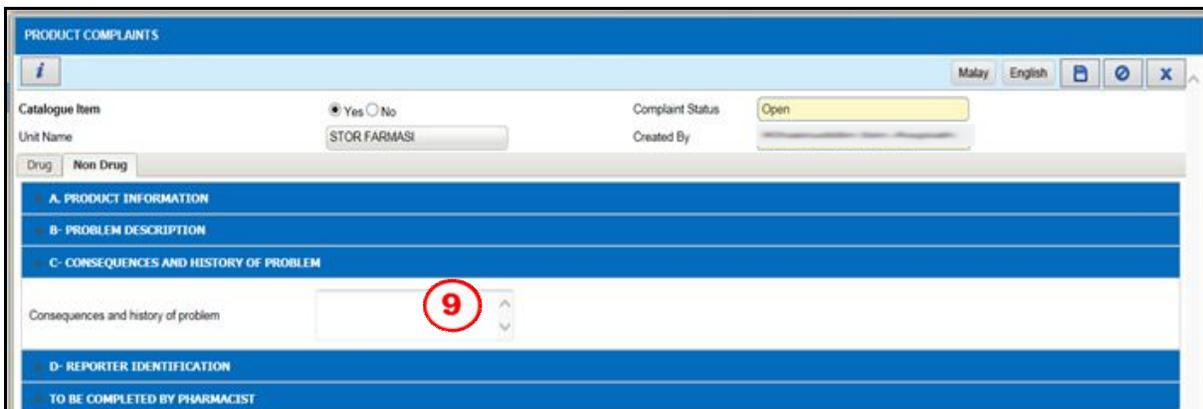


The screenshot shows the 'PRODUCT COMPLAINTS' form. The 'Problem Description' field is highlighted with a red circle containing the number 8. The form includes fields for 'Catalogue Item', 'Unit Name' (STOR FARMASI), 'Complaint Status' (Open), and 'Created By'. There are also radio buttons for 'Drug' and 'Non Drug'. The form is divided into sections: A. PRODUCT INFORMATION, B. PROBLEM DESCRIPTION, C. CONSEQUENCES AND HISTORY OF PROBLEM, D. REPORTER IDENTIFICATION, and TO BE COMPLETED BY PHARMACIST.

Figure 3.2.3-6 Problem Description

STEP 9

Enter the **Consequences and History of Problem**



The screenshot shows the 'PRODUCT COMPLAINTS' form. The 'Consequences and history of problem' field is highlighted with a red circle containing the number 9. The form includes fields for 'Catalogue Item', 'Unit Name' (STOR FARMASI), 'Complaint Status' (Open), and 'Created By'. There are also radio buttons for 'Drug' and 'Non Drug'. The form is divided into sections: A. PRODUCT INFORMATION, B. PROBLEM DESCRIPTION, C. CONSEQUENCES AND HISTORY OF PROBLEM, D. REPORTER IDENTIFICATION, and TO BE COMPLETED BY PHARMACIST.

Figure 3.2.3-7 Consequences and history of the problem

Note

- The status of the Product Complaints record will be changed to Investigation – Pending.
- DIS Pharmacist will receive the Investigation – Pending Product Complaints record in the Task List.

Note

After clicking on  button, alert message will be displayed as per Figure 3.2.3-8 & Figure 3.2.3-9.

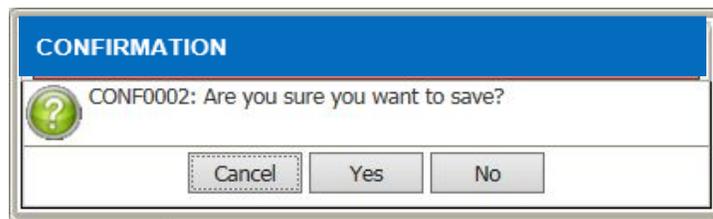
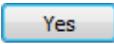


Figure 3.2.3-8 Save Record

- Click on the  button to confirm save.

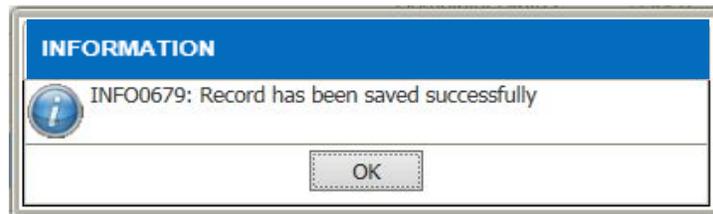
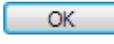


Figure 3.2.3-9 Message Information

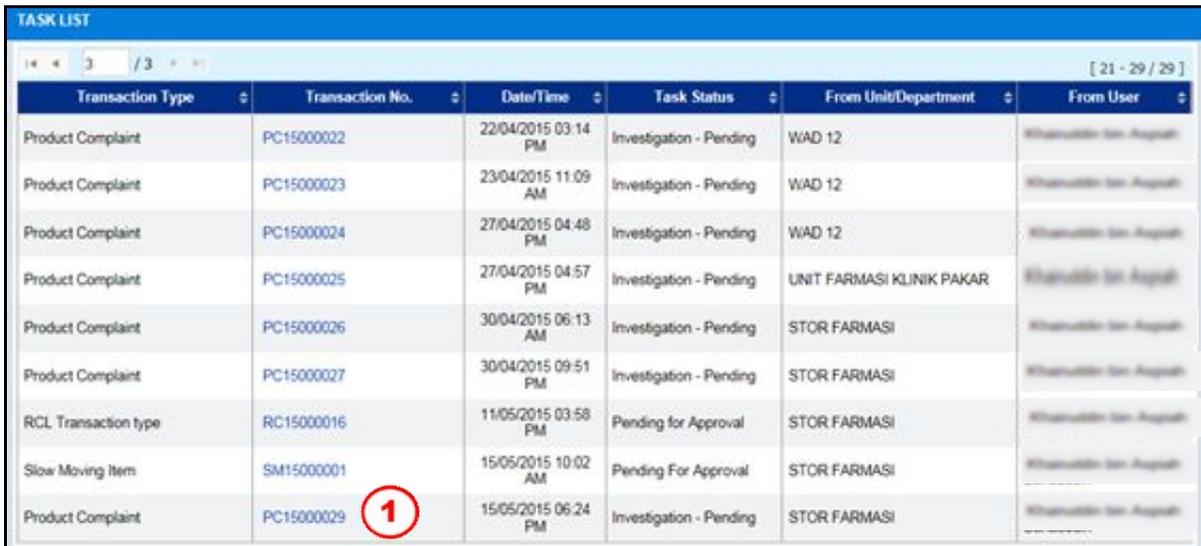
- Click on the  button.
- **Complaints No** will be automatically generated for future reference.
-  button will be enabled when  button is clicked.

3.2.3 Investigation

The pharmacist at Pharmacy Store will receive notification for Investigation - Pending records to investigate the validity of the Product Complaints

Note

The Pharmacist will receive the 'Investigation – Pending' transaction in the Task List.



Transaction Type	Transaction No.	Date/Time	Task Status	From Unit/Department	From User
Product Complaint	PC1500022	22/04/2015 03:14 PM	Investigation - Pending	WAD 12	Khairuddin bin Asyraf
Product Complaint	PC1500023	23/04/2015 11:09 AM	Investigation - Pending	WAD 12	Khairuddin bin Asyraf
Product Complaint	PC1500024	27/04/2015 04:48 PM	Investigation - Pending	WAD 12	Khairuddin bin Asyraf
Product Complaint	PC1500025	27/04/2015 04:57 PM	Investigation - Pending	UNIT FARMASI KLINIK PAKAR	Khairuddin bin Asyraf
Product Complaint	PC1500026	30/04/2015 06:13 AM	Investigation - Pending	STOR FARMASI	Khairuddin bin Asyraf
Product Complaint	PC1500027	30/04/2015 09:51 PM	Investigation - Pending	STOR FARMASI	Khairuddin bin Asyraf
RCL Transaction type	RC1500016	11/05/2015 03:58 PM	Pending for Approval	STOR FARMASI	Khairuddin bin Asyraf
Slow Moving Item	SM1500001	15/05/2015 10:02 AM	Pending For Approval	STOR FARMASI	Khairuddin bin Asyraf
Product Complaint	PC1500029	15/05/2015 06:24 PM	Investigation - Pending	STOR FARMASI	Khairuddin bin Asyraf

Figure 3.2.4-1 Task List

STEP 1

Click on the Transaction No. hyperlink and the Product Complaints screen will be displayed as shown in the Figure 3.2.4-1

Note

The pharmacist is also able to refer to section 3.1.Product Complaints Listing Page to search for the 'Investigation - Pending' Product Complaints record.

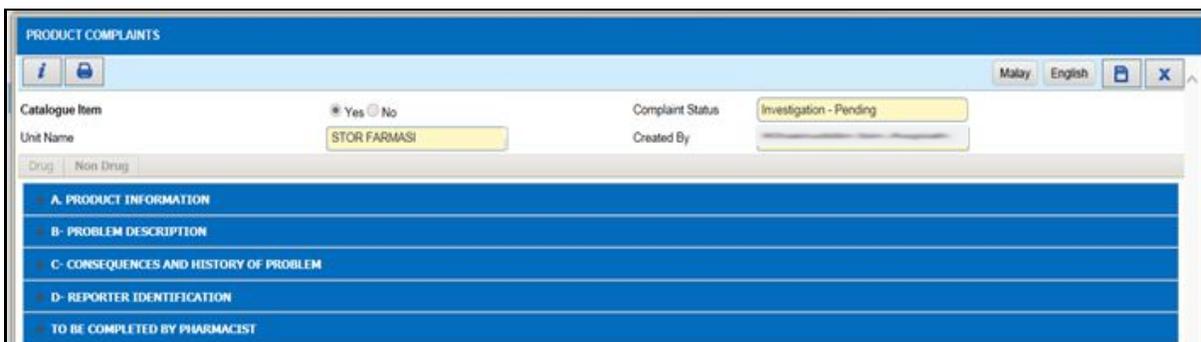


Figure 3.2.4-2 Investigation – Pending Product Complaints record

Note

- These five (5) panels can be maximized / minimized by clicking on its Header in the Investigation - Pending Product Complaints form:
 - i. Product Particulars
 - ii. Problem Description
 - iii. Consequences and History of Problem
 - iv. Reporter Identification
 - v. To be Completed by Pharmacist

- DIS pharmacist needs to fill in the 'To Be Completed by Pharmacist' section as shown in Figure 3.2.4-3.

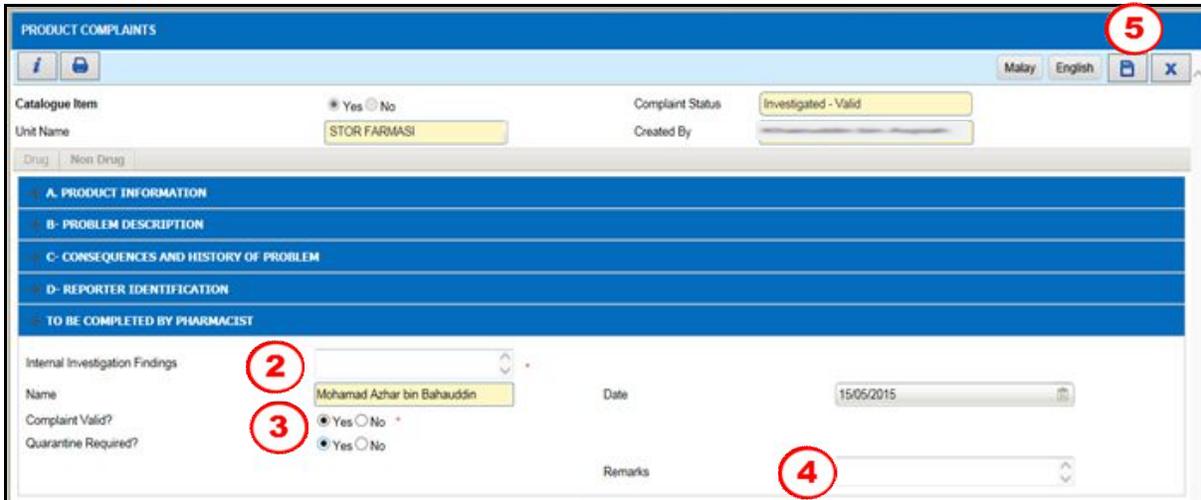


Figure 3.2.4-3 Investigation – Valid Product Complaints record

STEP 2

Enter **Internal Investigation Findings**

STEP 3

Select from the 'Yes' radio button for **Complaint Valid?**

Note

If 'Yes' is selected, **Quarantine Required?** 'Yes' or 'No' radio button will be enabled.

Select from the 'Yes' or 'No' for **Quarantine Required?** radio button

Note

- If 'Yes' is selected, this Product **Complaints No** will be available in the Quarantine Module.
- If 'No' is selected, this Product **Complaints No** will not be available in the Quarantine Module.

STEP 4

Enter **Remarks** if applicable

STEP 5

Click on the Save  button to save the record

Note

After save record, alert message will be displayed as per Figure 3.2.4-4 & Figure 3.2.4-5.

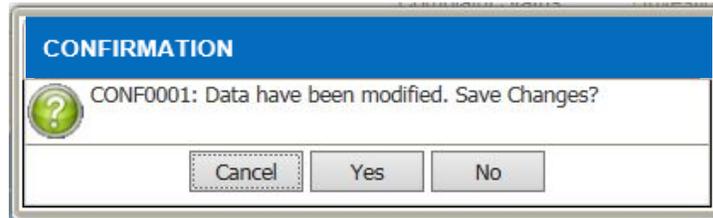
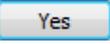


Figure 3.2.4-4 Save Record

- Click on the  button to confirm save.

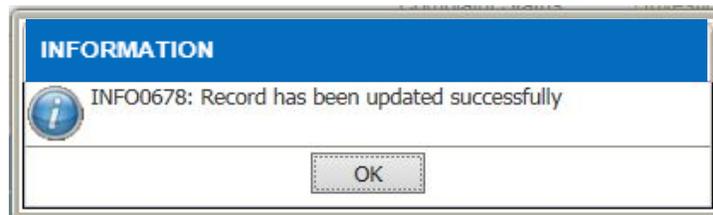
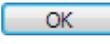


Figure 3.2.4-5 Message Information

- Click on the  button.
- The Status of the Product Complaints record will be changed to Investigated – Valid.

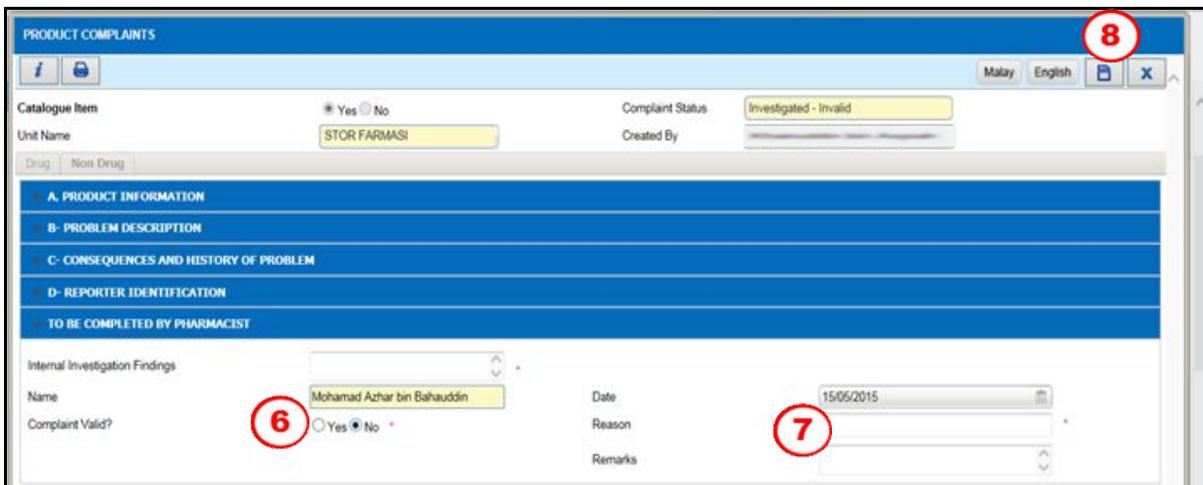


Figure 3.2.4-6 Investigation – Invalid Product Complaints record

STEP 6

Enter **Internal Investigation Findings** and select the 'No' radio button for **Complaint Valid**

Note

- If 'No' is selected, Reason field will be enabled.
- If 'No' is selected, 'Quarantine required?' 'Yes' or 'No' radio button will not be enabled.



STEP 7

Enter **Reason**

Enter **Remarks** if applicable

STEP 8

Click on the Save  button to save the record

Note

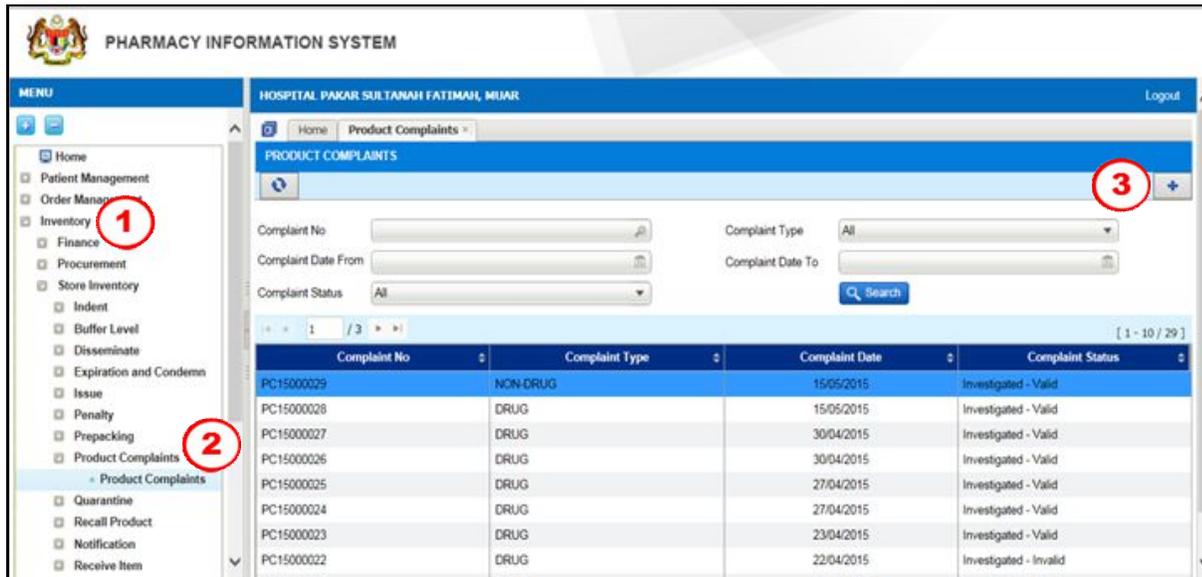
The status of the Product Complaints record will be changed to Investigated – Invalid.

3.3 Product Complaints Non Catalogue Item

Non Catalogue Items are items that are not available in the facility's unit catalogue. Pharmacist at the Pharmacy Store will then decide the Complaints' validity but the Complaints will stop after the investigation results by the DIS Pharmacy.

3.3.1 Product Complaints – Drug

To create a new Drug Product Complaints – Non Catalogue item, perform the steps below:



The screenshot displays the 'PHARMACY INFORMATION SYSTEM' interface for 'HOSPITAL PAKAR SULTANAH FATIMAH, MUAR'. The left-hand menu is expanded to show 'Inventory' (1), which is further expanded to 'Store Inventory' and then 'Product Complaints' (2). The main area shows the 'PRODUCT COMPLAINTS' screen with search filters for Complaint No., Complaint Type (All), Complaint Date From/To, and Complaint Status (All). A '+ Add' button (3) is visible in the top right of the main area. Below the filters is a table listing complaint records.

Complaint No	Complaint Type	Complaint Date	Complaint Status
PC15000029	NON-DRUG	15/05/2015	Investigated - Valid
PC15000028	DRUG	15/05/2015	Investigated - Valid
PC15000027	DRUG	30/04/2015	Investigated - Valid
PC15000026	DRUG	30/04/2015	Investigated - Valid
PC15000025	DRUG	27/04/2015	Investigated - Valid
PC15000024	DRUG	27/04/2015	Investigated - Valid
PC15000023	DRUG	23/04/2015	Investigated - Valid
PC15000022	DRUG	22/04/2015	Investigated - Invalid

Figure 3.3.1-1 Product Complaints Listing Page

STEP 1

Click on 'Inventory' menu and click on 'Store Inventory' Sub-Menu

STEP 2

Click on 'Product Complaints'

STEP 3

Click on the  button

Note

Product Complaints screen will be displayed in Figure 3.3.1-2

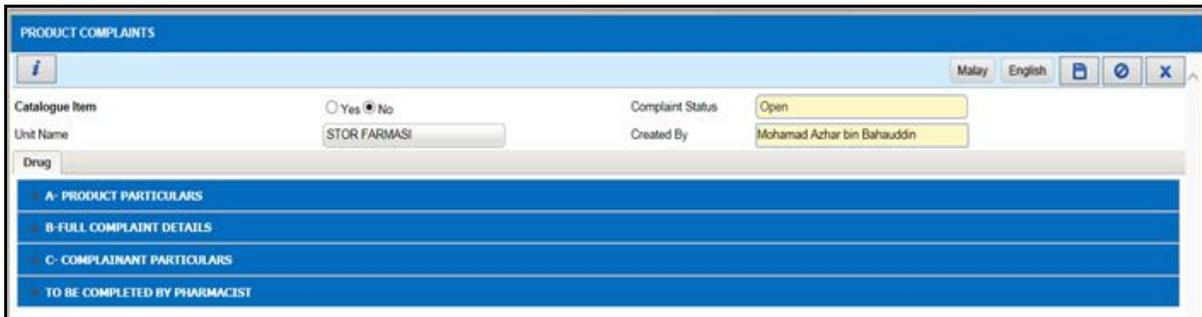


Figure 3.3.1-2 New Drug Product Complaints – Catalogue Item

Note

- Default language is English; however, it is changeable to Malay language by clicking on the button.
- The Catalogue Item radio button is default to 'Yes'. Change to 'No' as the Product Complaints item is not a catalogue item for the facility.
- After 'No' is selected for the Catalogue Item radio button, the Non Drug tab will be removed from the Product Complaints form.
- These four (4) in a New Product Complaints form are required to be filled:
 - I. Product Particulars
 - II. Full Complaints Details
 - III. Complainant Particulars
 - IV. To Be Completed By Pharmacist
- The sections can be maximized or minimized by clicking on its Header.
-

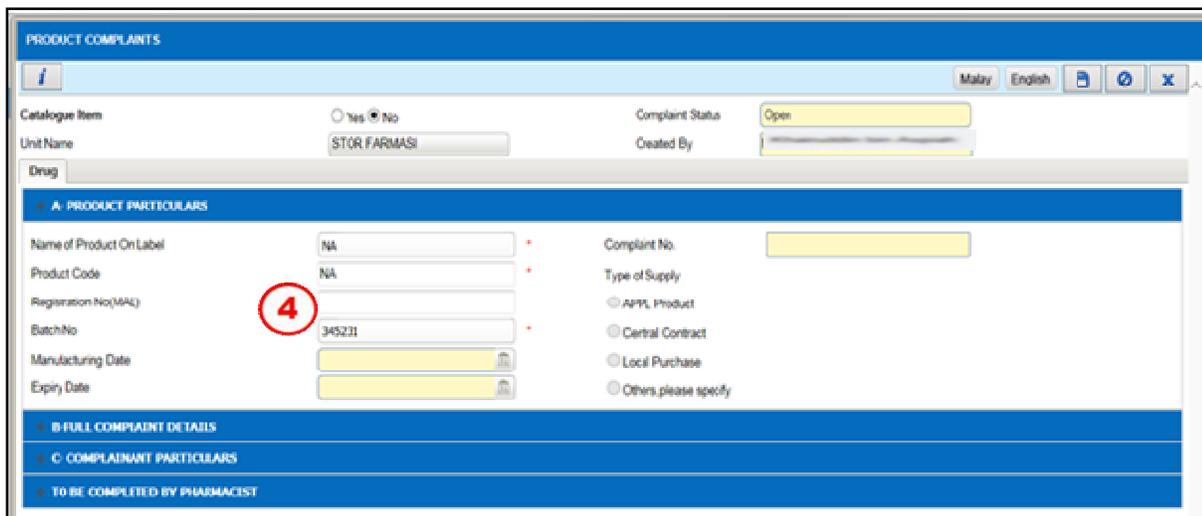


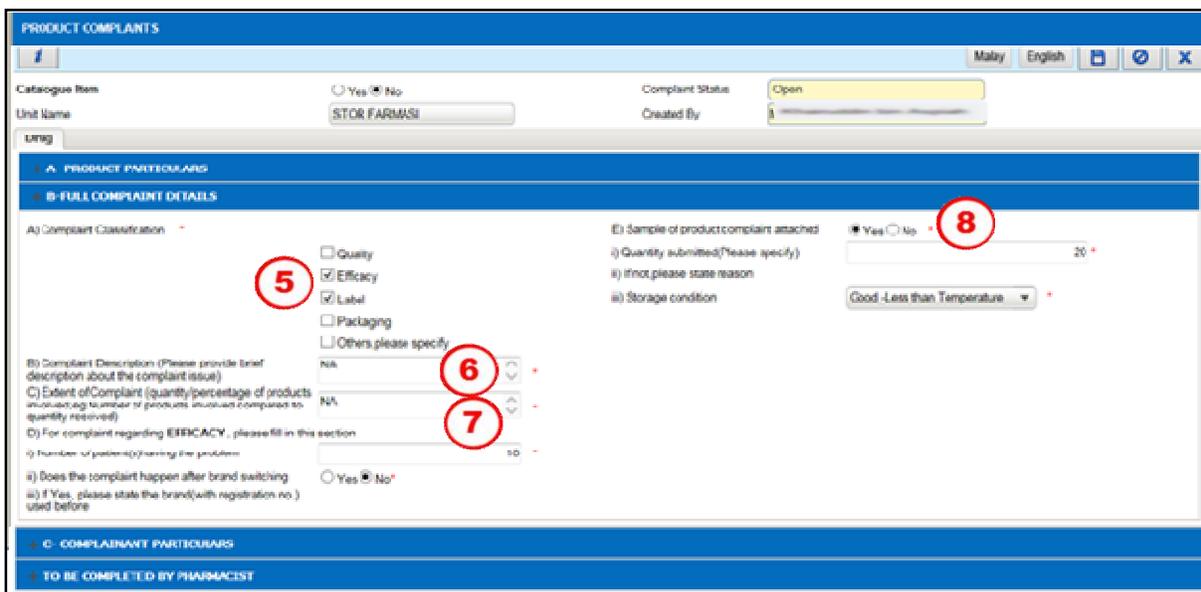
Figure 3.3.1-3 Non Catalogue - Drug Product Complaints – Product Particulars

STEP 4

- Enter the **Name of Product on Label**
- Enter the **Product Code**
- Enter the **Registration No (MAL)**
- Enter the **Batch No**
- Select **Manufacturing Date** from the  icon
- Select **Expiry Date** from the  icon
- Select **Type of Supply** from the radio button
 - APPL Product
 - Central Contract
 - Local Purchase
 - Others, please specify

Note

If 'Others' radio button is selected, Please Specify field will be enabled for the user to enter.



The screenshot shows the 'PRODUCT COMPLAINTS' form with the following details:

- Product Name:** Lung
- Unit Name:** STOR FARMASI
- Complaint Status:** Open
- Section B-FULL COMPLAINT DETAILS:**
 - A) Complaint Classification:**
 - Quality
 - Efficacy (5)
 - Label
 - Packaging
 - Others, please specify
 - B) Complaint Description:** (Please provide brief description about the complaint issue) - (6)
 - C) Extent of Complaint:** (quantity/percentage of products involved; eg number of products involved compared to quantity received) - (7)
 - D) For complaint regarding EFFICACY, please fill in this section:**
 - i) Number of patients/having the problem:
 - ii) Does the complaint happen after brand switching? Yes No*
 - iii) If Yes, please state the brand (with registration no.) used before:
 - E) Sample of product complaint attached:** Yes No (8)
 - i) Quantity submitted (Please specify):**
 - ii) If not, please state reason:**
 - iii) Storage condition:** Good - Less than Temperature

Figure 3.3.1-4 Full Complaints Details

STEP 5

Select **A) Complaint Classification** from the options in checkbox

- Quality
- Efficacy
- Label
- Packaging
-
- Others

Note

If Complaints Classification is selected as Others, Please Specify Field will be displayed.

STEP 6

Enter description for **B) Complaint Description**

STEP 7

Enter **C) Extent of Complaint** (quantity/percentage of products involved compared to the quantity received)

Note

- If the Complaints Classification is selected as Efficacy, these fields will be enabled for the user to enter/select:
 - Number of Patient(s) having the problem.
 - Does the Complaints happen after Brand switching
- If 'Yes' radio button is selected for 'Does the Complaints happen after brand switching', User has to state the iii) brand (with Registration No.) used before.

STEP 8

Select from the Yes/No radio button for e) **Sample of product Complaint attached**

Note

- If 'Yes' radio button is selected, User has to state the i) **Quantity submitted** and the ii) **Storage Condition**.
- If 'No' radio button is selected, the user has to state only the ii) **Reason**

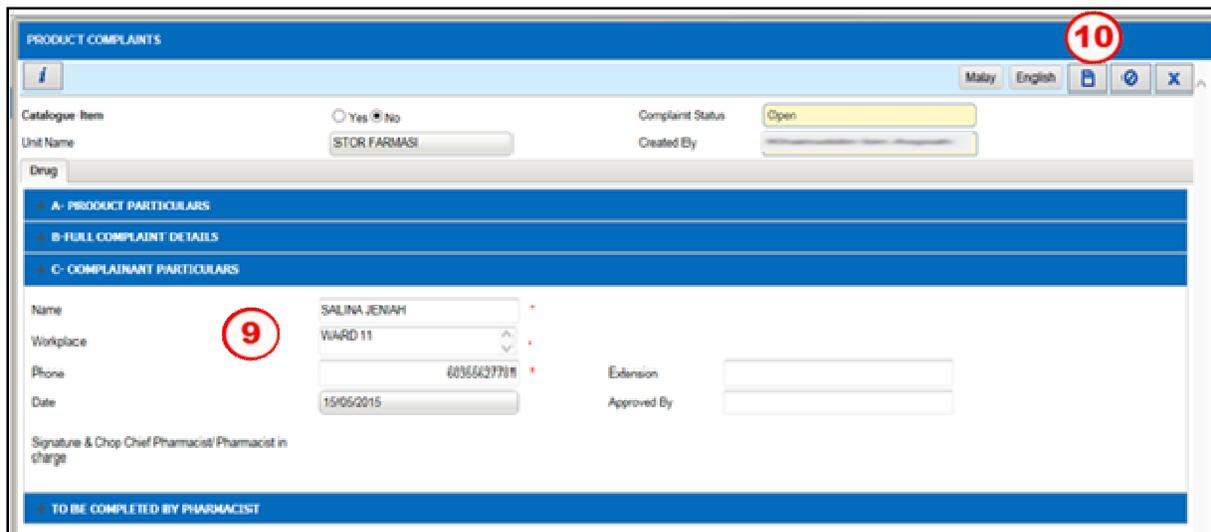


Figure 3.3.1-5 Complainant Particulars

STEP 9

Enter the **Complainant's Name, Workplace, Phone No, Phone Extension** (if any)

Note

The date is defaulted to the system date.

STEP 10

Click on the Save  button to save the record

Note

- After clicking on  button, alert message will be displayed in Figure 3.3.1-6 and Figure 3.3.1-7

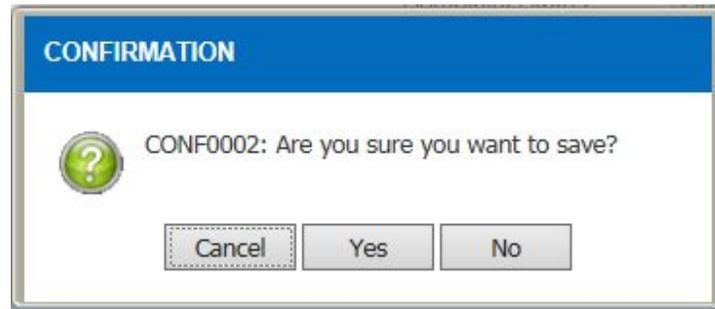
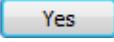


Figure 3.3.1-6 Save Record

- Click on the  button.

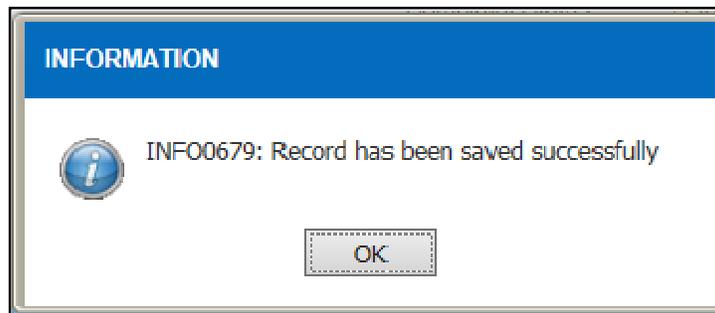
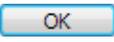


Figure 3.3.1-7 Message Information

- Click on the  button.
- Complaints No will be automatically generated for future reference.
-  button will be enabled when Product Complaints record is saved.

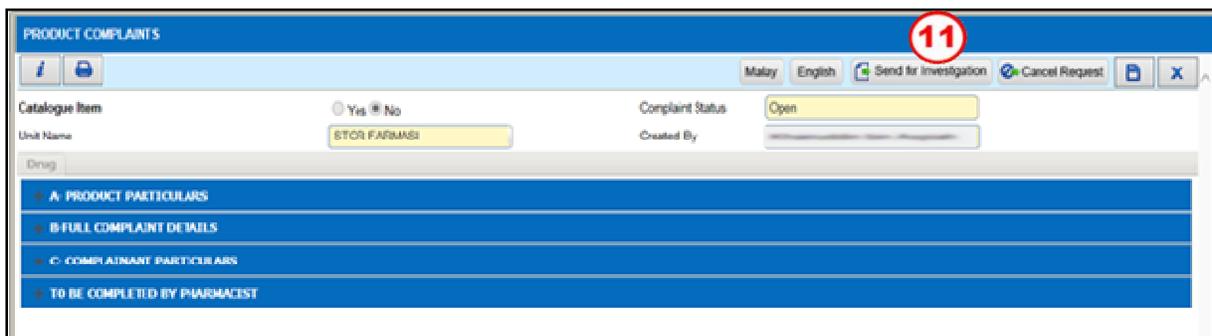


Figure 3.3.1-8 Send for Investigation

STEP 11

Click on the  button to send the Product Complaints record to the DIS Pharmacy for Investigation

Note

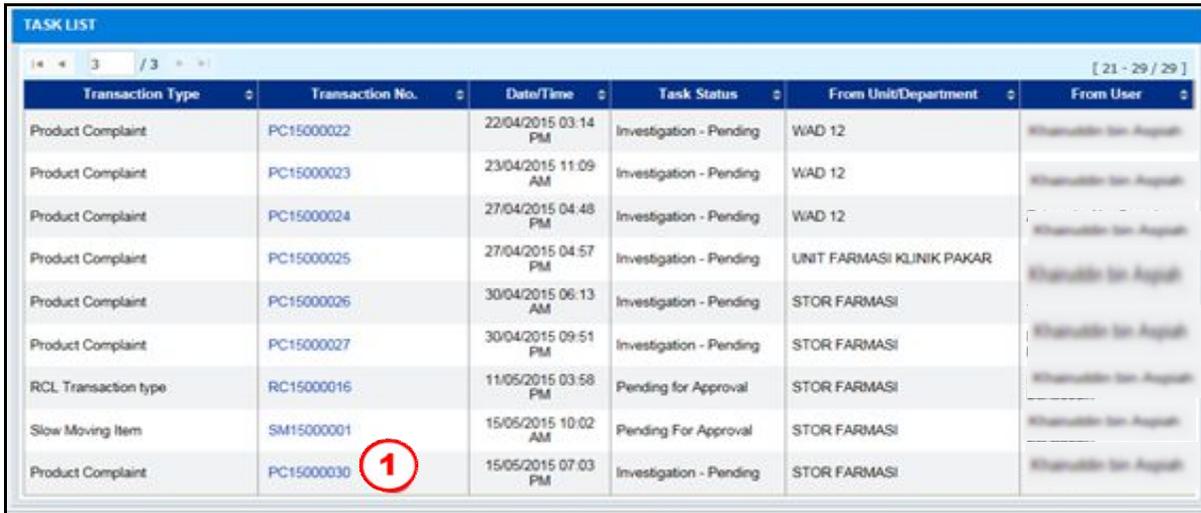
- The status of the Product Complaints record will be changed to Investigation – Pending.
- Click on the  button to close the Product Complaints screen

3.3.2 Product Complaint Investigation

Pharmacist in charge will receive notification for Investigation - Pending records to investigate the validity of the Product Complaints

Note

The Pharmacist will receive the 'Investigation – Pending' transaction in the Task List.



Transaction Type	Transaction No.	Date/Time	Task Status	From Unit/Department	From User
Product Complaint	PC15000022	22/04/2015 03:14 PM	Investigation - Pending	WAD 12	Wahabudin bin Asyraf
Product Complaint	PC15000023	23/04/2015 11:09 AM	Investigation - Pending	WAD 12	Wahabudin bin Asyraf
Product Complaint	PC15000024	27/04/2015 04:48 PM	Investigation - Pending	WAD 12	Wahabudin bin Asyraf
Product Complaint	PC15000025	27/04/2015 04:57 PM	Investigation - Pending	UNIT FARMASI KLINIK PAKAR	Wahabudin bin Asyraf
Product Complaint	PC15000026	30/04/2015 06:13 AM	Investigation - Pending	STOR FARMASI	Wahabudin bin Asyraf
Product Complaint	PC15000027	30/04/2015 09:51 PM	Investigation - Pending	STOR FARMASI	Wahabudin bin Asyraf
RCL Transaction type	RC15000016	11/05/2015 03:58 PM	Pending for Approval	STOR FARMASI	Wahabudin bin Asyraf
Slow Moving Item	SM15000001	15/05/2015 10:02 AM	Pending For Approval	STOR FARMASI	Wahabudin bin Asyraf
Product Complaint	PC15000030	15/05/2015 07:03 PM	Investigation - Pending	STOR FARMASI	Wahabudin bin Asyraf

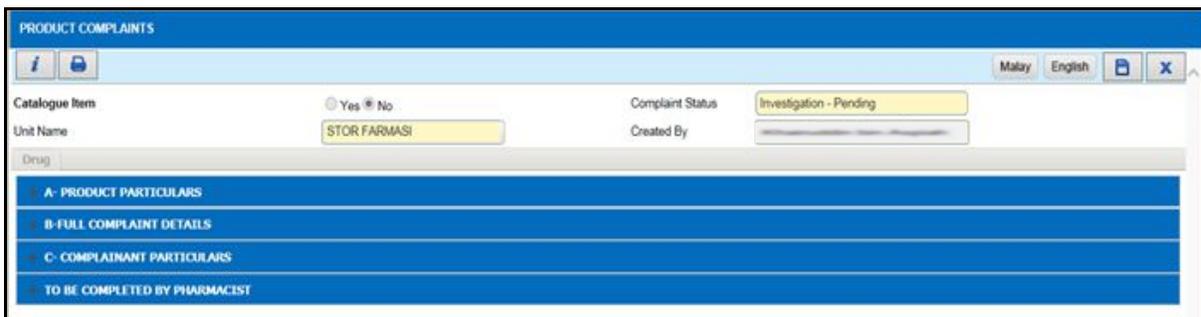
Figure 3.3.2-1 Task List

STEP 1

Click on the Transaction No. hyperlink and the Product Complaints screen will be displayed as shown in the Figure 3.3.2-2

Note

The pharmacist is also able to refer to section 3.1. Product Complaints Listing Page to search for the 'Investigation - Pending' Product Complaints record.



PRODUCT COMPLAINTS

Malay English

Catalogue Item Yes No Complaint Status

Unit Name Created By

Drug

- A- PRODUCT PARTICULARS
- B- FULL COMPLAINT DETAILS
- C- COMPLAINANT PARTICULARS
- TO BE COMPLETED BY PHARMACIST

Figure 3.3.2-2 Investigation – Pending Product Complaints record

Note

- These four (4) panels can be maximized / minimized in the Investigation - Pending Product Complaints form:
 - I. Product Particulars
 - II. Full Complaints Details
 - III. Complainant Particulars
 - IV. To Be Completed by Pharmacist
- DIS pharmacist needs to fill in the 'To Be Completed by Pharmacist' section as shown in Figure 3.3.2-3.

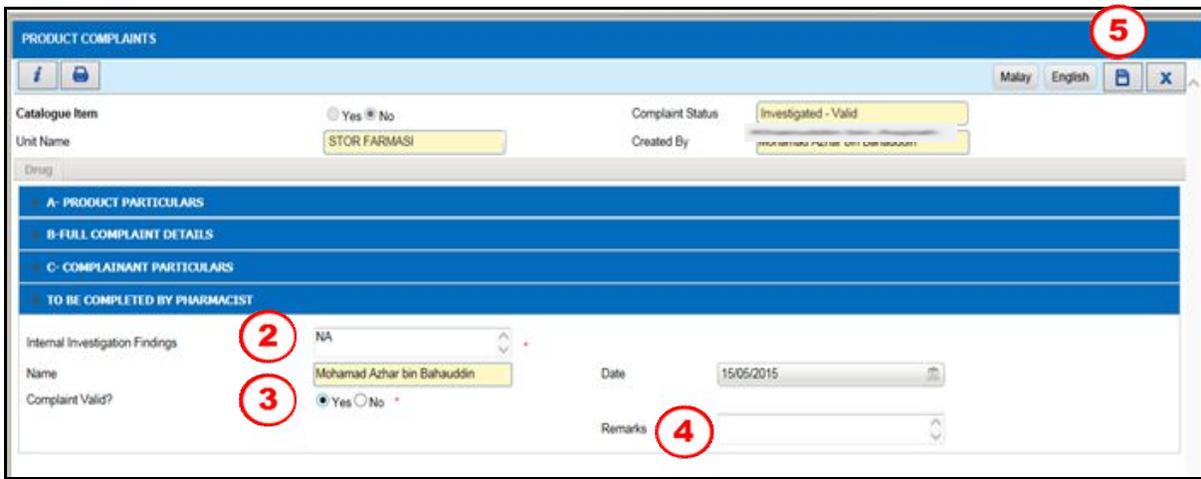


Figure 3.3.2-3 Investigation – Valid Product Complaints record

STEP 2

Enter **Internal Investigation Findings**

STEP 3

Select 'Yes' from the radio button for **Complaint Valid?**

STEP 4

Enter **Remarks** if applicable

STEP 5

Click on the Save  button to save the record

Note

After save record, alert message will be displayed as per Figure 3.3.2-4 & Figure 3.3.2-5.

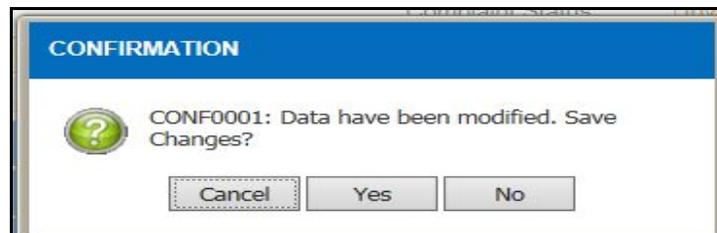
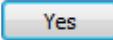


Figure 3.3.2-4 Save Record

- Click on the  button to confirm save.

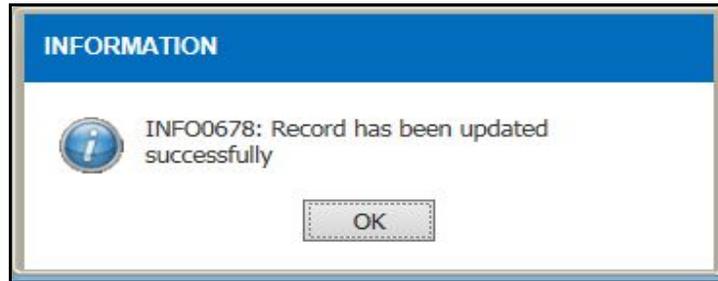


Figure 3.3.2-5 Message Information



4.0 Acronyms

Abbreviation	Definition
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
MOH	Ministry Of Health
HQ	Headquarters
UOM	Unit Of Measure
SKU	Store Keeping Unit
PKU	Packaging Keeping Unit
RFQ	Request for Quotation



5.0 Links to Inventory Modules

<i>No</i>	<i>Module</i>	<i>PDF Links</i>	<i>No</i>	<i>Module</i>	<i>PDF Links</i>
1	<i>Finance</i>	Click Here	15	<i>Internal Indent</i>	Click Here
2	<i>Procurement Standard APPL</i>	Click Here	16	<i>Issue</i>	Click Here
3	<i>Procurement standard LP</i>	Click Here	17	<i>Receive From Supplier</i>	Click Here
4	<i>Procurement Standard Contract</i>	Click Here	18	<i>Receive Inter Facility</i>	Click Here
5	<i>Procurement Standard Quotation</i>	Click Here	19	<i>Receive Intra Facility</i>	Click Here
6	<i>Procurement Standard (RFQ)</i>	Click Here	20	<i>Return to Supplier</i>	Click Here
7	<i>Procurement Non Standard (Requisition Order)</i>	Click Here	21	<i>Return to Supplying Unit</i>	Click Here
8	<i>Quarantine</i>	Click Here	22	<i>Slow Moving</i>	Click Here
9	<i>Product Complaint</i>	Click Here	23	<i>Stock Taking And Verification</i>	Click Here
10	<i>Recalculate Buffer Level</i>	Click Here	24	<i>Stock Transfer</i>	Click Here
11	<i>Expiration And Condemn</i>	Click Here	25	<i>Year End</i>	Click Here
12	<i>Recall Product</i>	Click Here	26	<i>Penalty</i>	Click Here
13	<i>Payment</i>	Click Here	27	<i>IWP Budget</i>	Click Here
14	<i>External Indent</i>	Click Here	28	<i>IWP Order Authorization</i>	Click Here