



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

User Manual Pharmacy Inventory - Product Complaint

Version	: 9th EDITION
Document ID	: 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

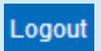
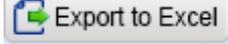
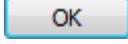
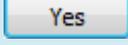
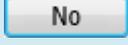
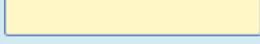
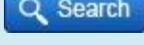
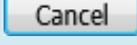
1.3 Organised Sections

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	<input type="checkbox"/>	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.



2.2 Latest Enhancement and Updates

Latest Functions	Page

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

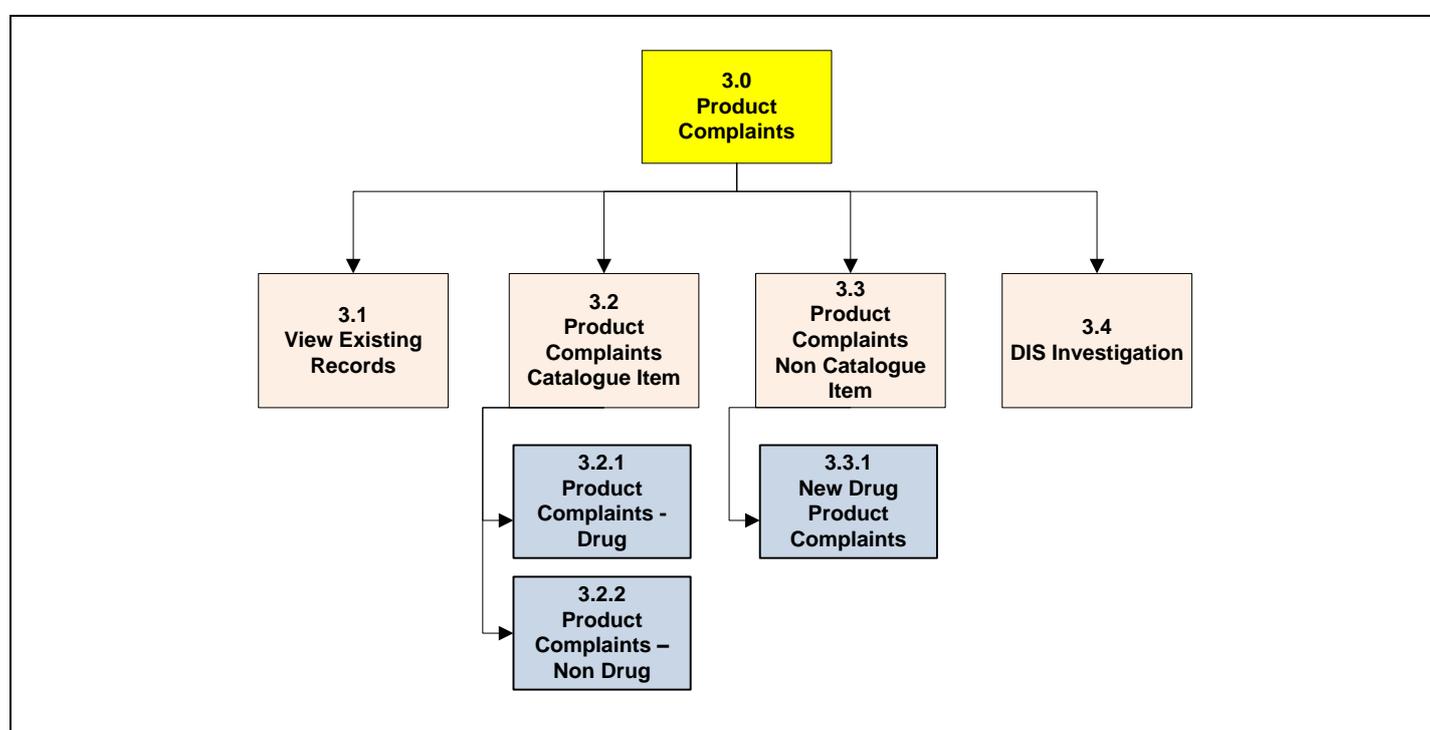


Figure 3.1

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:

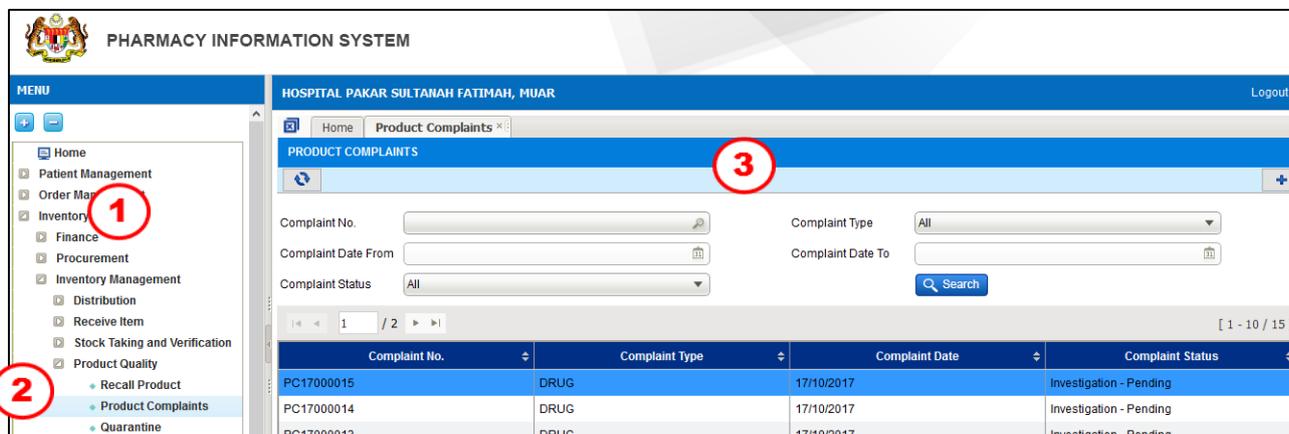


Figure 3.1-1 Create New Product Complaints

STEP 1

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

STEP 2

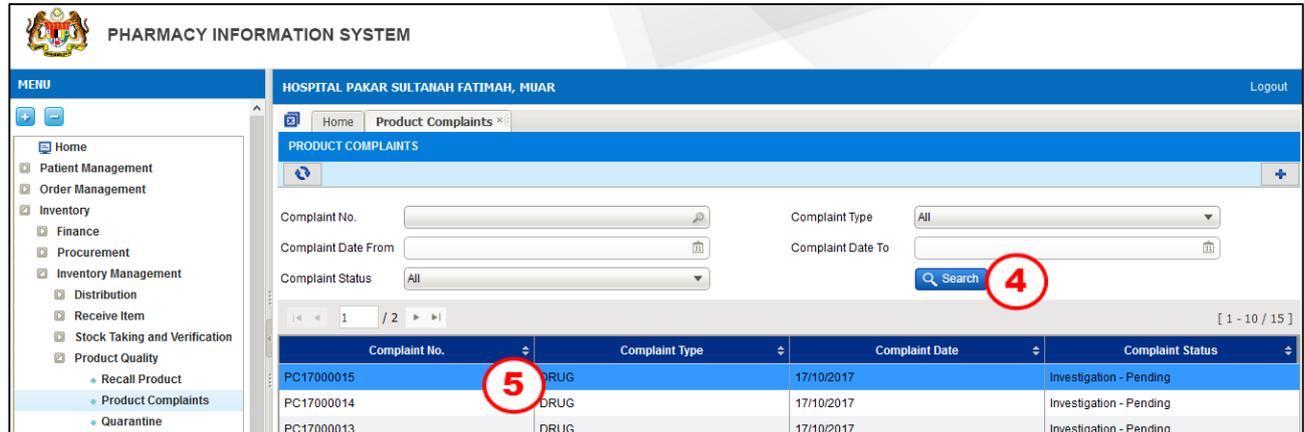
Click on 'Product Quality' and click on 'Product Complaints' Sub menu

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



PHARMACY INFORMATION SYSTEM

HOSPITAL PAKAR SULTANAH FATIMAH, MUAR

Home | Product Complaints x

PRODUCT COMPLAINTS

Complaint No. Complaint Type

Complaint Date From Complaint Date To

Complaint Status **4**

[1 - 10 / 15]

Complaint No.	Complaint Type	Complaint Date	Complaint Status
PC17000015	DRUG	17/10/2017	Investigation - Pending
PC17000014	DRUG	17/10/2017	Investigation - Pending
PC17000013	DRUG	17/10/2017	Investigation - Pending

Figure 3.1-2 Create New Product Complaints

STEP 4

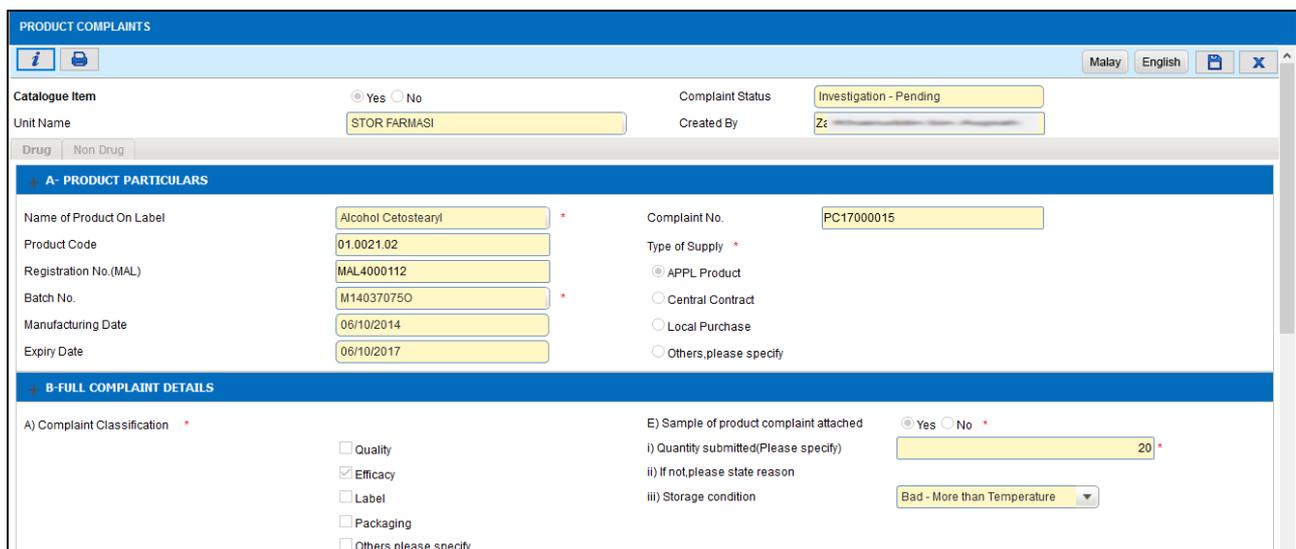
Click on the button

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



PRODUCT COMPLAINTS

Catalogue Item Yes No Complaint Status

Unit Name Created By

Drug Non Drug

A- PRODUCT PARTICULARS

Name of Product On Label * Complaint No.

Product Code Type of Supply *

Registration No.(MAL) APPL Product

Batch No. * Central Contract

Manufacturing Date Local Purchase

Expiry Date Others,please specify

B-FULL COMPLAINT DETAILS

A) Complaint Classification *

Quality

Efficacy

Label

Packaging

Others,please specify

E) Sample of product complaint attached Yes No *

i) Quantity submitted(Please specify) *

ii) If not,please state reason

iii) Storage condition

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:

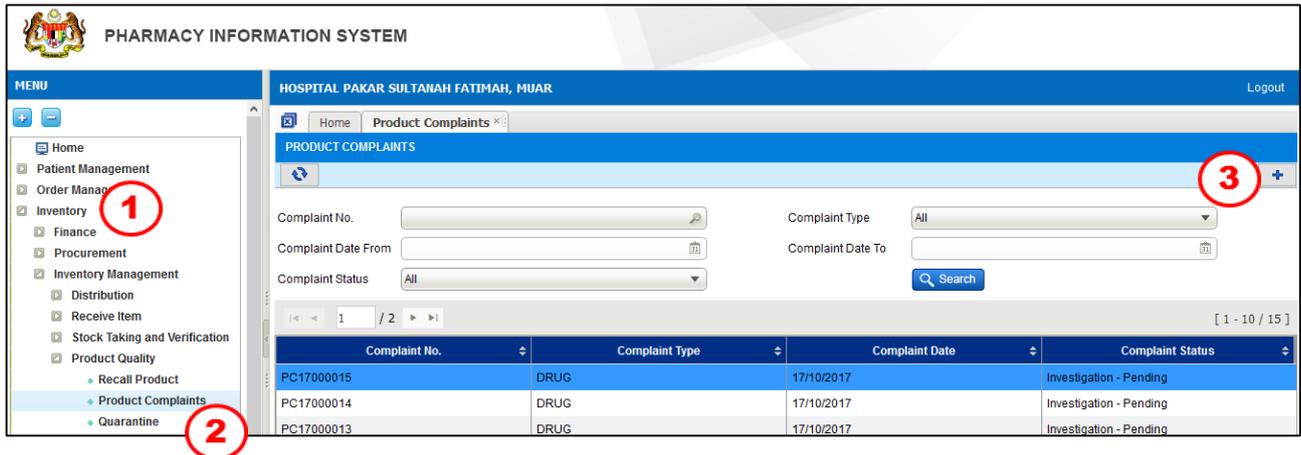


Figure 3.2.1-1 Product Complaints

STEP 1

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

STEP 2

Click on 'Product Quality' and click on 'Product Complaints' Sub-Menu.

STEP 3

Click on the  button to record new complaints

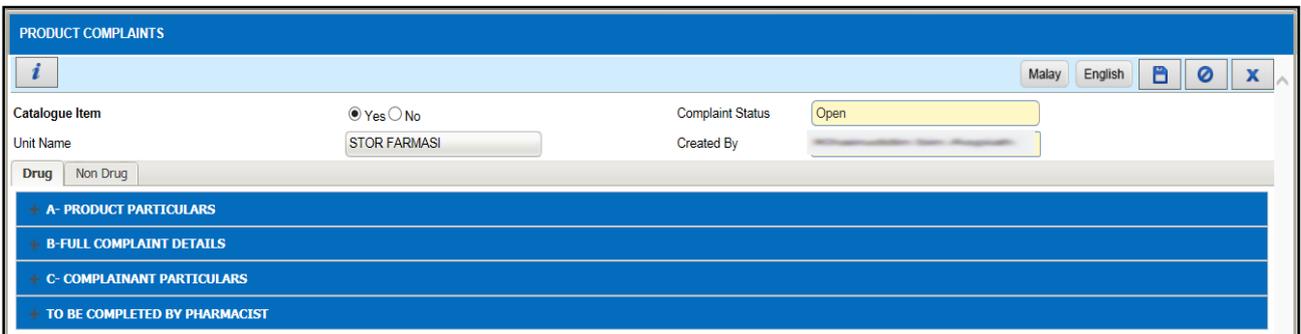
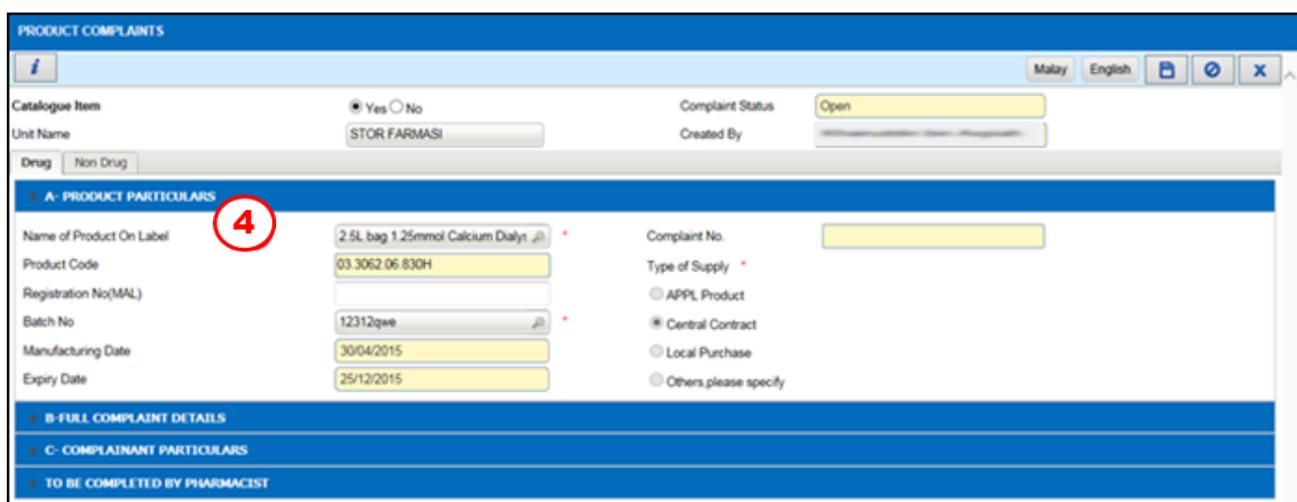


Figure 3.2.1-2 New Drug Product Complaints – Catalogue Item

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 **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 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.

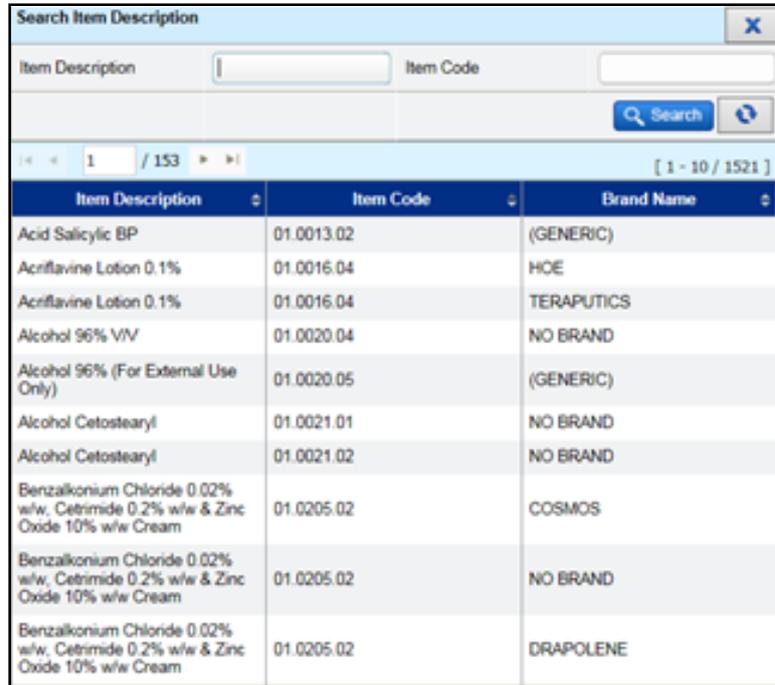


The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top, there are language options for 'Malay' and 'English'. Below that, there are fields for 'Catalogue Item' (Yes/No), 'Complaint Status' (Open), and 'Unit Name' (STOR FARMASI). There are also 'Drug' and 'Non Drug' tabs. The main section is 'A - PRODUCT PARTICULARS', which contains several input fields: 'Name of Product On Label' (with a red circle and the number 4), 'Product Code', 'Registration No(MAL)', 'Batch No', 'Manufacturing Date', and 'Expiry Date'. 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). Below this section are three collapsed sections: 'B - FULL COMPLAINT DETAILS', 'C - COMPLAINANT PARTICULARS', and 'TO BE COMPLETED BY PHARMACIST'.

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	HOE
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.

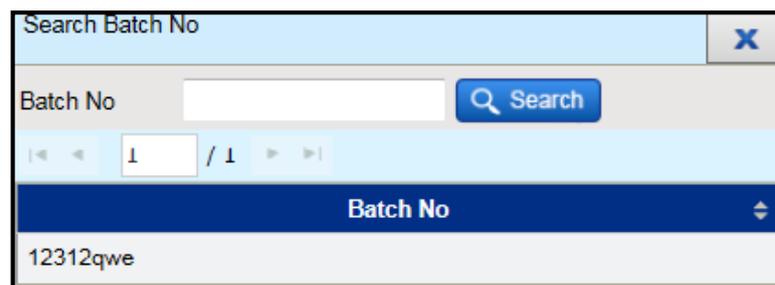
Click on the  button.

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

Product Code will be displayed automatically 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

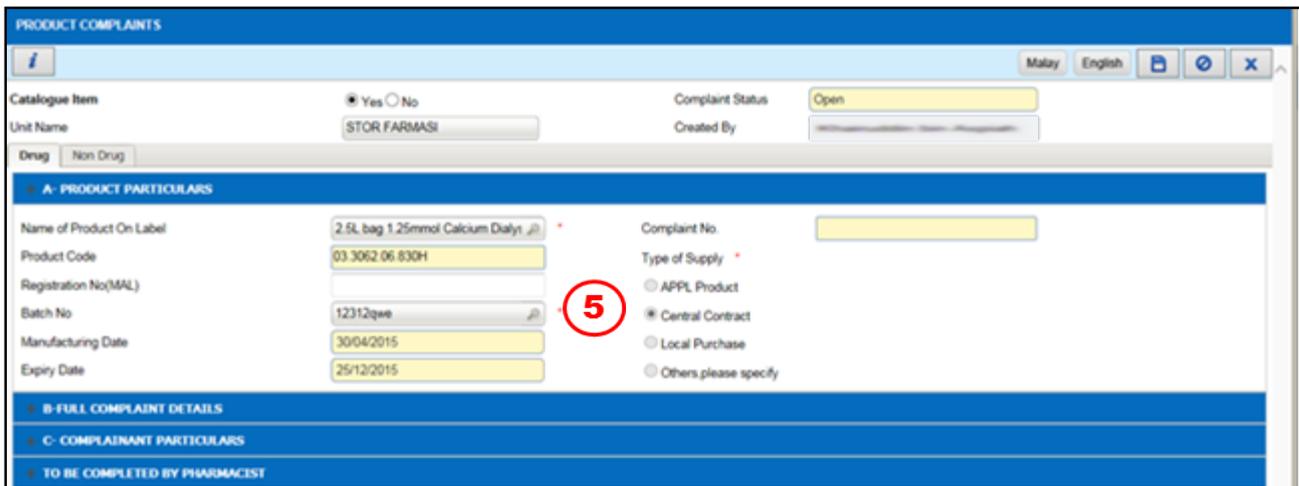
Note

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.

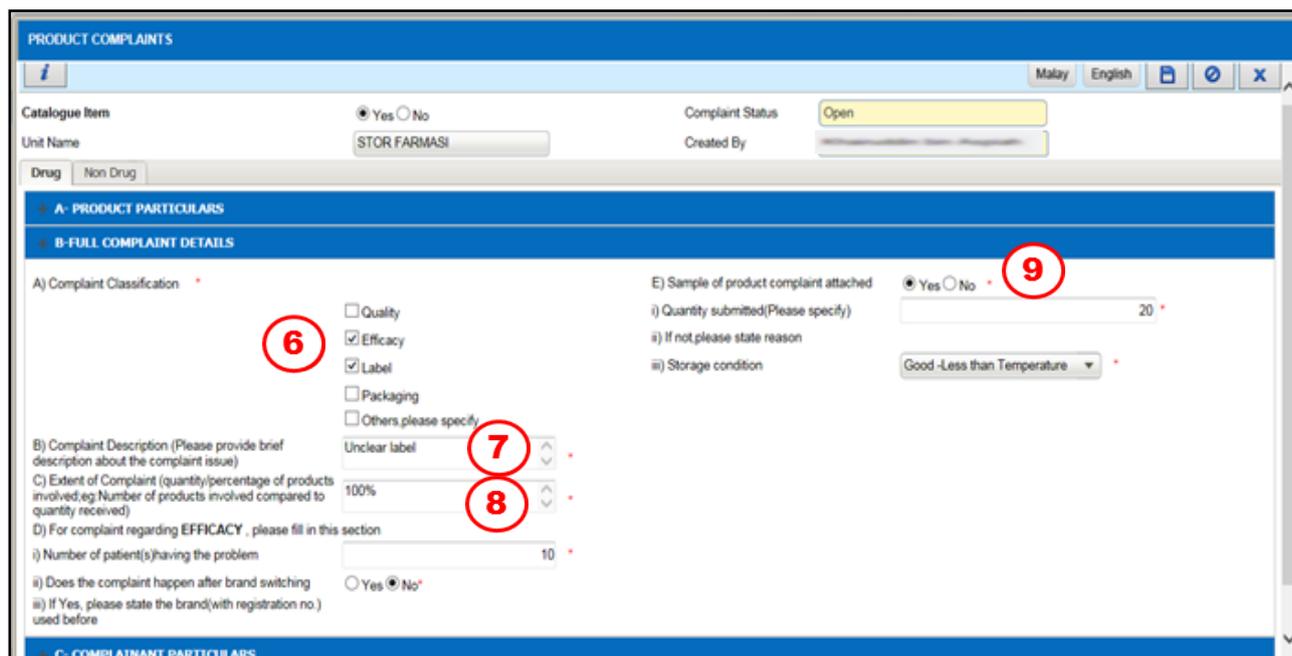
Click on the  button.

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



The screenshot shows a web application window titled "PRODUCT COMPLAINTS". At the top right, there are language options for "Malay" and "English", and window control buttons. Below the title bar, there are several input fields: "Catalogue Item" with a "Yes/No" radio button, "Unit Name" with a dropdown menu showing "STOR FARMASI", "Complaint Status" with a dropdown menu showing "Open", and "Created By" with a dropdown menu. Below these is a "Drug" vs "Non Drug" toggle. The main section is titled "A- PRODUCT PARTICULARS" and contains several fields: "Name of Product On Label" (text input), "Product Code" (text input), "Registration No(MAL)" (text input), "Batch No" (text input, highlighted with a red circle containing the number 5), "Manufacturing Date" (date input), "Expiry Date" (date input), "Complaint No." (text input), and "Type of Supply" with radio buttons for "APPL Product", "Central Contract" (selected), "Local Purchase", and "Others please specify". Below this section are three expandable sections: "B- FULL COMPLAINT DETAILS", "C- COMPLAINANT 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. Checked: Efficacy, Label.
- 7**: B) Complaint Description. Text: Unclear label.
- 8**: C) Extent of Complaint. Value: 100%.
- 9**: E) Sample of product complaint attached. Radio button: Yes.

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

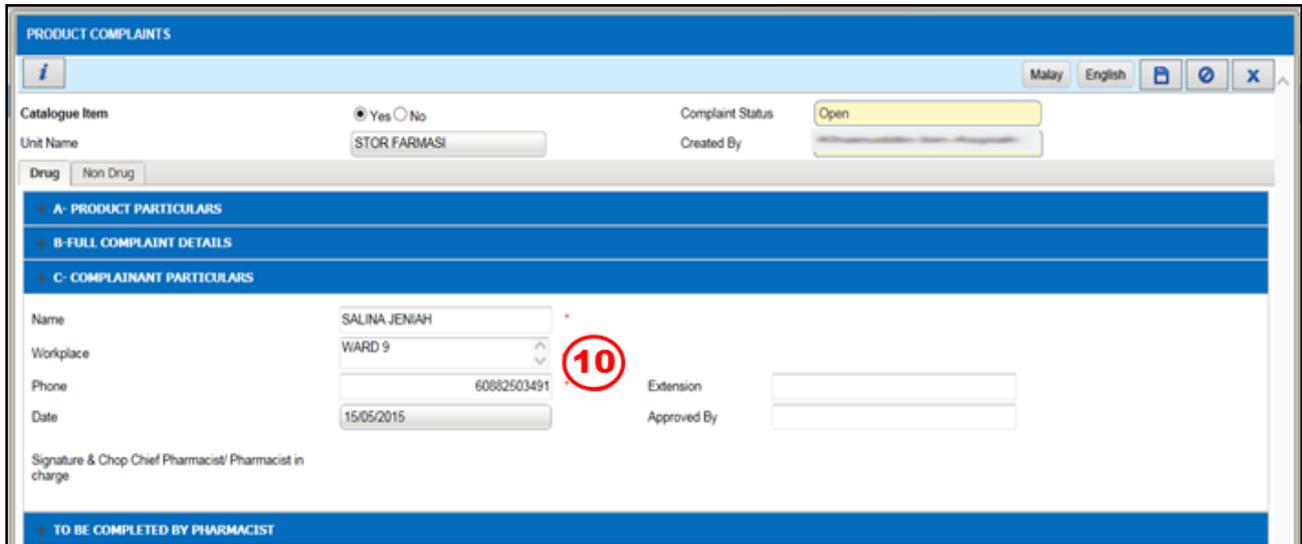


Figure 3.2.1-8 Complainant Particulars

STEP 10

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

Note

The date is defaulted to the current Date.

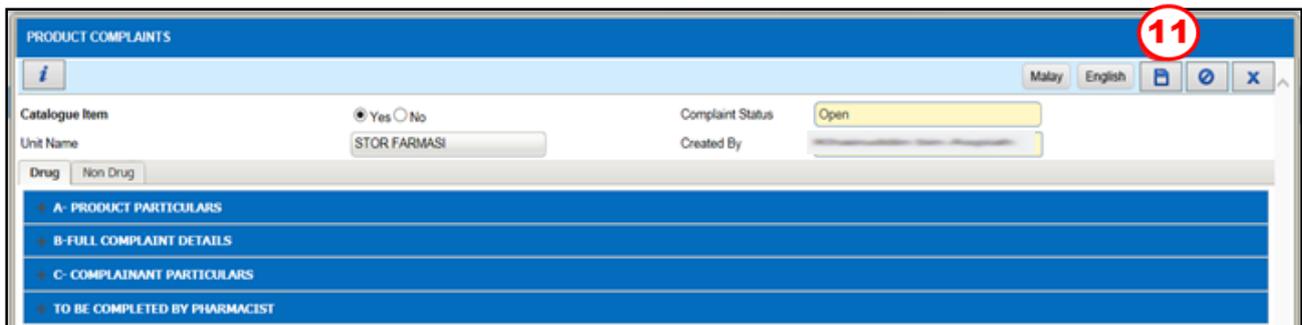


Figure 3.2.1-9 Save record

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

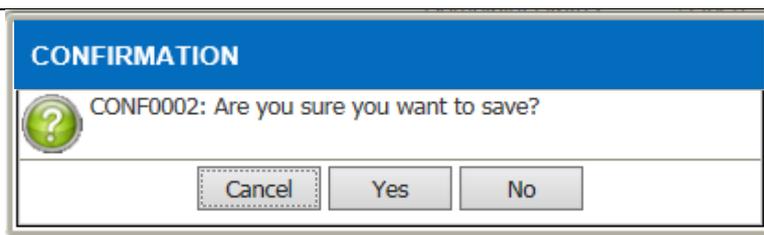
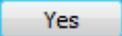


Figure 3.2.1-10 Save Record

- Click on the  button.

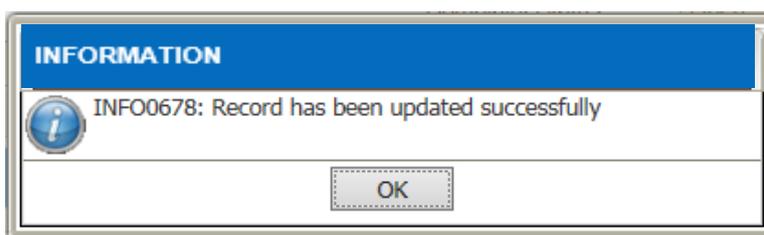
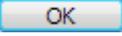


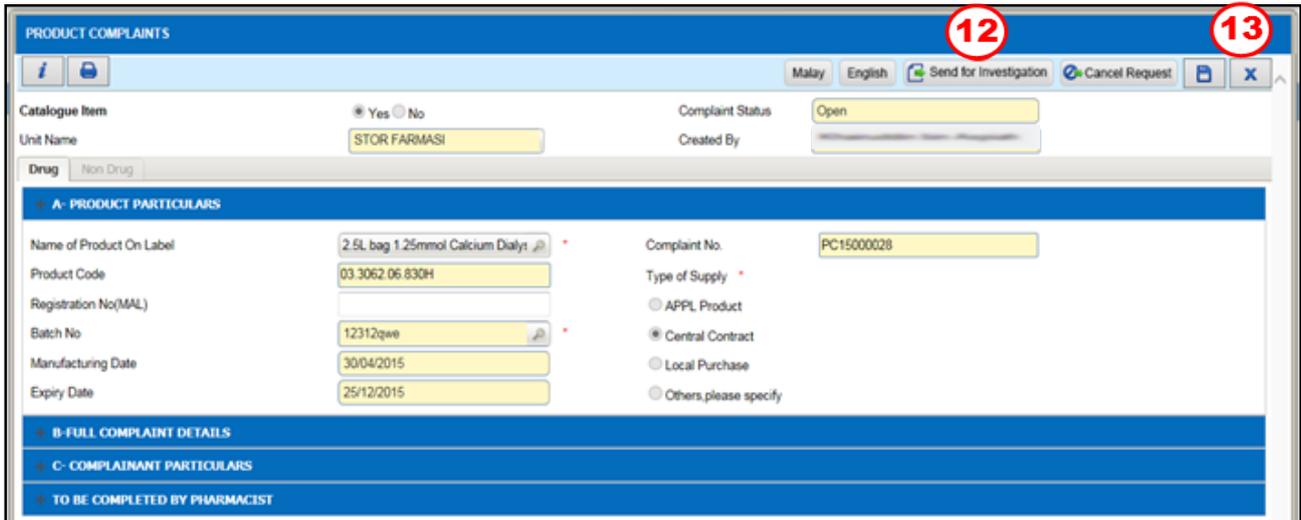
Figure 3.2.1-11 Message Information

- 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

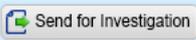
- Send for Investigation  button will be enabled once user saves the Product Complaints record.



The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top right, there are two buttons: 'Send for Investigation' (labeled 12) and 'Cancel Request'. Below the form, there are several sections: 'A- PRODUCT PARTICULARS', 'B- FULL COMPLAINT DETAILS', 'C- COMPLAINANT PARTICULARS', and 'TO BE COMPLETED BY PHARMACIST'. The 'Send for Investigation' button is highlighted with a red circle labeled 12, and the 'Close' button is highlighted with a red circle labeled 13.

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 change 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	Waharuddin bin Asyraf
Product Complaint	PC15000023	23/04/2015 11:09 AM	Investigation - Pending	WAD 12	Waharuddin bin Asyraf
Product Complaint	PC15000024	27/04/2015 04:48 PM	Investigation - Pending	WAD 12	Waharuddin bin Asyraf
Product Complaint	PC15000025	27/04/2015 04:57 PM	Investigation - Pending	UNIT FARMASI KLINIK PAKAR	Waharuddin bin Asyraf
Product Complaint	PC15000026	30/04/2015 06:13 AM	Investigation - Pending	STOR FARMASI	Waharuddin bin Asyraf
Product Complaint	PC15000027	30/04/2015 09:51 PM	Investigation - Pending	STOR FARMASI	Waharuddin bin Asyraf
RCL Transaction type	RC15000016	11/05/2015 03:58 PM	Pending for Approval	STOR FARMASI	Waharuddin bin Asyraf
Slow Moving Item	SM15000001	15/05/2015 10:02 AM	Pending For Approval	STOR FARMASI	Waharuddin bin Asyraf
Product Complaint	PC15000028	15/05/2015 05:10 PM	Investigation - Pending	STOR FARMASI	Waharuddin bin Asyraf

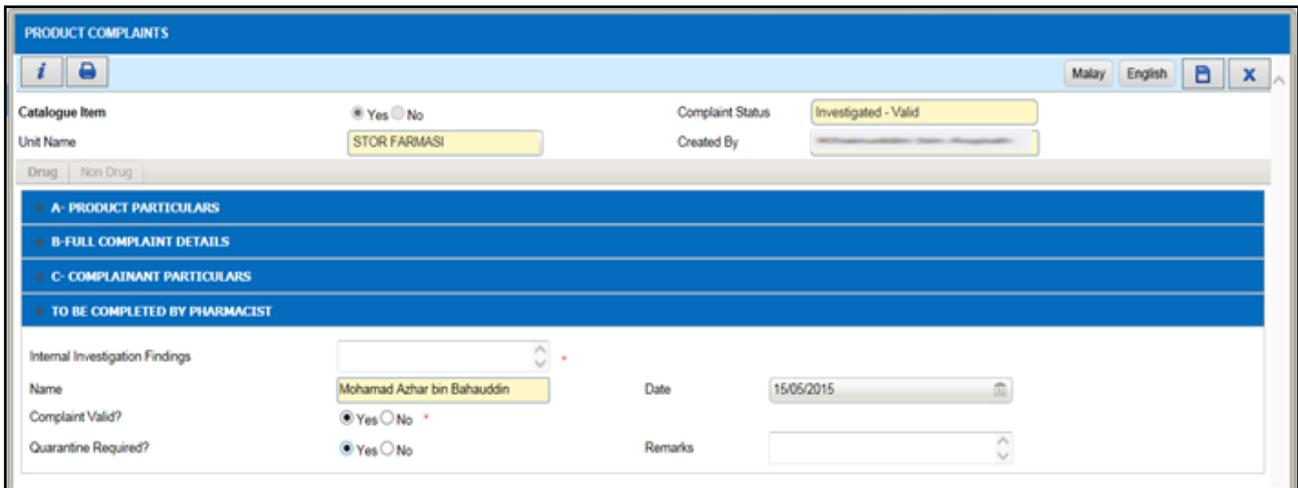
Figure 3.2.2-1 Task List

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' (Yes/No), 'Complaint Status' (Investigated - Valid), 'Unit Name' (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 contains fields for 'Internal Investigation Findings', 'Name' (Mohamad Azhar bin Bahaudin), 'Date' (15/05/2015), 'Complaint Valid?' (Yes/No), 'Quarantine Required?' (Yes/No), and 'Remarks'.

Figure 3.2.2-2 Product Complaints

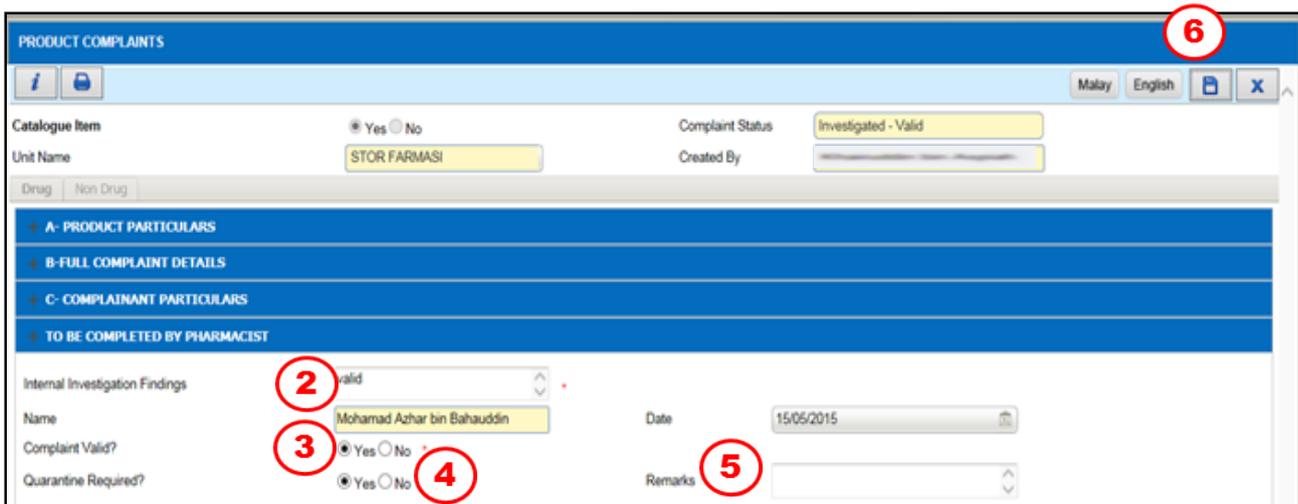
Note

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 includes red circles highlighting specific fields: '6' is at the top right corner; '2' is on the 'Internal Investigation Findings' dropdown menu; '3' is on the 'Complaint Valid?' radio buttons; '4' is on the 'Quarantine Required?' radio buttons; and '5' is on the 'Remarks' text input field.

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.

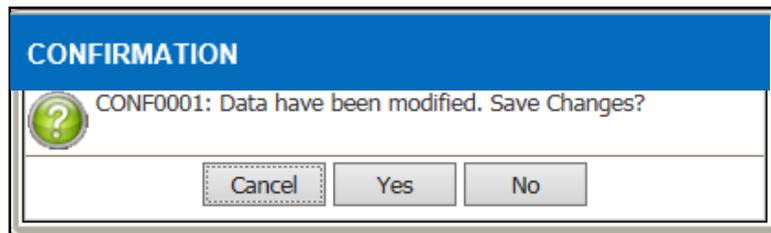
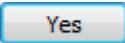


Figure 3.2.2-4 Confirmation message

- Click on the  button to confirm save.

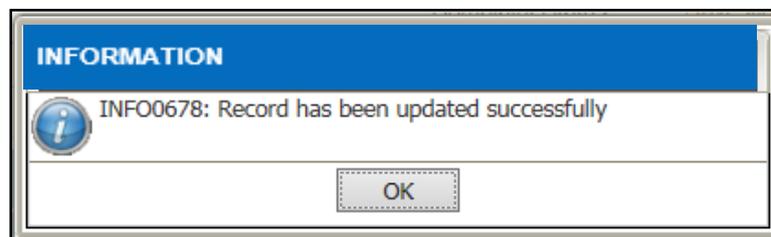
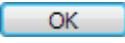
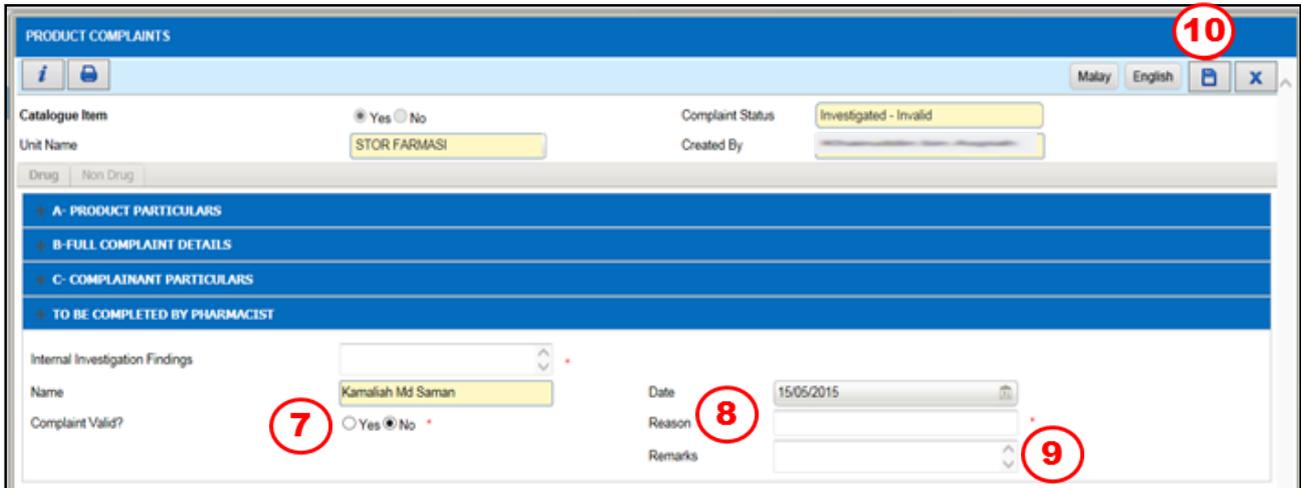


Figure 3.2.2-5 Message Information

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



The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top right, there is a 'Save' button (10). Below it, the 'Complaint Status' is set to 'Investigated - Invalid'. The 'Unit Name' is 'STOR FARMASI'. The 'Internal Investigation Findings' section contains the following fields: 'Name' (Kamalah Md Saman), 'Date' (15/05/2015), 'Complaint Valid?' (7) with 'No' selected, 'Reason' (8), and 'Remarks' (9). There are also expandable sections for 'A- PRODUCT PARTICULARS', 'B- FULL COMPLAINT DETAILS', 'C- COMPLAINANT PARTICULARS', and 'TO BE COMPLETED BY PHARMACIST'.

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.

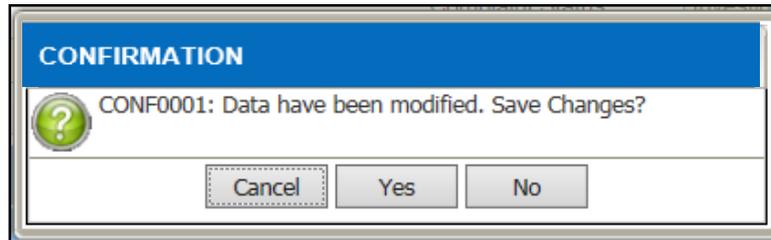
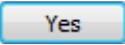


Figure 3.2.2-7 Save Record

- Click on the  button to confirm save.

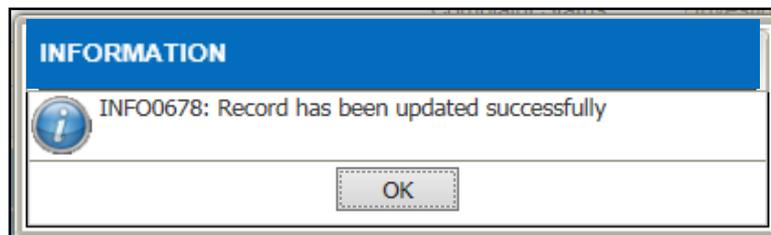
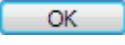


Figure 3.2.2-8 Message Information

- 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.

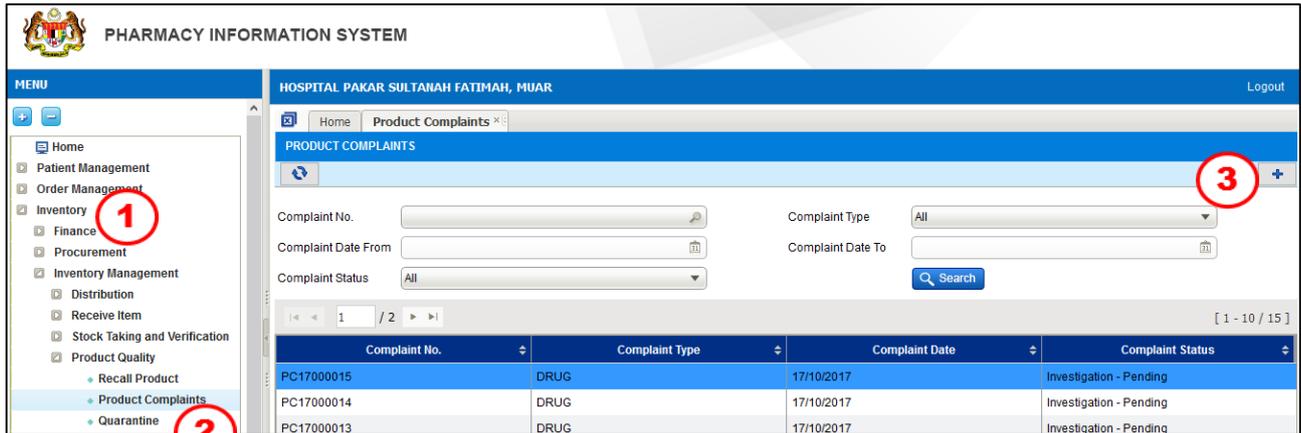


Figure 3.2.3-1 Create New Product Complaints

STEP 1

Click on 'Inventory' menu and click on 'Inventory Management' Sub-Menu.

STEP 2

Click on 'Product Quality' and click on 'Product Complaints' Sub-Menu.

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

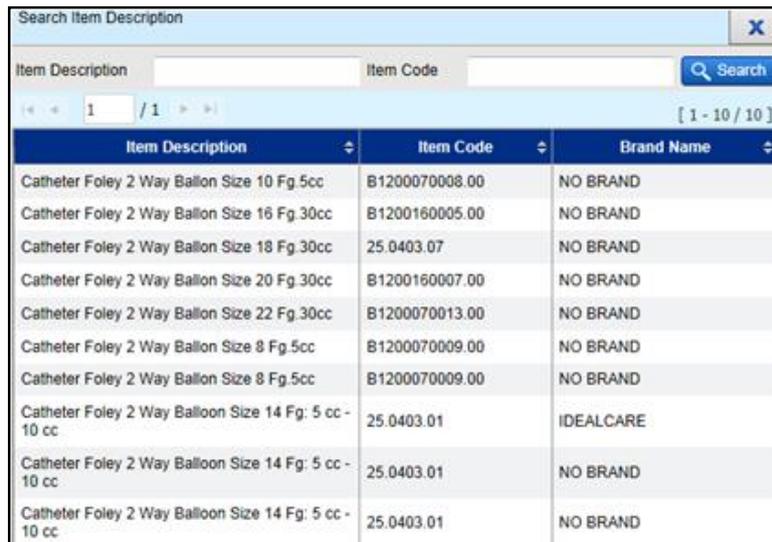
Enter the **Product Type/Application (e.g. Urinary catheter)**

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 Ballon Size 10 Fg.5cc	B1200070008.00	NO BRAND
Catheter Foley 2 Way Ballon Size 16 Fg.30cc	B1200160005.00	NO BRAND
Catheter Foley 2 Way Ballon Size 18 Fg.30cc	25.0403.07	NO BRAND
Catheter Foley 2 Way Ballon Size 20 Fg.30cc	B1200160007.00	NO BRAND
Catheter Foley 2 Way Ballon Size 22 Fg.30cc	B1200070013.00	NO BRAND
Catheter Foley 2 Way Ballon Size 8 Fg.5cc	B1200070009.00	NO BRAND
Catheter Foley 2 Way Ballon Size 8 Fg.5cc	B1200070009.00	NO BRAND
Catheter Foley 2 Way Ballon Size 14 Fg: 5 cc - 10 cc	25.0403.01	IDEALCARE
Catheter Foley 2 Way Ballon Size 14 Fg: 5 cc - 10 cc	25.0403.01	NO BRAND
Catheter Foley 2 Way Ballon Size 14 Fg: 5 cc - 10 cc	25.0403.01	NO BRAND

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

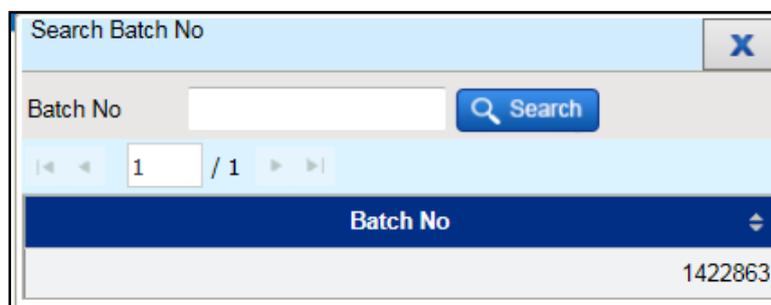
- Enter a partially or fully search criteria of Item Description and/or Item Code and click the  button.
- Click on the  button to close the Search Item Code text box.

STEP 6

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

Note

- System will display as Figure 3.2.3-5.



Batch No
1422863

Figure 3.2.3-5 Search Batch No.

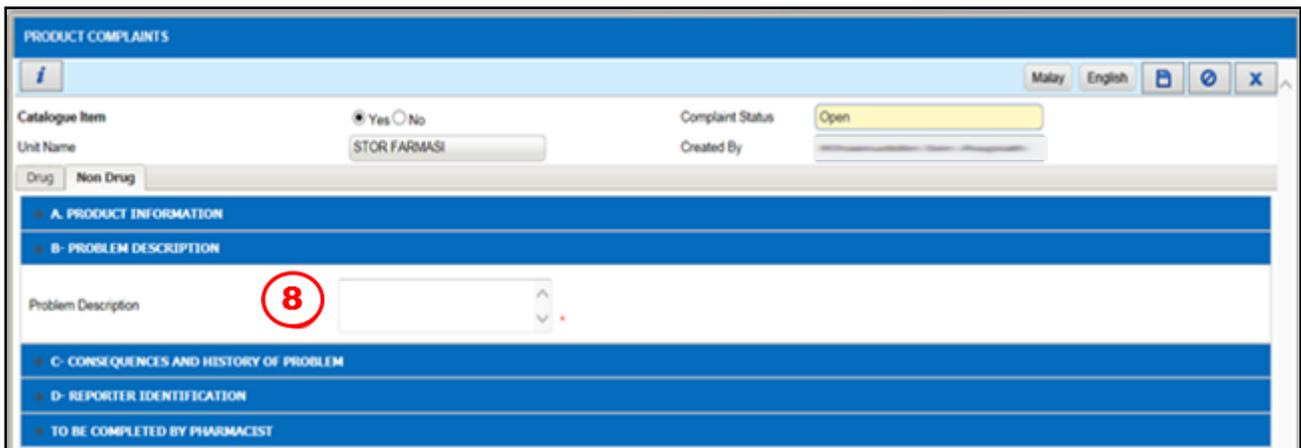
- Only available **Batch No** in the unit will be listed in the Batch No list.
- Click on the button to close the Search Batch No text box.
- **Date of Manufacture, Date of Purchase and Date of Expiry** will be displayed automatically based on the **Serial/Batch/Lot Number** selected.

STEP 7

Select the button for question 8 & 9

STEP 8

Enter the **Problem Description**

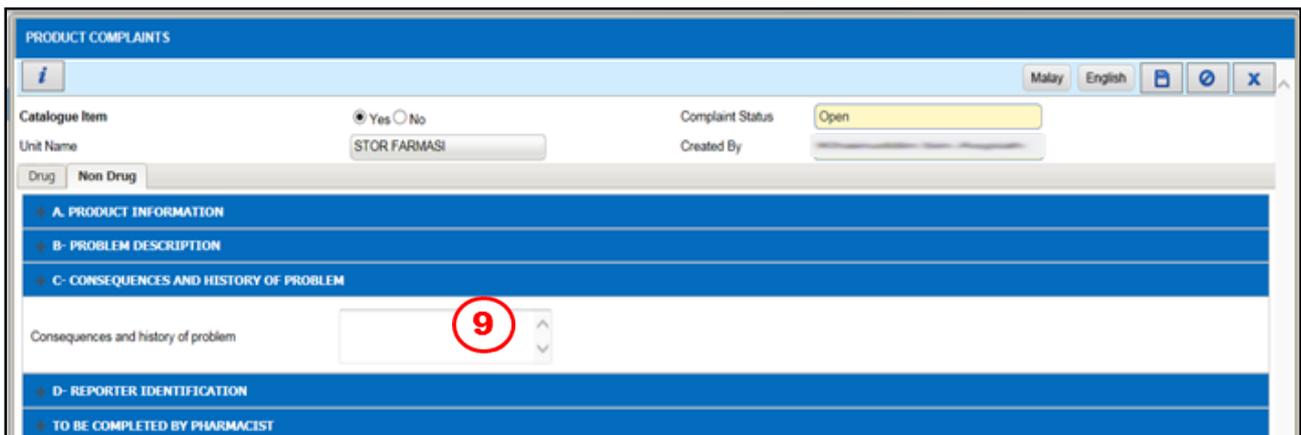


The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top, there are language options for 'Malay' and 'English', and window control buttons. Below this, there are fields for 'Catalogue Item' (Yes/No radio buttons), 'Complaint Status' (Open), 'Unit Name' (STOR FARMASI), and 'Created By'. A section for 'Drug' and 'Non Drug' is also present. The main content area is divided into several sections: 'A. PRODUCT INFORMATION', 'B. PROBLEM DESCRIPTION', 'C. CONSEQUENCES AND HISTORY OF PROBLEM', 'D. REPORTER IDENTIFICATION', and 'TO BE COMPLETED BY PHARMACIST'. The 'B. PROBLEM DESCRIPTION' section is currently active, and the 'Problem Description' text area is highlighted with a red circle containing the number 8.

Figure 3.2.3-6 Problem Description

STEP 9

Enter the **Consequences and History of Problem**



This screenshot is identical to the previous one, showing the 'PRODUCT COMPLAINTS' form. In this view, the 'C. CONSEQUENCES AND HISTORY OF PROBLEM' section is active, and the 'Consequences and history of problem' text area is highlighted with a red circle containing the number 9.

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.

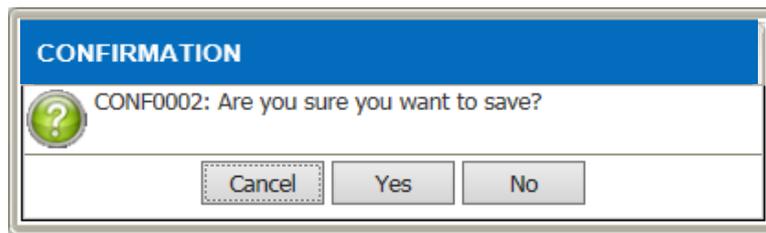
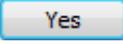


Figure 3.2.3-8 Save Record

- Click on the  button to confirm save.

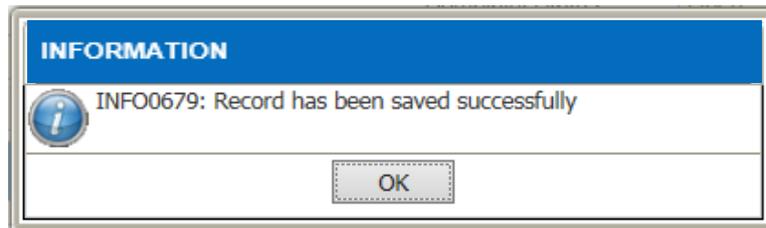
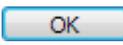


Figure 3.2.3-9 Message Information

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

3.2.4 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.

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	Khanubdin bin Asyraf
Product Complaint	PC15000023	23/04/2015 11:09 AM	Investigation - Pending	WAD 12	Khanubdin bin Asyraf
Product Complaint	PC15000024	27/04/2015 04:48 PM	Investigation - Pending	WAD 12	Khanubdin bin Asyraf
Product Complaint	PC15000025	27/04/2015 04:57 PM	Investigation - Pending	UNIT FARMASI KLINIK PAKAR	Khanubdin bin Asyraf
Product Complaint	PC15000026	30/04/2015 06:13 AM	Investigation - Pending	STOR FARMASI	Khanubdin bin Asyraf
Product Complaint	PC15000027	30/04/2015 09:51 PM	Investigation - Pending	STOR FARMASI	Khanubdin bin Asyraf
RCL Transaction type	RC15000016	11/05/2015 03:58 PM	Pending for Approval	STOR FARMASI	Khanubdin bin Asyraf
Slow Moving Item	SM15000001	15/05/2015 10:02 AM	Pending For Approval	STOR FARMASI	Khanubdin bin Asyraf
Product Complaint	PC15000029	15/05/2015 06:24 PM	Investigation - Pending	STOR FARMASI	Khanubdin 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.

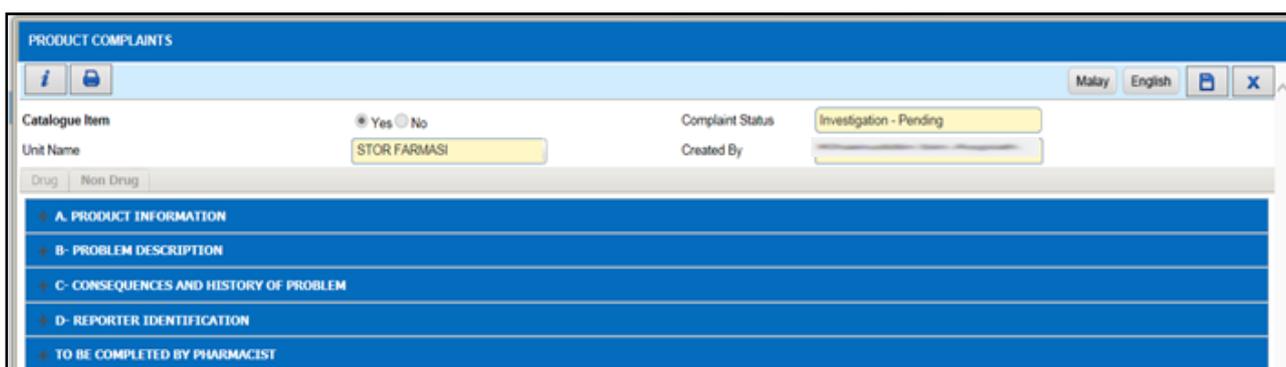


Figure 3.2.4-2 Investigation – Pending Product Complaints record

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.*

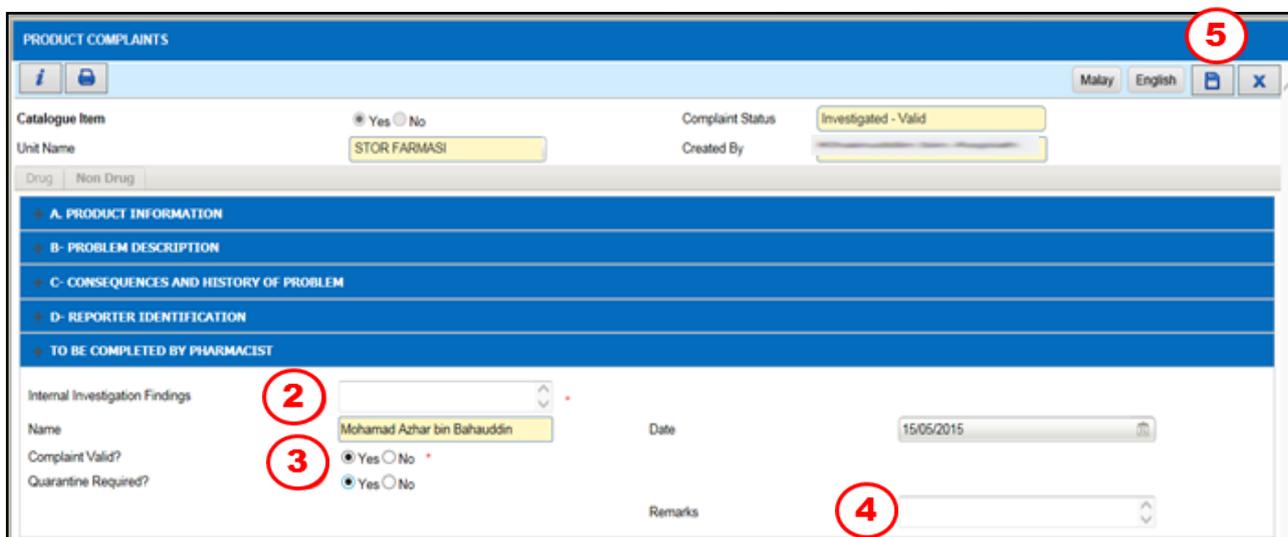


Figure 3.2.4-3 Investigation – Valid Product Complaints record

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.

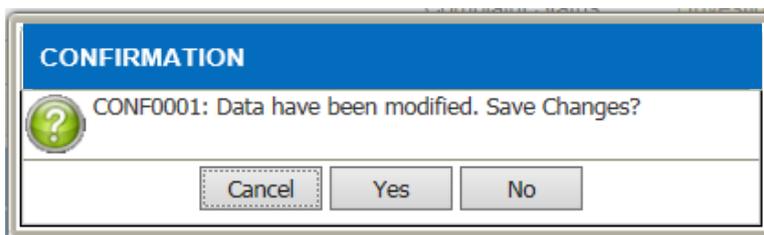
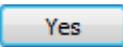


Figure 3.2.4-4 Save Record

- Click on the  button to confirm save.

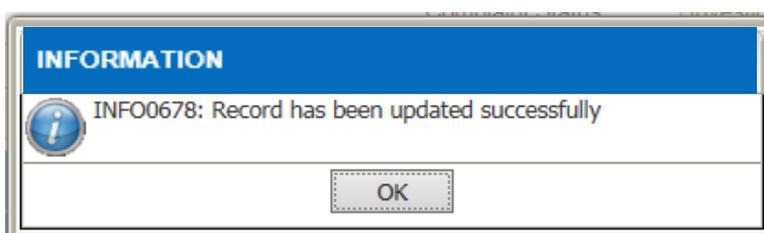


Figure 3.2.4-5 Message Information

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

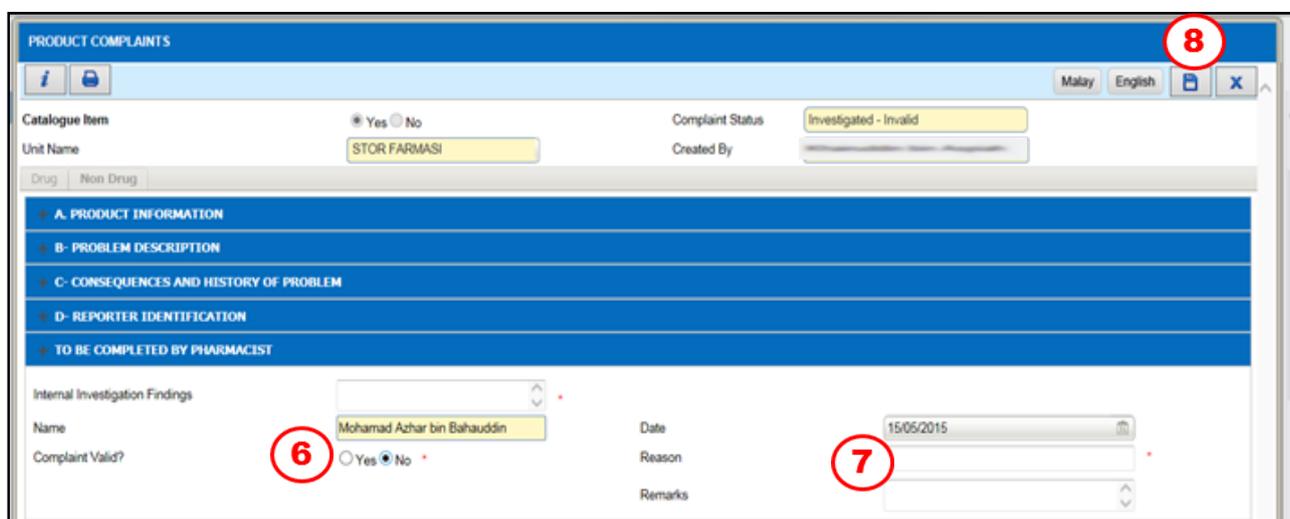


Figure 3.2.4-6 Investigation – Invalid Product Complaints record

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

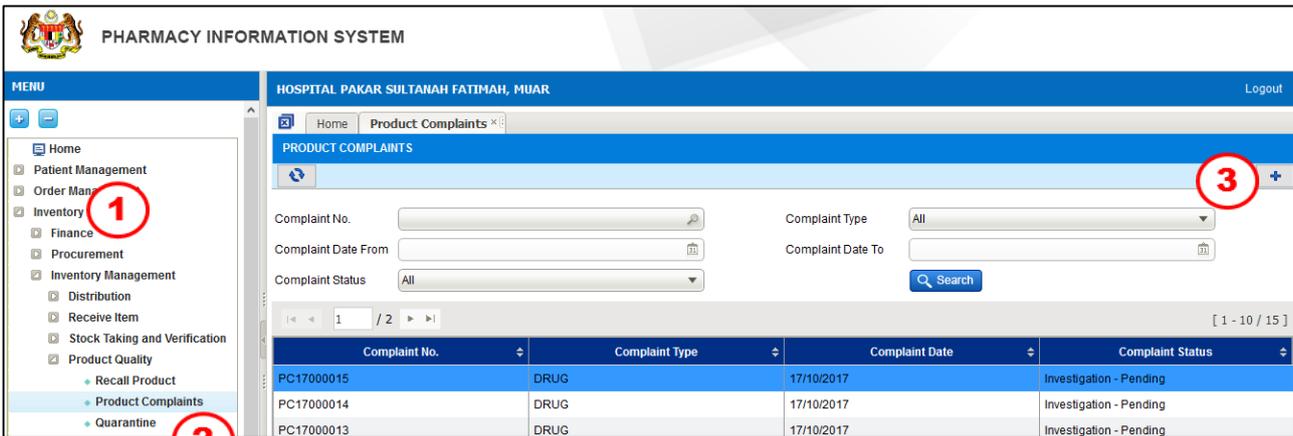
The status of the Product Complaints record will be changed to Investigated – Invalid.

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 Management' (1), which includes 'Product Complaints' (2). The main area shows the 'PRODUCT COMPLAINTS' screen with search filters for Complaint No., Complaint Date, and Complaint Status. A table lists three drug complaints from 17/10/2017, all with a status of 'Investigation - Pending'. A '+ Add' button (3) is visible in the top right of the main area.

Complaint No.	Complaint Type	Complaint Date	Complaint Status
PC17000015	DRUG	17/10/2017	Investigation - Pending
PC17000014	DRUG	17/10/2017	Investigation - Pending
PC17000013	DRUG	17/10/2017	Investigation - Pending

Figure 3.3.1-1 Product Complaints Listing Page

STEP 1

Click on 'Inventory' menu and click on 'Inventory Management' Sub-Menu.

STEP 2

Click on "Product Quality" and click on 'Product Complaints' Sub-Menu.

STEP 3

Click on the  button

Note

Product Complaints screen will be displayed in Figure 3.3.1-2

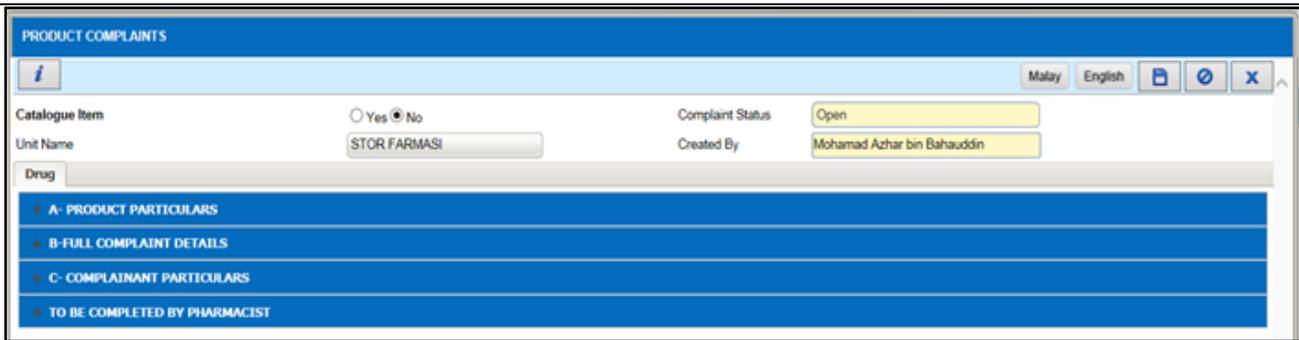


Figure 3.3.1-2 New Drug Product Complaints – Catalogue Item

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.

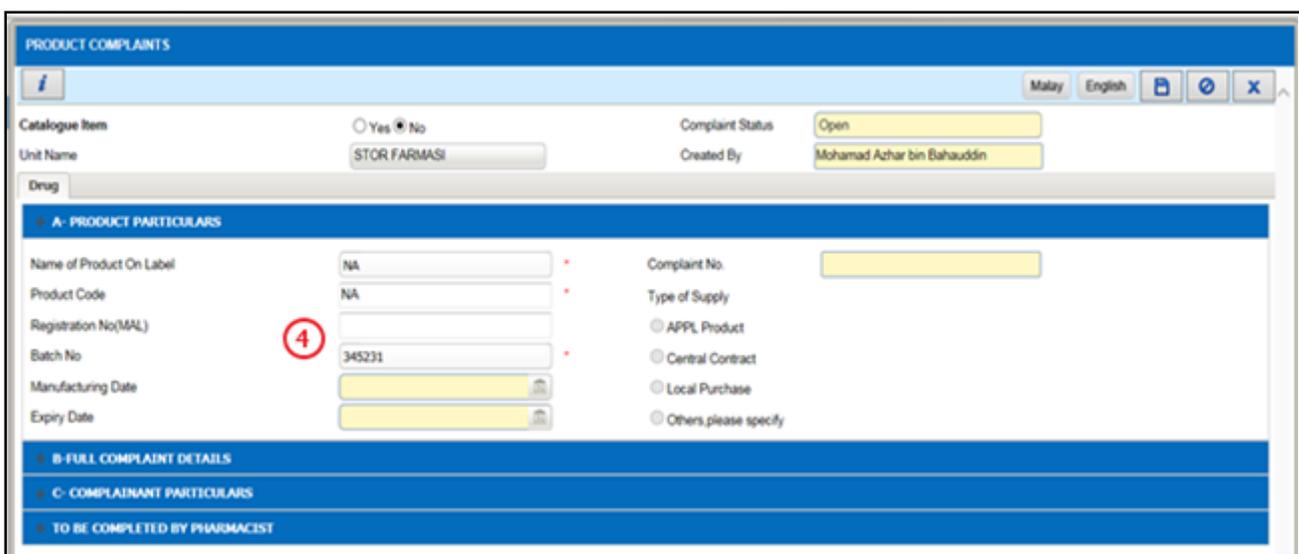


Figure 3.3.1-3 Non Catalogue - Drug Product Complaints – Product Particulars

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.

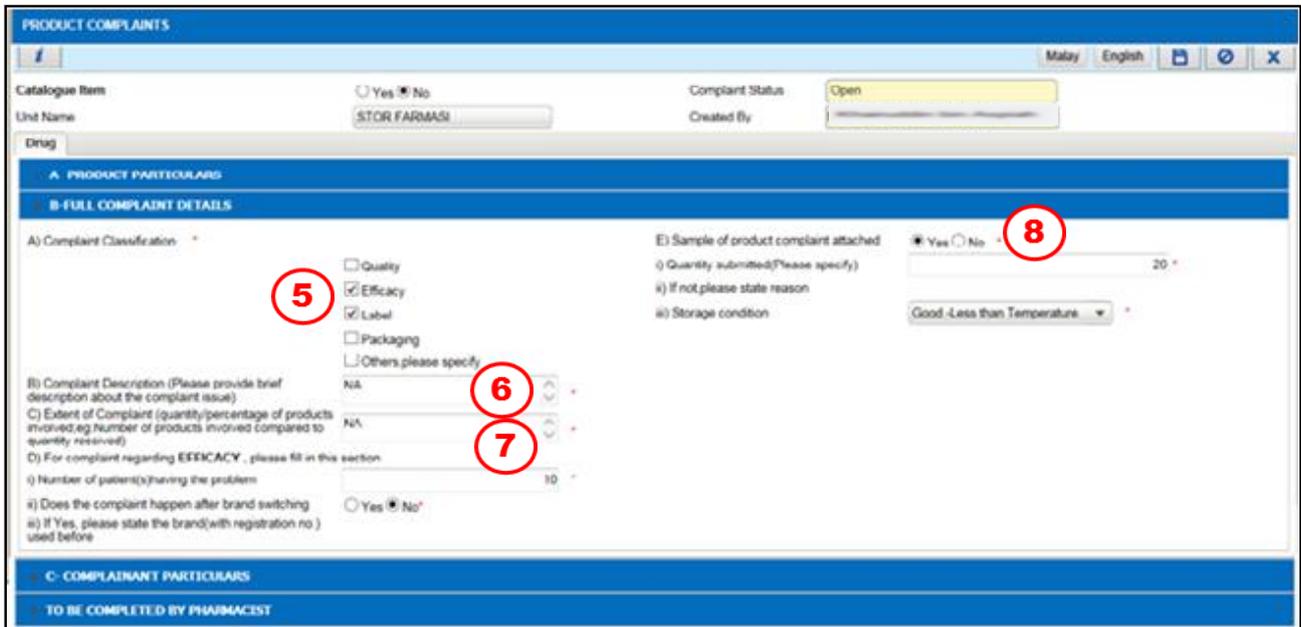


Figure 3.3.1-4 Full Complaints Details

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**

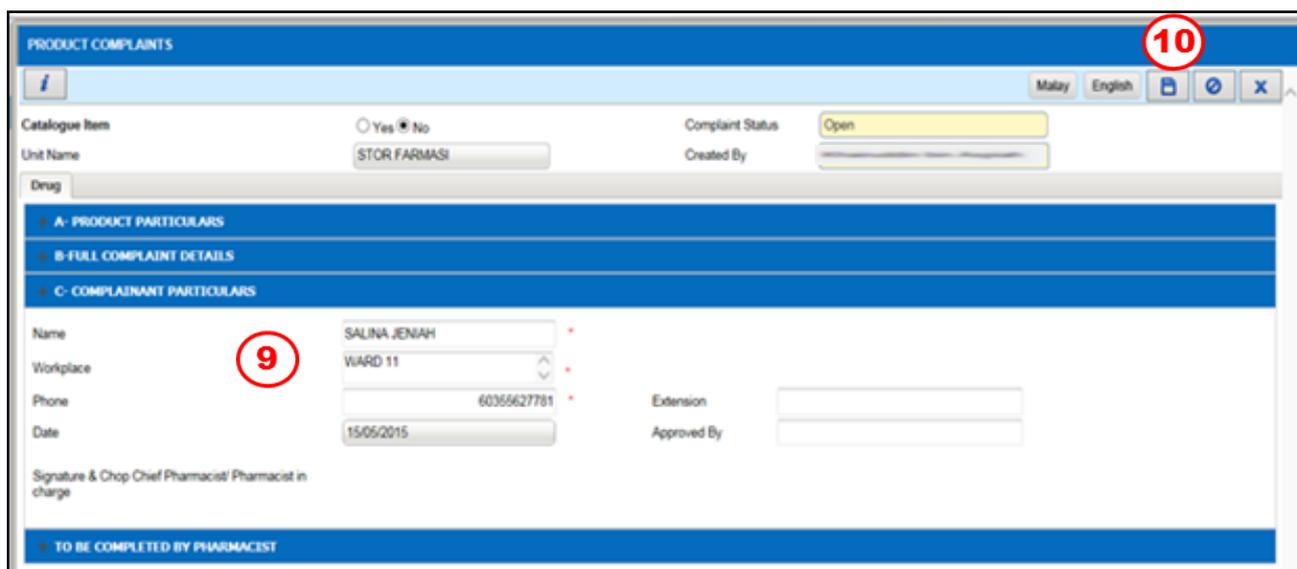


Figure 3.3.1-5 Complainant Particulars

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

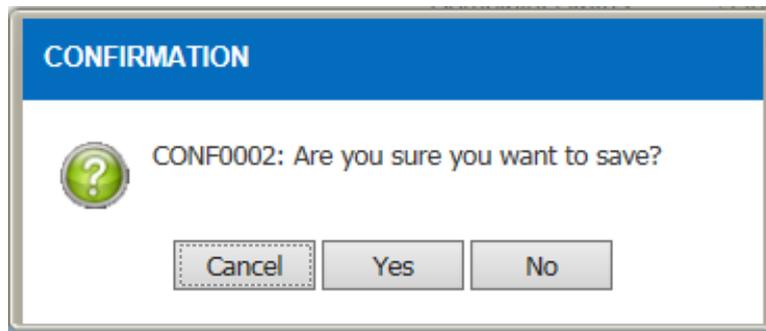
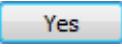


Figure 3.3.1-6 Save Record

- Click on the  button.

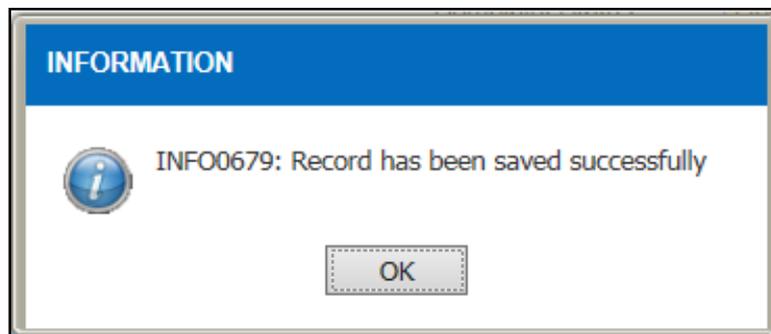
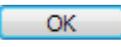


Figure 3.3.1-7 Message Information

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

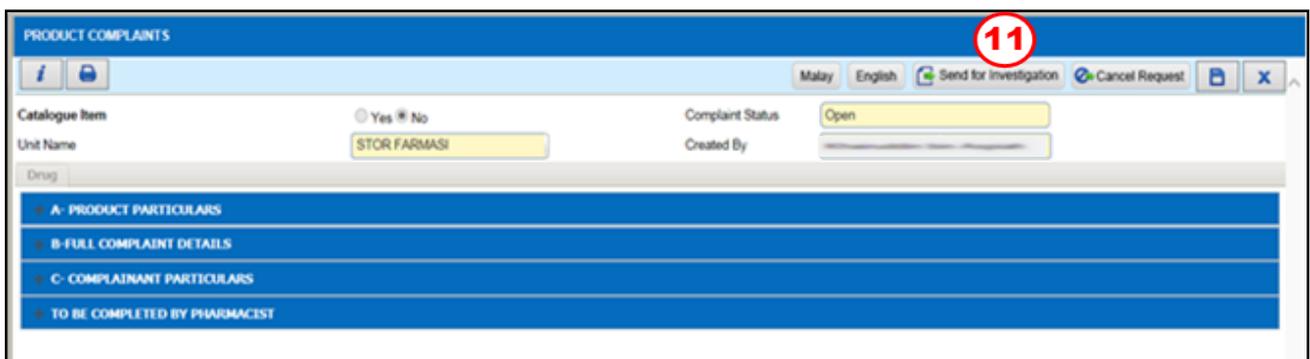


Figure 3.3.1-8 Send for Investigation

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.

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	Khanubdin bin Asyraf	
Product Complaint	PC15000023	23/04/2015 11:09 AM	Investigation - Pending	WAD 12	Khanubdin bin Asyraf	
Product Complaint	PC15000024	27/04/2015 04:48 PM	Investigation - Pending	WAD 12	Khanubdin bin Asyraf	
Product Complaint	PC15000025	27/04/2015 04:57 PM	Investigation - Pending	UNIT FARMASI KLINIK PAKAR	Khanubdin bin Asyraf	
Product Complaint	PC15000026	30/04/2015 06:13 AM	Investigation - Pending	STOR FARMASI	Khanubdin bin Asyraf	
Product Complaint	PC15000027	30/04/2015 09:51 PM	Investigation - Pending	STOR FARMASI	Khanubdin bin Asyraf	
RCL Transaction type	RC15000016	11/05/2015 03:58 PM	Pending for Approval	STOR FARMASI	Khanubdin bin Asyraf	
Slow Moving Item	SM15000001	15/05/2015 10:02 AM	Pending For Approval	STOR FARMASI	Khanubdin bin Asyraf	
Product Complaint	PC15000030	15/05/2015 07:03 PM	Investigation - Pending	STOR FARMASI	Khanubdin 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: Investigation - Pending

Unit Name: STOR FARMASI Created By: [User Name]

Drag

- 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.

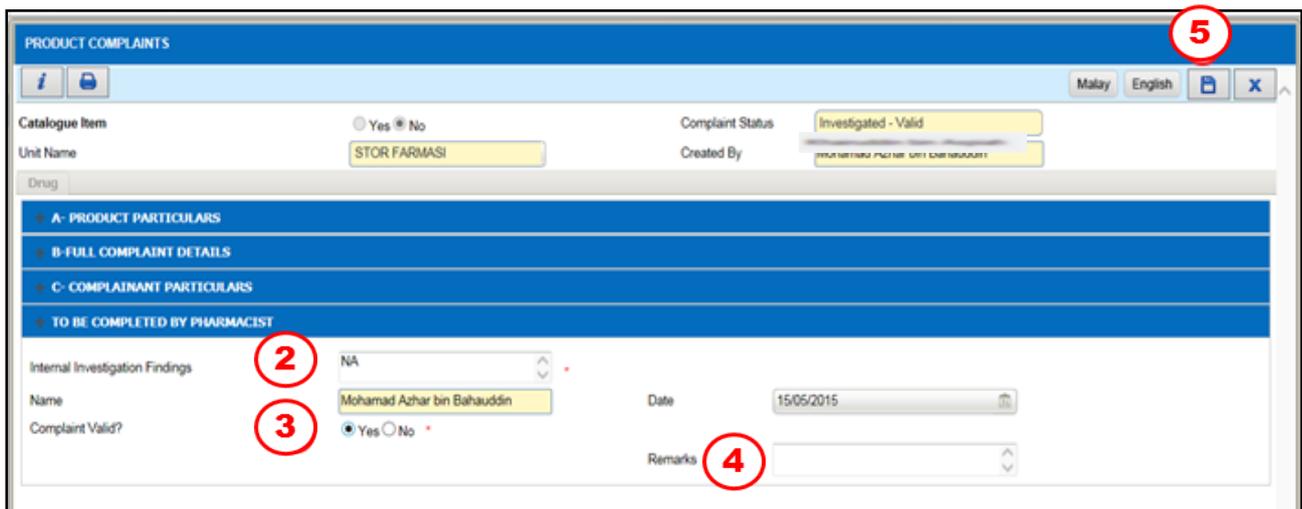


Figure 3.3.2-3 Investigation – Valid Product Complaints record

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.

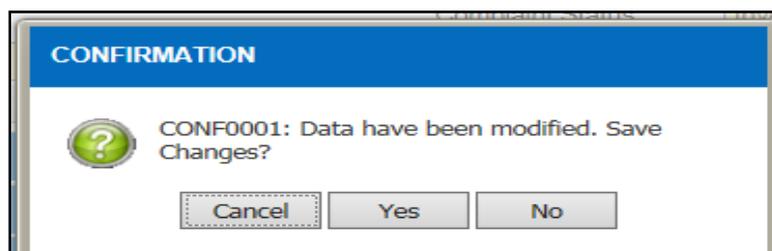
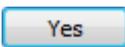


Figure 3.3.2-4 Save Record

- Click on the  button to confirm save.

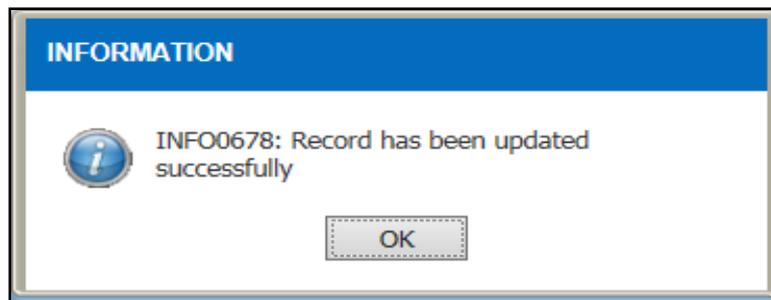


Figure 3.3.2-5 Message Information



4 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