



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

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## **Pharmacy Based User Manual Therapeutic Drug Monitoring (TDM)**

<b>Version</b>	<b>: 6<sup>th</sup> Edition</b>
<b>Document ID</b>	<b>: PB_U. MANUAL_THERAPEUTIC DRUG MONITORING</b>



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*Reference ID : PB\_U. MANUAL\_THERAPEUTIC DRUG MONITORING-6<sup>th</sup> Edition*

*Application reference: PhIS & CPS v1.6.1*



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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 geared towards 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 Therapeutic Drug Monitoring (TDM) module and its key features/functionalities. The primary objective is to help guide user through the process of completing PhIS application process. User will understand the following activities in details:

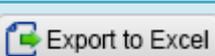
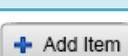
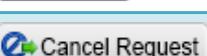
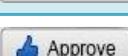
### 1.3 Organised Sections

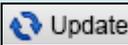
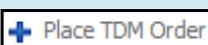
These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Therapeutic Drug Monitoring
- Section 4 : Acronyms
- Section 5 : Links To Clinical Modules

## 2.0 Application Standard Features

### 2.1 PhIS Legend

Standard Legend			
	Login to PhIS		Logout from PhIS
	Change Login Password		Reset Login Screen
	Expand Menu		Collapse Menu
	Display Home Tab		Expand Module
	Collapse Module		Close All Open Tabs
	Refresh Screen		Search Record
	Add/Create New Record		Show Help
	Print	*	Mandatory Field
	Calendar Icon		Search Icon
	Close Window		Radio Button
	Checkbox		Edit Record
	Cancel		Delete Record
	Save		Export and Open Report in Excel Format
	Add Item to the list		Delete Item from the list
	Request for Approval		Cancel the Request
	Approve Transaction		Reject Transaction
	Automatically Display/Retrieve Box		Empty Text Box
	Dropdown Box		

TDM Module Legend			
 Delete	Delete Record	 Update	Update Record
<a href="#">TDM Guidelines</a>	Display TDM Guidelines Details	 Add	Add Sampling Details
 Update	Update Sampling Details	<a href="#">Drug Info</a>	Display Selected TDM Drug Information
 New	Create New TDM Order	 Add New Sample	Add New Sampling Details
 Place TDM Order	Display TDM Order Screen to Place New TDM Order	<a href="#">Details</a>	Display Reporting Details Screen
<a href="#">Register Patient</a>	Register External Patient for Outsource	<a href="#">Manage Sample</a>	Display External TDM Resulting Screen

**Note**

To learn more about Login Information, kindly click [Login Information](#) module for descriptive steps.



## 2.2 Latest Enhancement and Updates

Latest Functions	Page
TDM Reporting <ul style="list-style-type: none"><li>✓ To autocapture height &amp; weight fill up during TDM Order</li><li>✓ Actual sampling time, to be displayed (in details table next to actual drug admin)</li></ul>	<a href="#">11 &amp; 18</a>
TDM Report printing <ul style="list-style-type: none"><li>✓ To rename sampling date time to 'Actual Sampling date time'</li><li>✓ To add drug dosage and frequency in TDM report printing</li></ul>	<a href="#">18 &amp; 22</a>

## 3.0 Therapeutic Drug Monitoring (TDM)

### Overview

The Order Management - Therapeutic Drug Monitoring (TDM) module handles all the information to specify the ordered items as per local drug formulary, MOH and non-MOH including registered and non-registered drugs. This function is to enable data mining. All medication orders must be prescribed by authorized personnel only and in compliance with guidelines on prescribing in the drug formulary (drug category, discipline / specialty) as defined by MOH.

### User Group

This module is intended for Pharmacist, Assistant Pharmacist and Nurse.

### Functional Diagram

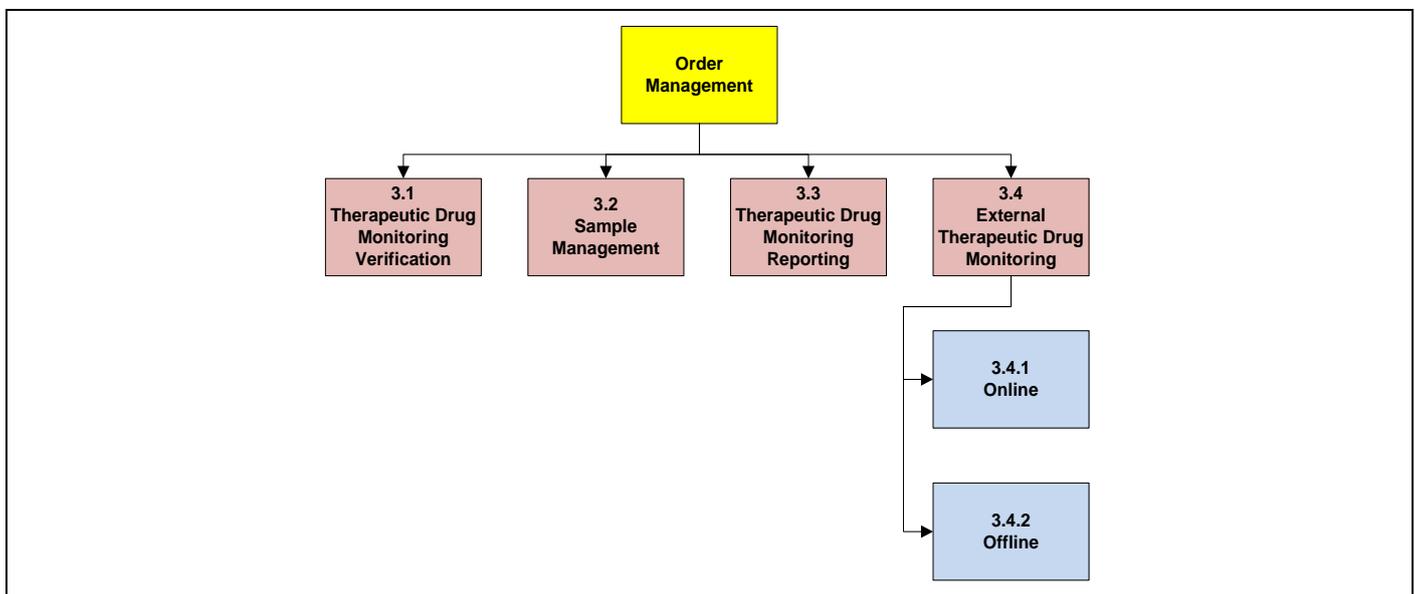


Figure 3.0-1

### Functional Description

Therapeutic Drug Monitoring (TDM) comprises of four (4) main functions:

- **Verification**  
Verification is for pharmacist to verify the prescriptions received from order management. This process is mandatory for all prescriptions receive before the user can proceed with reporting.
- **Sample Management**  
TDM Sampling Management is to record the sampling details into the system including information of the samples which need to be send outsource.
- **Reporting**  
TDM Reporting is to enter the TDM resulting and the interpretation to the Doctor.
- **External TDM**  
External TDM is for record TDM resulting received from other facility

### 3.1 Search Registered Patient

To view existing patient record, perform steps below:

#### STEP 1

Click on 'Order Management' menu followed by 'Record Prescription' and screen will be displayed as per Figure 3.1-1

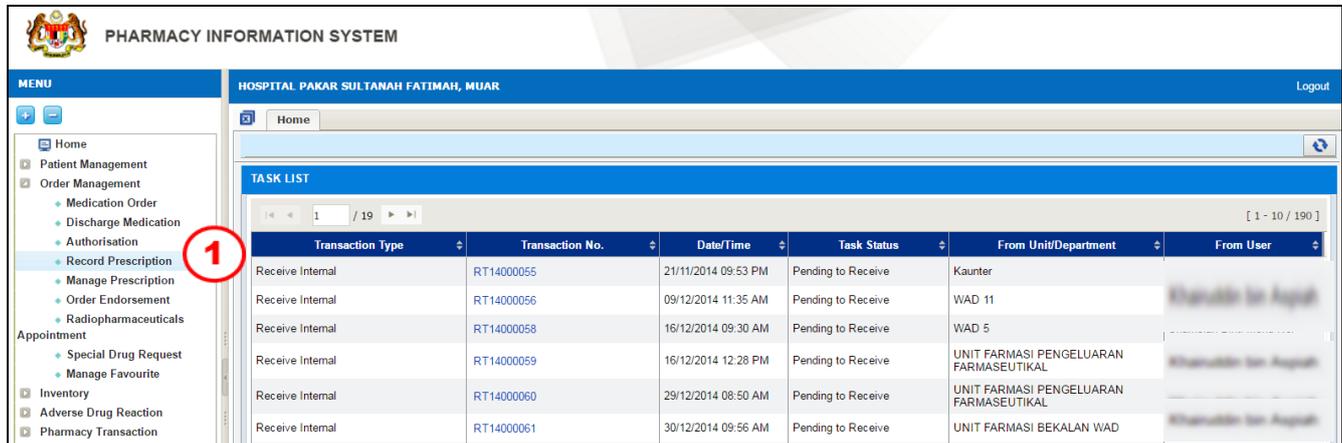


Figure 3.1-1 PhIS Home page

#### STEP 2

Enter registered patient name

#### STEP 3

Click on the  button to search for a registered patient

#### Note

- This page is used to search for a registered patient
- If the patient is not registered, click on the  button and the Patient Registration screen will be displayed.

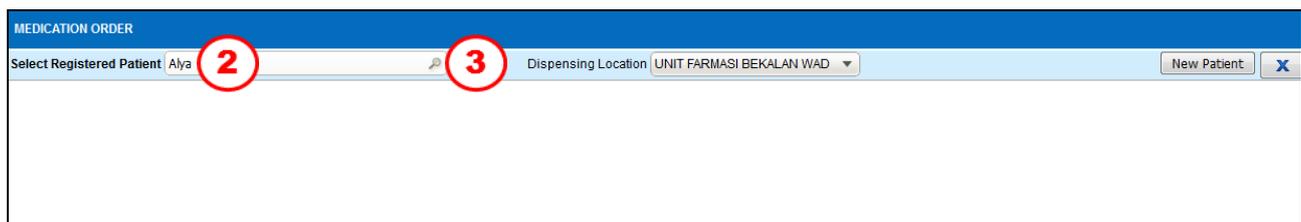


Figure 3.1-2 Medication Order

#### STEP 4

Double-click on the selected patient and the details will be displayed as per Figure 3.1-4

#### Note

- Click on the 'Renew Visit' hyperlink to renew a visit for the same location.
- Select the 'Visit Type' and 'Location' to create a new visit.
- Click on the  button to assess 'Visit Management' Screen. (Refer to Appendix 1).

**MEDICATION ORDER**

Select Registered Patient:  Dispensing Location:

Patient Search

5 / 5 [ 41 - 46 / 46 ]

MRN Number	ID Number	Patient Name
HPSF00029460	860225015124M	[Redacted]
HPSF00029472	800615016160	[Redacted]
HPSF00030656	S2166223B	[Redacted]
HPSF00031200	080526010194	[Redacted]
<b>HPSF00031804</b>	<b>061202011138</b>	[Redacted]
HPSF00031844	881024095052	[Redacted]

Figure 3.1-3 Search Patient

**MEDICATION ORDER**

Select Registered Patient:  Dispensing Location:

My [Redacted]
Age 07 Years 08 Months 24 Days
Gender Female
MRN HPSF00031804

Address [Redacted]
Phone And Email [Redacted]
Diagnosis [Redacted]
No known Allergies

Height [Redacted] cm
Weight [Redacted] kg
BMI/BSA 0/0 m<sup>2</sup>
 (Last Updated: 17/07/2014)

[Lab Results](#)
[Counselling History](#)
[Demographic](#)
[Pharmacist Notes](#)
[Medication Profile](#)
[Other Appointment](#)

**VISIT/ADMISSION**

Encounter No:  Visit Type:  Location:  Department:

Breast Feeding  Pregnant  Weeks

Encounter No	Visit/Admission Date	Visit Type	Visit Location	Discharge Date	Renew Visit
0214	17/07/2014	Outpatient	KLINIK PAKAR KANAK-KANAK		Renew Visit

**PARTIAL SUPPLY**

Order Date	Order Location	Prescription No	Next Collection Date	Next Collection Mode	Prescription Status
No Records Found!					

Figure 3.1-4 Medication Order Screen

**STEP 5**

Double-click on the selected visit as per Figure 3.1-5

**MEDICATION ORDER**

Select Registered Patient:  Dispensing Location:

My [Redacted]
Age 07 Years 08 Months 24 Days
Gender Female
MRN HPSF00031804

Address [Redacted]
Phone And Email [Redacted]
Diagnosis [Redacted]
No known Allergies

Height [Redacted] cm
Weight [Redacted] kg
BMI/BSA 0/0 m<sup>2</sup>
 (Last Updated: 17/07/2014)

[Lab Results](#)
[Counselling History](#)
[Demographic](#)
[Pharmacist Notes](#)
[Medication Profile](#)
[Other Appointment](#)

**VISIT/ADMISSION**

Encounter No:  Visit Type:  Location:  Department:

Breast Feeding  Pregnant  Weeks

Encounter No	Visit/Admission Date	Visit Type	Visit Location	Discharge Date	Renew Visit
0214	17/07/2014	Outpatient	KLINIK PAKAR KANAK-KANAK		Renew Visit

**PARTIAL SUPPLY**

Order Date	Order Location	Prescription No	Next Collection Date	Next Collection Mode	Prescription Status
No Records Found!					

Figure 3.1-5 Visit/Admission Detail

### 3.2 New Patient Registration

This page is used to register new patient

To register new patient in to the system, perform the steps below:

#### STEP 1

Click on 'Order Management' menu followed by 'Record Prescription' and screen will be displayed as per Figure 3.2-1

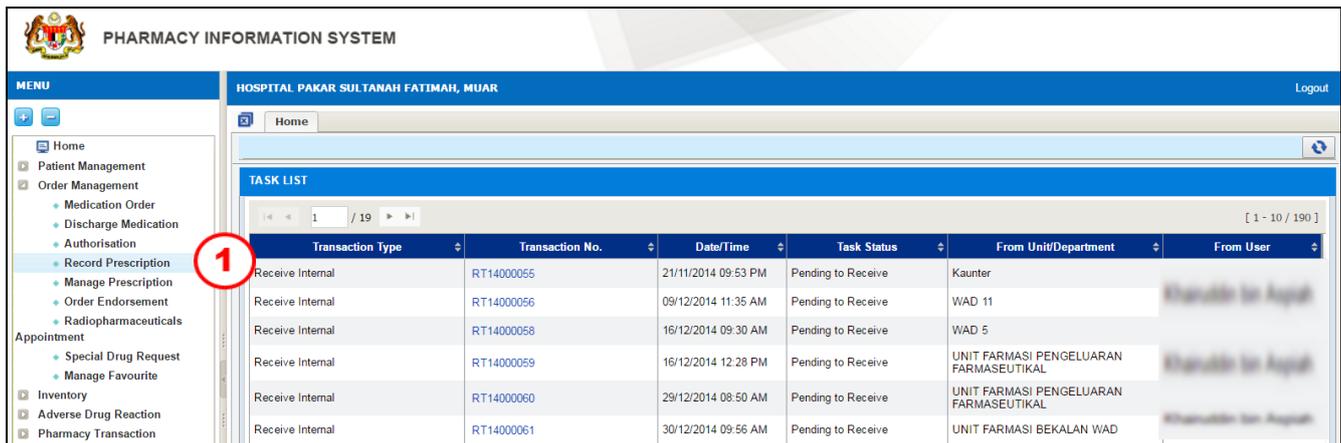


Figure 3.2-1 PhIS Home Page

#### STEP 2

Click on the  to register for new patient

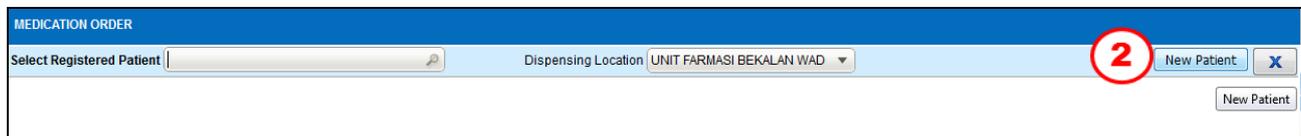


Figure 3.2-2 Transcribe Order Create New Patient

#### STEP 3

Enter **Patient Name**

#### STEP 4

Select from **Identification Card Number** drop down box:

- MYKAD
- MYKID

and enter the relevant number

#### Note

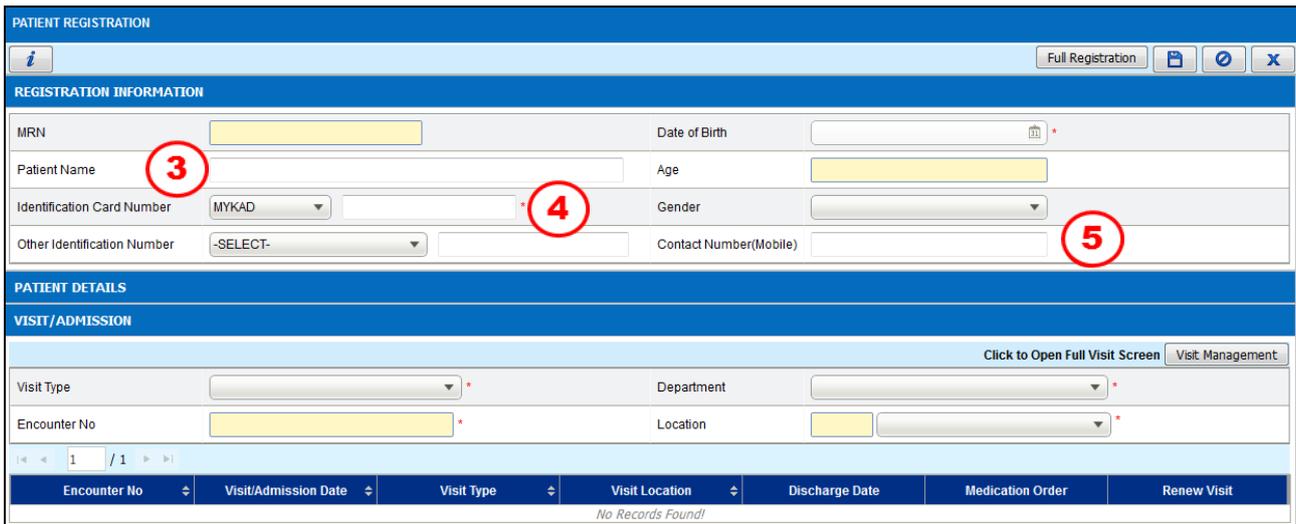
- After enter the Identification Card Number the below details will be displayed:
  - Date of Birth (dd/mm/yy)
  - Age (Y M D)
  - Gender (Male/Female/Unknown)
- If MYKAD/MYKID is unavailable, user is required to select the Other Identification Number dropdown box:
  - BIRTH CERTIFICATE
  - DRIVING LICENSE
  - FATHER IC
  - MILITARY CARD NUMBER
  - MOTHER IC
  - OLD IC
  - PASSPORT

- PENSION CARD
- POLICE CARD NUMBER
- UNKNOWN PATIENT
- WORK PERMIT

and enter the relevant number.

**STEP 5**

Enter **Contact Number (Mobile)**



The screenshot shows a 'PATIENT REGISTRATION' window with the following sections:

- REGISTRATION INFORMATION:**
  - MRN: [Text Field]
  - Date of Birth: [Text Field]
  - Patient Name: [Text Field] (circled 3)
  - Age: [Text Field]
  - Identification Card Number: MYKAD [Text Field] (circled 4)
  - Gender: [Dropdown Menu]
  - Other Identification Number: [-SELECT-] [Text Field]
  - Contact Number(Mobile): [Text Field] (circled 5)
- PATIENT DETAILS:**
- VISIT/ADMISSION:**
  - Visit Type: [Dropdown Menu]
  - Department: [Dropdown Menu]
  - Encounter No: [Text Field]
  - Location: [Text Field]

At the bottom, there is a table with columns: Encounter No, Visit/Admission Date, Visit Type, Visit Location, Discharge Date, Medication Order, and Renew Visit. Below the table, it says 'No Records Found!'.

**Figure 3.2-3 Registration Information**

**STEP 6**

Select the **Visit Type** from dropdown box:

- Daycare
- Emergency
- Inpatient
- Outpatient
- Outsource
- SPUB
- Walk-in

**STEP 7**

Select the **Department** from dropdown box:

**Note**

**Department** will tie to the selected **Visit Type**.

**STEP 8**

Select **Location** from dropdown box

**Note**

**Location** will tie to the selected **Department**.

**STEP 9**

Click on the  button to save the record and medication order screen will display as per Figure 3.2.5

**Note**

- After click the save button, system will automatically generate the MRN (Medical Record Number) and ,  and  buttons will be enabled.

- Click on the **Full Registration** button to assess 'Visit Management' Screen. (Refer to Appendix 2).
- Another option to register a new patient is to click on the **New Patient Registration** button located under Patient Quick Registration that will display the same screen as Figure 3.2-3.

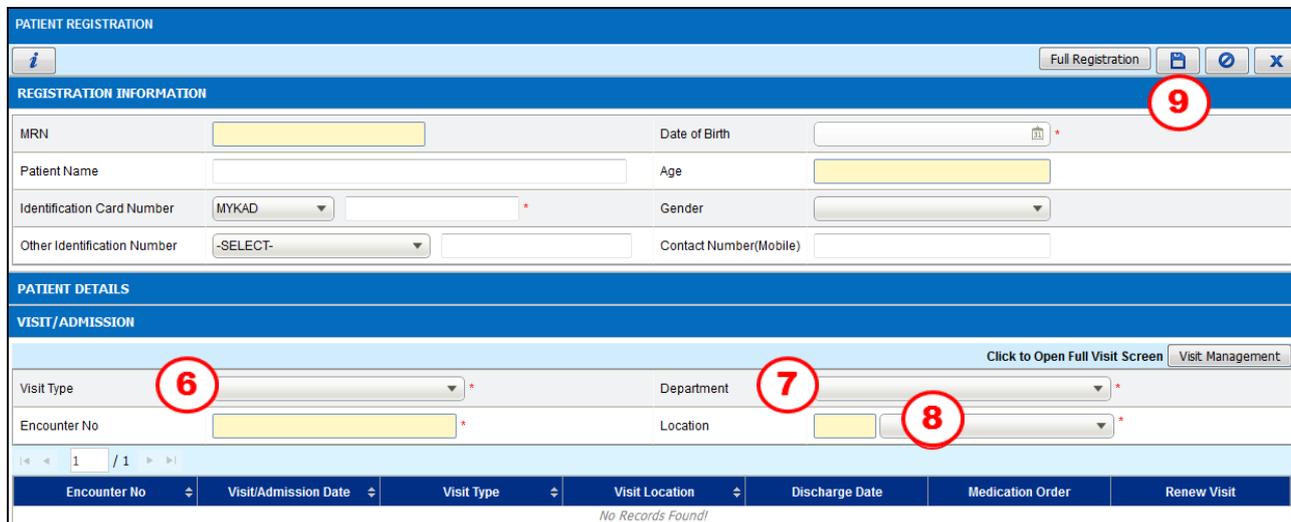


Figure 3.2-4 Visit/Admission

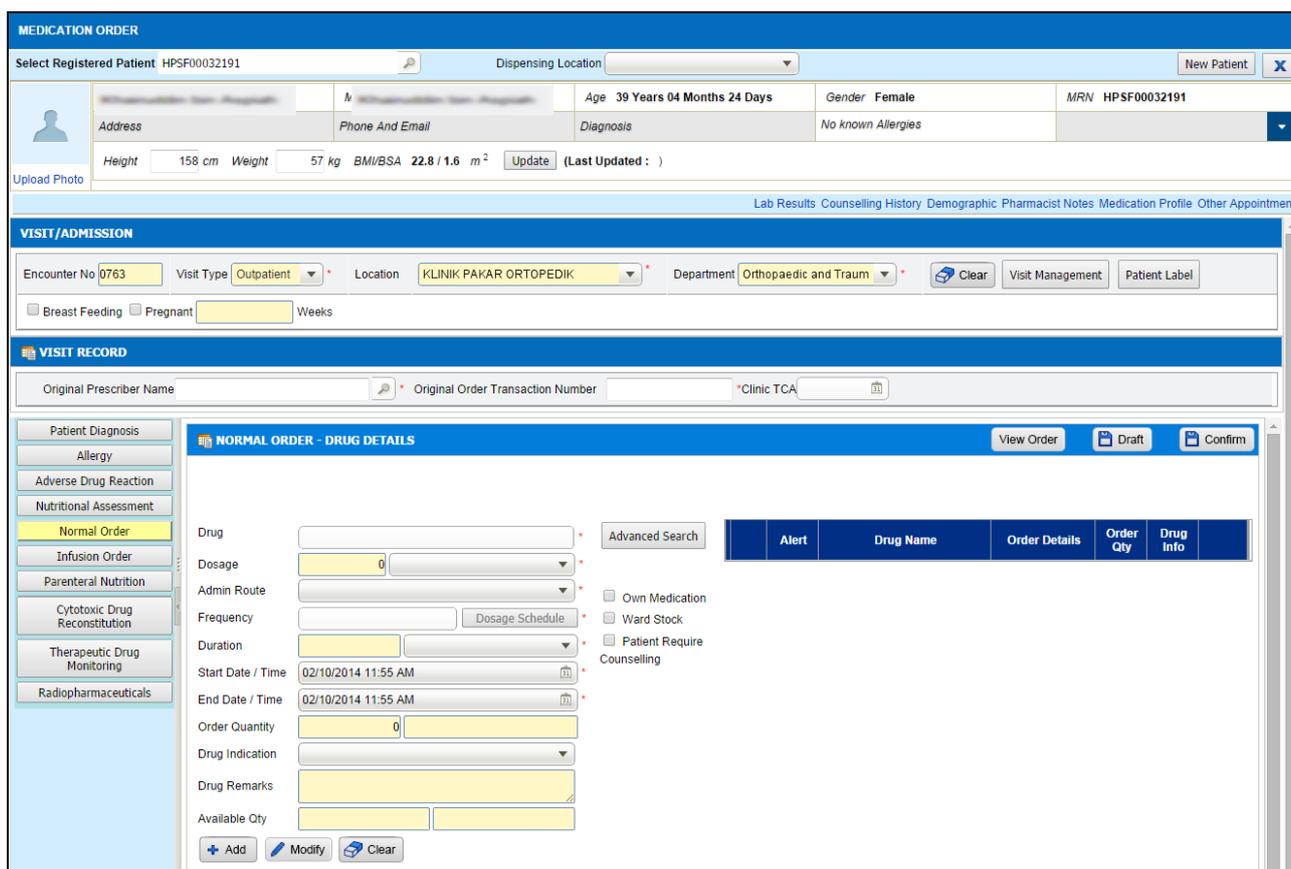


Figure 3.2-5 Medication Order

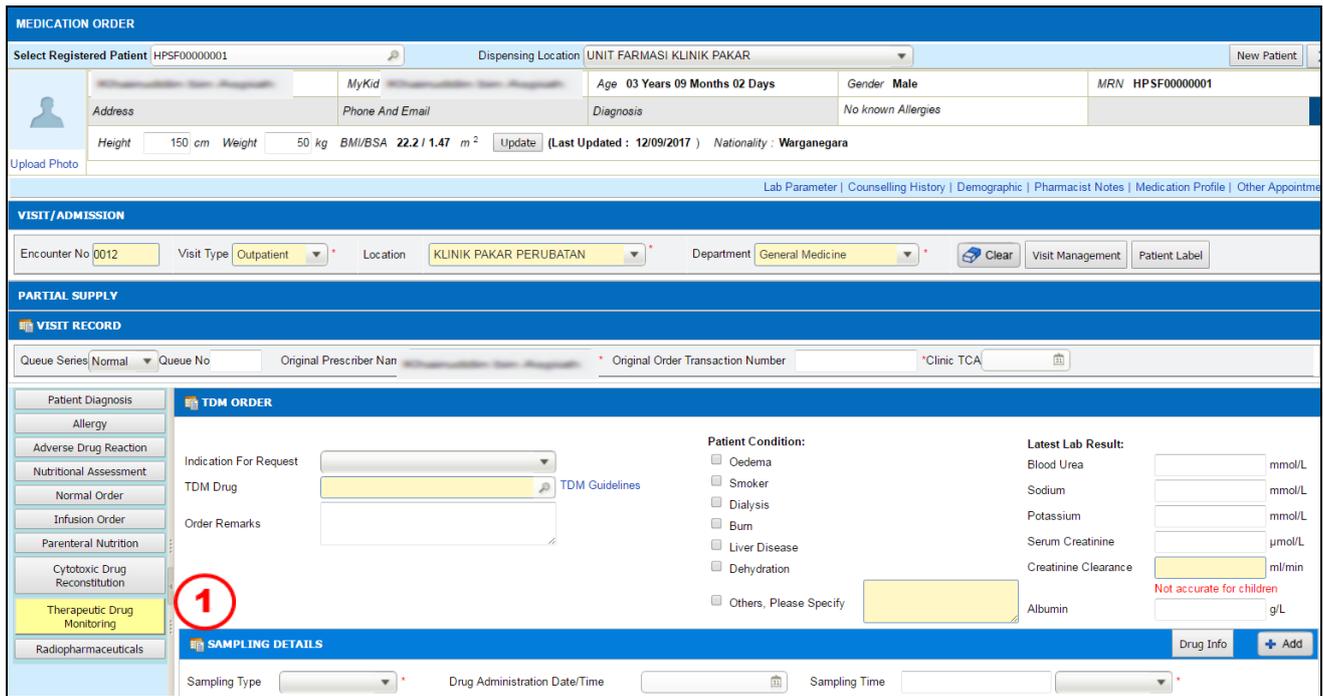
### 3.3 Therapeutic Drug Monitoring (TDM) Order

Perform these steps below to create new order for TDM

TDM Order screen allows Prescriber to place TDM Services order. The order will be sent to Pharmacist for verification and reporting.

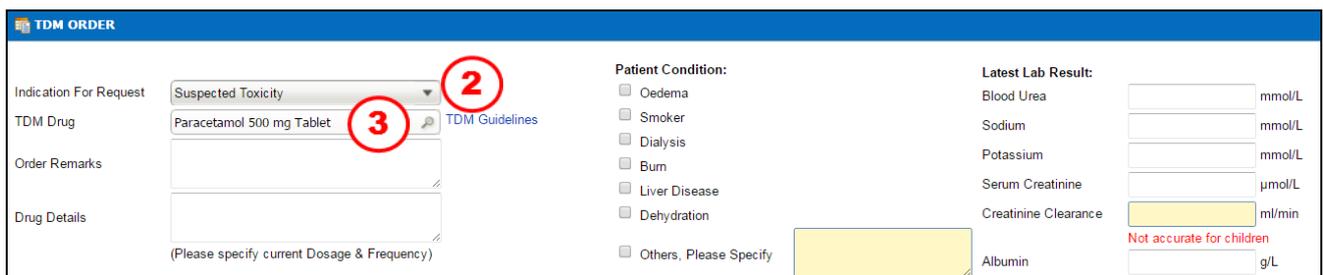
TDM Order User Groups:

- **Authorised Pharmacist**



The screenshot shows the 'MEDICATION ORDER' form. The 'TDM ORDER' section is highlighted with a red circle and the number 1. The form includes fields for patient information, visit details, and TDM order specifics.

Figure 3.3-1 Medication Order



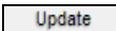
The screenshot shows the 'TDM ORDER' form. The 'Indication For Request' dropdown is highlighted with a red circle and the number 2. The 'TDM Drug' dropdown is highlighted with a red circle and the number 3.

Figure 3.3-2 TDM Order

#### STEP 1

Click on the  button to create TDM order

#### Note

- User is allowed to update patient's height and weight and click on the  button and system will automatically calculate the BMI/BSA in m<sup>2</sup>.
- Visit Record will display Breast Feeding and Pregnant checkboxes only if the patient is a female.

#### STEP 2

Select **Indication For Request** from dropdown box:

- Non Compliance
- Poor Response

- Therapeutic Monitoring
- Suspected Toxicity

**Note**

Selected Indication For Request will be the search key for TDM Drug field.



**TDM Drug Search**

Current Medication
  Previous Medication
  All Drugs

Drug Code:  Drug Name:

1 / 1 [ 1 - 5 / 5 ]

Drug Code	Drug Name	Order Txn Number	Start Date	End Date	Order Type
N02BE01000T1001XX	Paracetamol 500 mg Tablet	ANEC0000585746	14/07/2016 09:40 AM	21/07/2016 09:40 AM	NM
N02BE01000T1001XX	Paracetamol 500 mg Tablet	STFC0000796948	21/01/2017 10:49 AM	31/01/2017 10:49 AM	NM

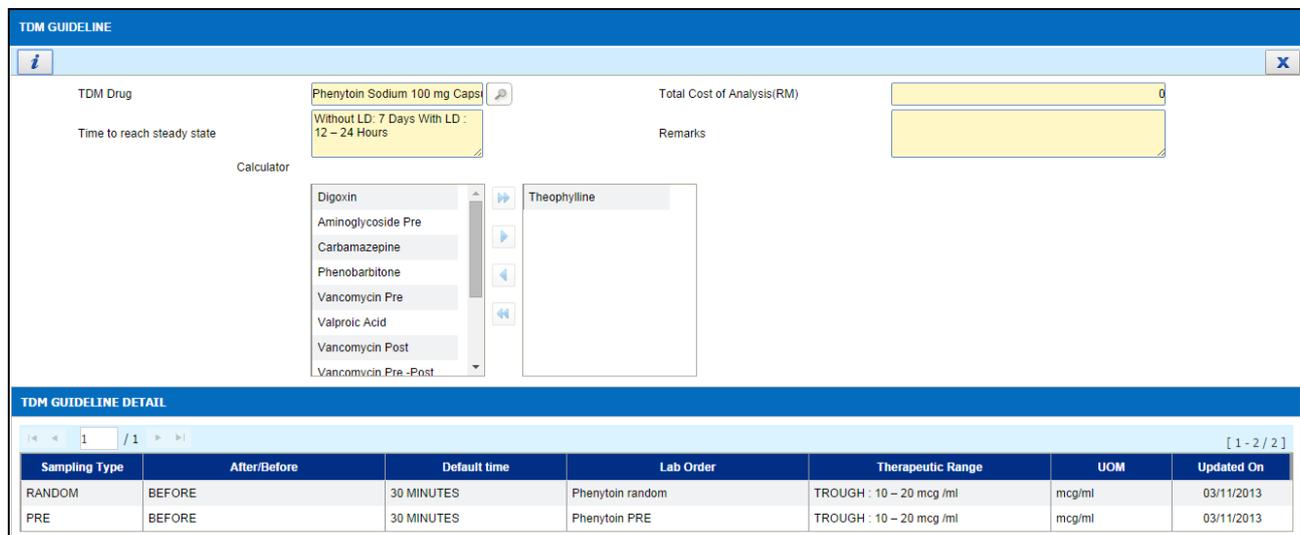
Figure 3.3-3 Drug Search



**DRUG DETAILS**

Rx No : ANEC0000585746      Dosage : 2 tablet      Frequency : QID PRN      Duration : 7 Days  
 Route : Oral      Start Date : 14/07/2016      End Date : 21/07/2016

Figure 3.3-4 Drug Details



**TDM GUIDELINE**

TDM Drug: Phenytoin Sodium 100 mg Caps

Time to reach steady state: Without LD: 7 Days With LD: 12 - 24 Hours

Calculator: Digoxin, Aminoglycoside Pre, Carbamazepine, Phenytoin, Vancomycin Pre, Valproic Acid, Vancomycin Post, Vancomycin Pre-Post

Theophylline

Total Cost of Analysis(RM): 0

Remarks:

**TDM GUIDELINE DETAIL**

Sampling Type	After/Before	Default time	Lab Order	Therapeutic Range	UOM	Updated On
RANDOM	BEFORE	30 MINUTES	Phenytoin random	TROUGH : 10 – 20 mcg /ml	mcg/ml	03/11/2013
PRE	BEFORE	30 MINUTES	Phenytoin PRE	TROUGH : 10 – 20 mcg /ml	mcg/ml	03/11/2013

Figure 3.3-5 TDM Guidelines

**STEP 3**

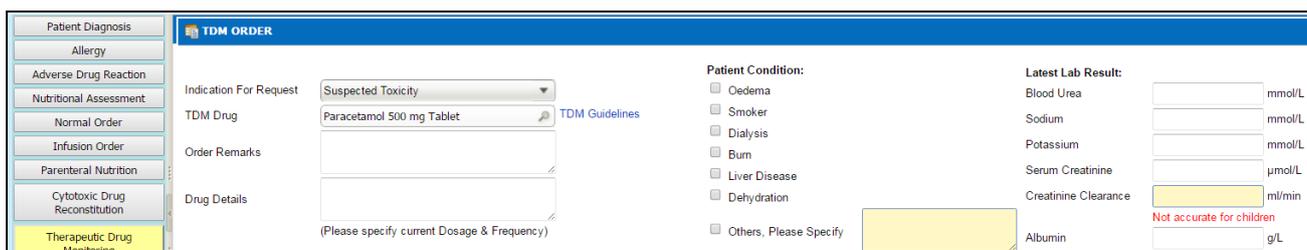
Click on the  button to search for TDM drug based on:

- Current Medication
- Previous Medication
- All Drugs

**Note**

- If the selected Indication for Request 'Non Compliance/ Poor Response/ Therapeutic Monitoring', TDM Drug search can be select from three (3) source:
- Current Medication
- Previous Medication
- All Drugs

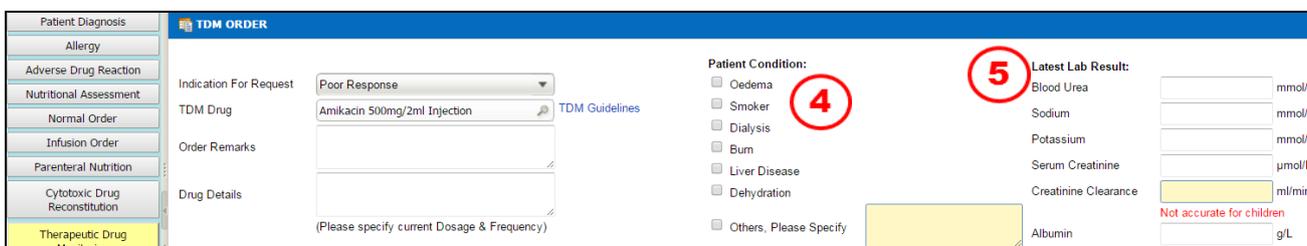
- If the selected TDM Drug is the Current Medication or Previous Medication, system will automatically display the Drug Details as per Figure 3.3-4.
- Click on [TDM Guidelines](#) hyperlink to view TDM Guideline details on the selected TDM Drug as per Figure 3.3-5.
- TDM Guideline master setup is controlled by HQ.
- If the selected Indication for Request is 'Suspected Toxicity', TDM Drug search will default to 'All drugs' which comes from drugs that have been set in TDM Guideline master.
- The Drug Details field will be a free text field for user to enter the current dosage and frequency.



The screenshot shows the 'TDM ORDER' form. On the left is a navigation menu with 'Therapeutic Drug Monitoring' selected. The main form has the following fields:

- Indication For Request:** Suspected Toxicity (dropdown)
- TDM Drug:** Paracetamol 500 mg Tablet (text field with a 'TDM Guidelines' link)
- Order Remarks:** (text area)
- Drug Details:** (text area with note: '(Please specify current Dosage & Frequency)')
- Patient Condition:**
  - Oedema
  - Smoker
  - Dialysis
  - Burn
  - Liver Disease
  - Dehydration
  - Others, Please Specify (text field)
- Latest Lab Result:**
  - Blood Urea: (text field) mmol/L
  - Sodium: (text field) mmol/L
  - Potassium: (text field) mmol/L
  - Serum Creatinine: (text field) µmol/L
  - Creatinine Clearance: (text field) ml/min (Note: Not accurate for children)
  - Albumin: (text field) g/L

Figure 3.3-6 TDM Order



This screenshot is similar to Figure 3.3-6 but with different values:

- Indication For Request:** Poor Response
- TDM Drug:** Amikacin 500mg/2ml Injection
- Patient Condition:** The checkboxes for Oedema, Smoker, Dialysis, Burn, Liver Disease, and Dehydration are highlighted with a red circle labeled '4'.
- Latest Lab Result:** The entire section is highlighted with a red circle labeled '5'.

Figure 3.3-7 Patient Condition



The screenshot shows the 'MEDICATION ORDER' form with patient information:

- Mykad:** Mykad
- Age:** 45 Years 05 Months 08 Days
- Gender:** Male
- MRN:** HPSF00026416
- Diagnosis:** Known Allergies (with a warning icon)
- Height:** 154 cm
- Weight:** 64 kg
- BMI/BSA:** 27 / 1.7 m<sup>2</sup>
- Update:** (Last Updated: 23/10/2014)

Figure 3.3-8 Lab Result Hyperlink

**STEP 4**

Select **Patient Condition** checkbox(es):

- Oedema
- Burn
- Smoker
- Liver Disease
- Dialysis
- Dehydration
- Others

**Note**

- User may select more than one condition.
- If 'Others' is selected, user needs to state the patient's condition in the text box provided.
- Fill in Order **Remarks** if applicable.

**STEP 5**

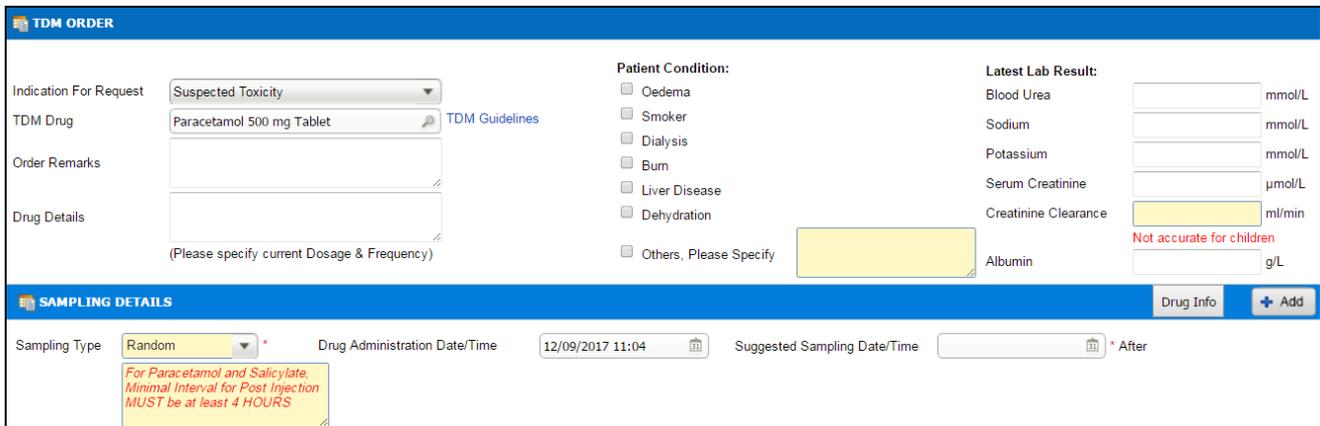
Enter **Latest Lab Result** which consists of:

- Blood Urea
- Sodium
- Potassium
- Serum Creatinine

- Creatinine Clearance
- Albumin

**Note**

*Creatinine Clearance will be automatically calculated by system in ml/min when Serum Creatinine is filled. Lab result data will be updated in the **Lab Result** hyperlink.*



**TDM ORDER**

Indication For Request: Suspected Toxicity

TDM Drug: Paracetamol 500 mg Tablet [TDM Guidelines](#)

Order Remarks:

Drug Details:   
(Please specify current Dosage & Frequency)

**Patient Condition:**

- Oedema
- Smoker
- Dialysis
- Burn
- Liver Disease
- Dehydration
- Others, Please Specify

**Latest Lab Result:**

- Blood Urea:  mmol/L
- Sodium:  mmol/L
- Potassium:  mmol/L
- Serum Creatinine:  µmol/L
- Creatinine Clearance:  ml/min  
*Not accurate for children*
- Albumin:  g/L

**SAMPLING DETAILS** Drug Info + Add

Sampling Type: Random \* Drug Administration Date/Time: 12/09/2017 11:04 Suggested Sampling Date/Time:  \* After

*For Paracetamol and Salicylate, Minimal Interval for Post Injection MUST be at least 4 HOURS*

**Figure 3.3-9 Sampling Details (Suspected Toxicity)**



**SAMPLING DETAILS** Drug Info + Add

Sampling Type: Pre **6** Drug Administration Date/Time: 12/09/2017 11:07 **7** Sampling Time:  30 Minutes **8** \* Before

1 / 1

**Figure 3.3-10 Sampling Details**

**Note**

- Screen for Sampling Details will be displayed differently based on selected 'Indication For Request' below:
- If 'Suspected Toxicity', Sampling Type is defaulted to 'Random' and the 'Suggested Sampling Date/Time' field will be displayed as per Figure 3.3-11.
- Click on the **Drug Info** button to view drug information on selected TDM drug.
- If 'Non Compliance/ Poor Response/ Therapeutic Monitoring', the 'Interval' field will be displayed as per Figure 3.3-12.

**STEP 6**

Select **Sampling Type** from dropdown box:

- Pre
- Post
- Random

**STEP 7**

Click on the  button to select **Drug Administration Date/Time**

**Note**

*Drug Administration Date/Time can be edited by user and the format should be 'DD/MM/YYYY HH:MM'.*

**STEP 8**

Select **Sampling Time** and enter *number* and select Hours/Minutes

**Note**

*The Interval field is only enable if user choose the Indication for Request as Non Compliance/Poor Response/Therapeutic Monitoring.*

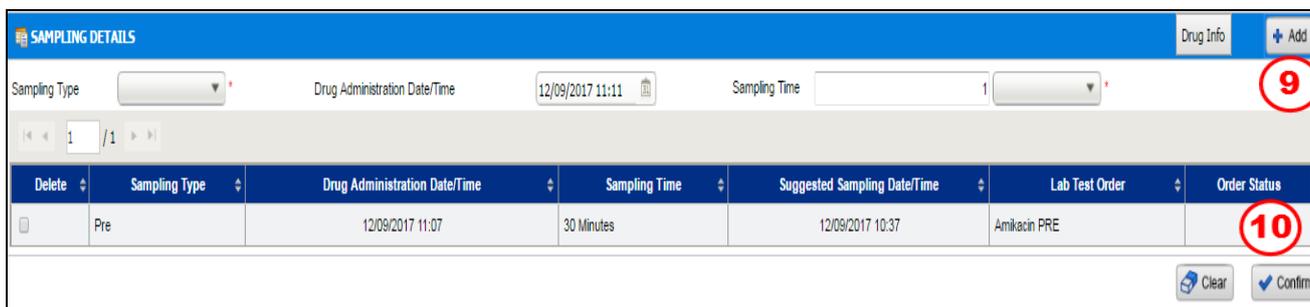


Figure 3.3-11 Add Drug for Sampling

**STEP 9**

Click on the  button to add sampling details

**Note**

- Repeat Step 6 to Step 9 to add more samples (for Pre and Post Sampling).
- Click on the  button to see the information of the drug in details as per Figure 3.3-12.

**STEP 10**

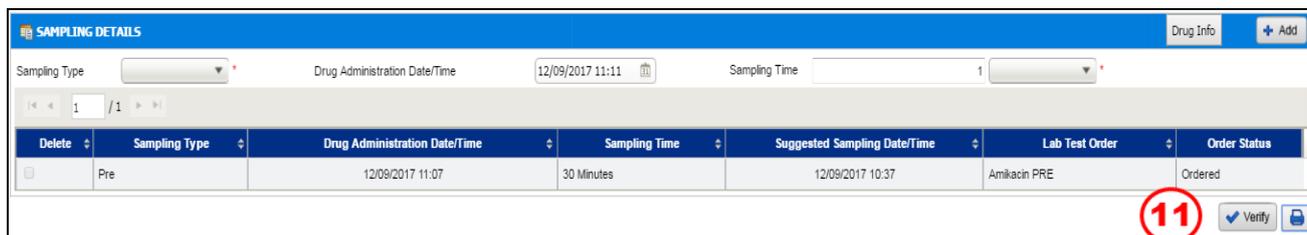
Click on the  to save TDM order and TDM Order No. will be generated

**Note**

- Click on the  button to clear all entered data.
- Click on the  button to create a new TDM Order and the system will reset all fields in TDM Order screen
- To delete sampling details added, check on  Delete checkbox.

Phenytoin Sodium 100 mg Capsule	
Contents	phenytoin
Dosage	<p><b>Oral</b> Epilepsy Adult: Initially, 3-4 mg/kg daily as single dose or in divided doses. Alternatively, 150-300 mg daily increased gradually to 600 mg daily if necessary. Maintenance: 200-500 mg daily. Child: Initially, 5 mg/kg daily in 2-3 divided doses. Maintenance: 4-8 mg/kg daily in divided doses. Max dose: 300 mg daily.</p> <p><b>Intravenous</b> Tonic-clonic status epilepticus Adult: Adjunctive therapy with a benzodiazepine (e.g. diazepam): 10-15 mg/kg by slow inj or intermittent infusion at a max rate of 50 mg/min. Maintenance: 100 mg IV (or orally) given every 6-8 hr. Child: Neonates: 20 mg/kg as a loading dose, then 2.5-5 mg/kg bid; 1 mth-12 yr: 18 mg/kg as a loading dose, then 2.5-5 mg/kg bid; &gt;12 yr: 18 mg/kg as a loading dose, then up to 100 mg 3-4 times daily.</p>
Contraindications	Pregnancy, IV admin in sinus bradycardia, heart block, or Stokes-Adams syndrome.
Special precautions	Cardiovascular disease, e.g. sinus bradycardia, heart blocks; DM; hepatic impairment; hypoalbuminemia; porphyria; seizures (may increase frequency of petit mal seizures); debilitated patients; elderly. Caution in IV admin in hypotension, heart failure or MI, monitor BP and ECG during therapy. IV must be given slowly (too rapid admin may cause hypotension, CNS depression, cardiac arrhythmias and impaired heart conduction). Extravasation and intra-arterial admin must be avoided. Do not discontinue abruptly (may increase seizure frequency), unless safety concerns require a more rapid withdrawal. May impair ability to drive or operate machinery.
Adverse reactions	Hypersensitivity, lack of appetite, headache, dizziness, tremor, transient nervousness, insomnia, GI disturbances (e.g. nausea, vomiting, constipation), tenderness and hyperplasia of the gums, acne, hirsutism, coarsening of the facial features, rashes, osteomalacia. Phenytoin toxicity as manifested as a syndrome of cerebellar, vestibular, ocular effects, notably nystagmus, diplopia, slurred speech, and ataxia, also with mental confusion, dyskinesias, exacerbations of seizure frequency, hyperglycaemia. Solutions for inj may cause local irritation or phlebitis. Prolonged use may produce subtle effects on mental function and cognition, especially in children. <b>Potentially Life-Threatening Adverse Drug Reaction:</b> Toxic epidermal necrolysis, Stevens-Johnson syndrome.
Drug interactions	Effects with other sedative drugs or ethanol may be potentiated. Enhances toxic effects of paracetamol, lithium. Increased risk of osteomalacia with acetazolamide. Decreased serum levels/effects with acyclovir, antineoplastics, benzodiazepines, ciprofloxacin, CYP2C9 inducers (e.g. carbamazepine), CYP2C19 inducers (e.g. rifampin), folic acid, vigabatrin. Increased serum concentrations with allopurinol, capecitabine, cimetidine, CYP2C9 inhibitors (e.g. fluconazole), CYP2C19 inhibitors (e.g. delavirdine), disulfiram, methyphenidate, metronidazole, omeprazole, SSR, trazodone, trimethoprim. Increases metabolism of antiarrhythmics, anticonvulsants, antipsychotics, beta-blockers, calcium channel blockers, chloramphenicol, corticosteroids, doxycycline, oestrogens, HMC-CoA reductase inhibitors, methadone, theophylline, TCAs. Decreases levels/effects of clozapine, ciclosporin, tacrolimus, CYP2B6 substrates (e.g. bupropion, selegiline), CYP2C8 substrates (e.g. amiodarone), CYP2C9 substrates (e.g. celecoxib), CYP2C19 substrates (e.g. citalopram), CYP3A4 substrates (e.g. benzodiazepines), digoxin, itraconazole, levodopa, neuromuscular-blocking agents, thyroid hormones, topiramate. Increases levels/effect of dopamine, ticlopidine. Valproic acid may displace phenytoin from binding sites, and affect phenytoin serum concentrations. Transiently increases the hypothermia response to warfarin initially, followed by an inhibition of the response. <b>Potentially Hazardous Interaction:</b> Enhances the hypotensive properties of dopamine and the cardiac depressant properties of lidocaine.
Mechanism of action	Phenytoin acts as an anticonvulsant by increasing efflux or decreasing influx of sodium ions across cell membranes in the motor cortex during generation of nerve impulses, thus stabilising neuronal membranes and decreasing seizure activity. It acts as an antiarrhythmic by extending the effective refractory period and suppressing ventricular pacemaker automaticity, shortening action potential in the heart. <b>Absorption:</b> Slow but almost complete from the GI tract (oral); much slower absorption (IM). <b>Distribution:</b> Widely distributed; Protein-binding: 90%. <b>Metabolism:</b> Extensively hepatic; converted to inactive metabolites. <b>Excretion:</b> Via urine as hydroxylated metabolite; elimination half life at steady state: 22 hr.
MIMS Class	Anticonvulsants
ATC Classification	N03AB02 - phenytoin; Belongs to the class of hydantoin derivatives antiepileptics. Used in the management of epilepsy.

Figure 3.3-12 Drug Information



Delete	Sampling Type	Drug Administration Date/Time	Sampling Time	Suggested Sampling Date/Time	Lab Test Order	Order Status
<input type="checkbox"/>	Pre	12/09/2017 11:07	30 Minutes	12/09/2017 10:37	Amikacin PRE	Ordered

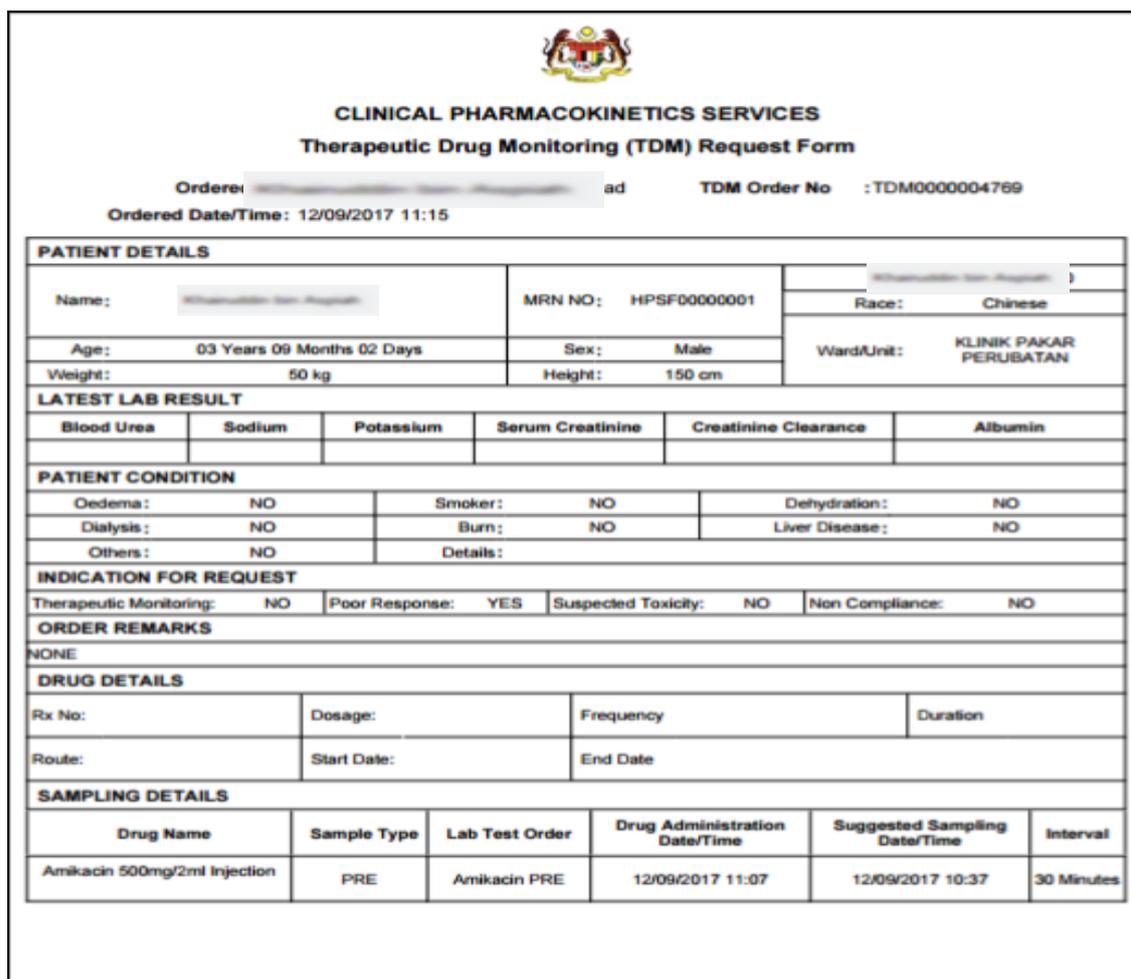
Figure 3.3-13 Verify Sampling Details

**STEP 11**

Click on the  button to verify order

**Note**

- Order Status changed to “Verified”.
- Users not allowed to update sampling details if order status is “Verified”.
- Click on the  button to print TDM Request Form

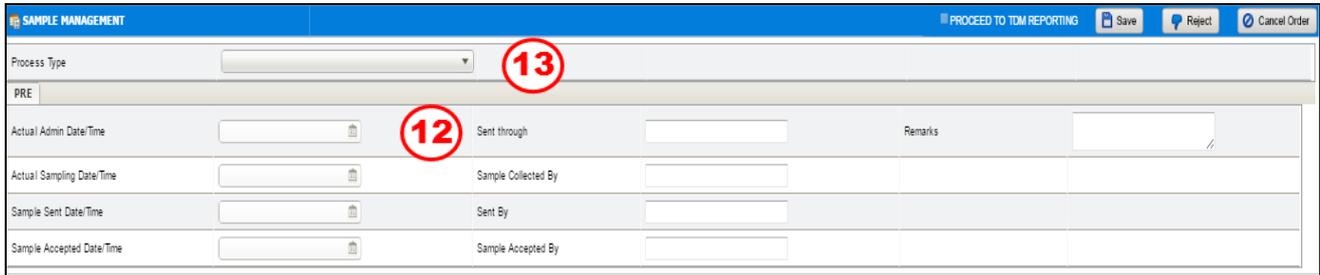


**CLINICAL PHARMACOKINETICS SERVICES**  
**Therapeutic Drug Monitoring (TDM) Request Form**

Order No: [Redacted] ad TDM Order No : TDM0000004769  
Ordered Date/Time: 12/09/2017 11:15

PATIENT DETAILS					
Name:	[Redacted]	MRN NO:	HPSF00000001	Race:	Chinese
Age:	03 Years 09 Months 02 Days	Sex:	Male	Ward/Unit:	KLINIK PAKAR PERUBATAN
Weight:	50 kg	Height:	150 cm		
LATEST LAB RESULT					
Blood Urea	Sodium	Potassium	Serum Creatinine	Creatinine Clearance	Albumin
PATIENT CONDITION					
Oedema:	NO	Smoker:	NO	Dehydration:	NO
Dialysis:	NO	Burn:	NO	Liver Disease:	NO
Others:	NO	Details:			
INDICATION FOR REQUEST					
Therapeutic Monitoring:	NO	Poor Response:	YES	Suspected Toxicity:	NO
				Non Compliance:	NO
ORDER REMARKS					
NONE					
DRUG DETAILS					
Rx No:	Dosage:	Frequency	Duration		
Route:	Start Date:	End Date			
SAMPLING DETAILS					
Drug Name	Sample Type	Lab Test Order	Drug Administration Date/Time	Suggested Sampling Date/Time	Interval
Amikacin 500mg/2ml Injection	PRE	Amikacin PRE	12/09/2017 11:07	12/09/2017 10:37	30 Minutes

Figure 3.3-14 TDM Request Form



**SAMPLE MANAGEMENT** | PROCEED TO TDM REPORTING | Save | Reject | Cancel Order

Process Type: [Dropdown] **13**

PRE

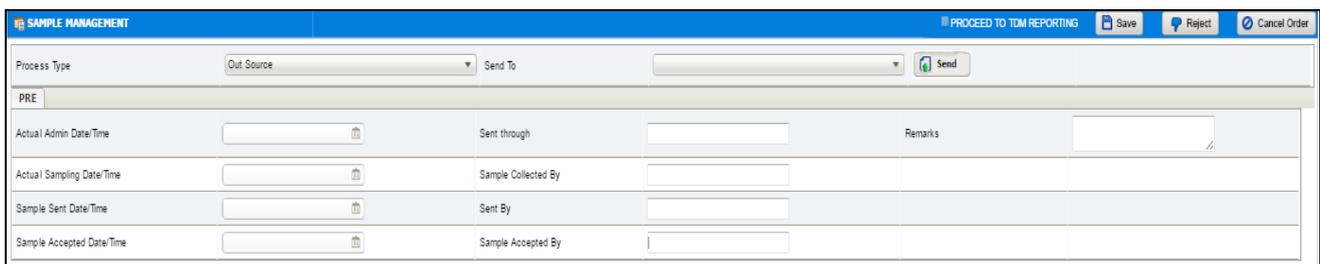
Actual Admin Date/Time: [Date/Time] **12** | Sent through: [Text] | Remarks: [Text]

Actual Sampling Date/Time: [Date/Time] | Sample Collected By: [Text]

Sample Sent Date/Time: [Date/Time] | Sent By: [Text]

Sample Accepted Date/Time: [Date/Time] | Sample Accepted By: [Text]

**Figure 3.3-15 Sampling Management**



**SAMPLE MANAGEMENT** | PROCEED TO TDM REPORTING | Save | Reject | Cancel Order

Process Type: Out Source | Send To: [Dropdown] | Send

PRE

Actual Admin Date/Time: [Date/Time] | Sent through: [Text] | Remarks: [Text]

Actual Sampling Date/Time: [Date/Time] | Sample Collected By: [Text]

Sample Sent Date/Time: [Date/Time] | Sent By: [Text]

Sample Accepted Date/Time: [Date/Time] | Sample Accepted By: [Text]

**Figure 3.3-16 Sampling Management – Out Source**

**STEP 12**

Enter details in these fields:

- Actual Admin Date/Time
- Actual Sampling Date/Time
- Sample Sent Date/Time
- Sample Accepted Date/Time
- Sent Through
- Sample Collected By
- Sent By
- Sample Accepted By

**STEP 13**

Select **Process Type** from dropdown box:

- Lab Based
- Outsource
- Pharmacy Based

**Note**

- If Process Type is "Outsource", user needs to select which facility to send the order to under Send To dropdown box and click on the  button.
- Click on the  button to reject the sampling details. User needs to place a new order.
- Click on the  button to cancel the order. User may not need to place new order.

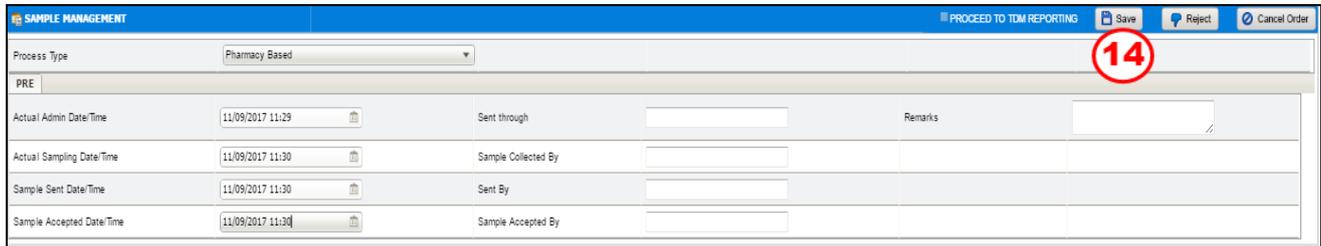
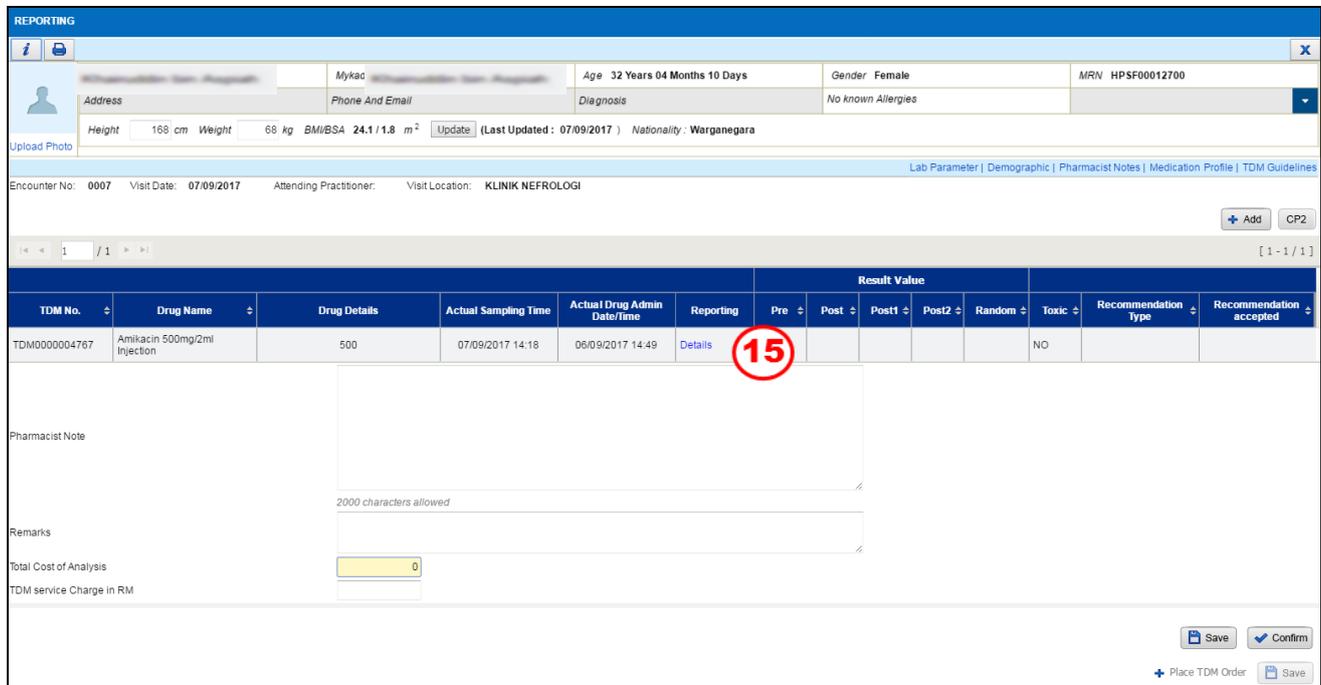


Figure 3.3-17 Save and Proceed to Reporting

**STEP 14**

Click on the  button to save record and select the  to perform the TDM reporting



TDM No.	Drug Name	Drug Details	Actual Sampling Time	Actual Drug Admin Date/Time	Reporting	Result Value					Toxic	Recommendation Type	Recommendation accepted
						Pre	Post	Post1	Post2	Random			
TDM0000004767	Amikacin 500mg/2ml Injection	500	07/09/2017 14:18	06/09/2017 14:49	Details						NO		

Figure 3.3-18 TDM Reporting

**STEP 15**

Click on  hyperlink to display Reporting screen

**Note**

- User needs to enter sample details for pre sample, post sample or random sample based on TDM order.
- Latest Lab Result will display the latest lab results recorded for:
  - Blood Urea
  - Sodium
  - Potassium
  - Serum Creatinine
  - Creatinine Clearance
  - Albumin

**REPORTING**

**i**
**X**

<p><b>Pre Sample</b></p> <p>Result Value <input type="text"/> <input type="button" value="v"/></p> <p>Reported By <input type="text"/> <a href="#">Details</a></p> <p><b>Post Sample</b></p> <p>Result Value <input type="text"/> <input type="button" value="v"/></p> <p>Reported By <input type="text"/> <a href="#">Details</a></p> <p><b>Random Sample</b></p> <p>Result Value <input type="text"/> <input type="button" value="v"/></p> <p>Reported By <input type="text"/> <a href="#">Details</a></p> <p>Calculator <input type="button" value="v"/></p> <p>Pharmacokinetics Profile <div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div></p> <p>Recommendation Type <input type="button" value="v"/></p> <p>Toxic <input type="checkbox"/> No</p>	<p><b>Latest Lab Result:</b></p> <p>Blood Urea <input type="text"/> mmol/L</p> <p>Sodium <input type="text"/> mmol/L</p> <p>Potassium <input type="text"/> mmol/L</p> <p>Serum Creatinine <input type="text"/> µmol/L</p> <p>Creatinine Clearance <input type="text"/> ml/min <small>Not accurate for Children</small></p> <p>Albumin <input type="text"/> g/L</p>
--	--

Figure 3.3-19 Reporting Detail

**DETAILS**

**i**
**X**

Reference Range	:	TROUGH : < 10 mcg / ml ; < 5 mcg/ ml (children)
Sample Collected Date/Time	:	06/09/2017 14:49
Actual Drug Admin Date/Time	:	06/09/2017 14:49
Out Source	:	NO

Figure 3.3-20 Sample Details

**STEP 16**

Enter sample details as below:

- Result Value
- Resulted By

**Note**



Click on **Details** hyperlink to view sample details. Sample Details consists of:

- Reference Range
- Sample Collected Date/Time
- Actual Drug Admin Date/Time
- Outsource

#### STEP 17

Select calculator from dropdown box. Please refer to [TDM Calculator](#) to view sample calculator calculation.

#### STEP 18

Enter **Pharmacokinetics Profile**

#### STEP 19

Select **Recommendation Type** from dropdown box:

- Increase The Dose
- Maintain The Dose
- Reduce The Dose
- Refer to Pharmacist Notes
- Stop The Dose
- Withhold The Dose

#### Notes

*Recommendation Type will be copied and displayed in Pharmacist Notes.*

#### STEP 20

Select **Toxic**:

- Yes
- No

#### STEP 21

Click on the **Ok** button to proceed with TDM reporting process

#### Note

- Pharmacist Notes field will automatically display:
- Drug Name
- Recommendation Type
- User may edit Pharmacist Note.
- Enter Remarks if applicable.
- Total Cost of Analysis will be based on TDM Guideline master setup.

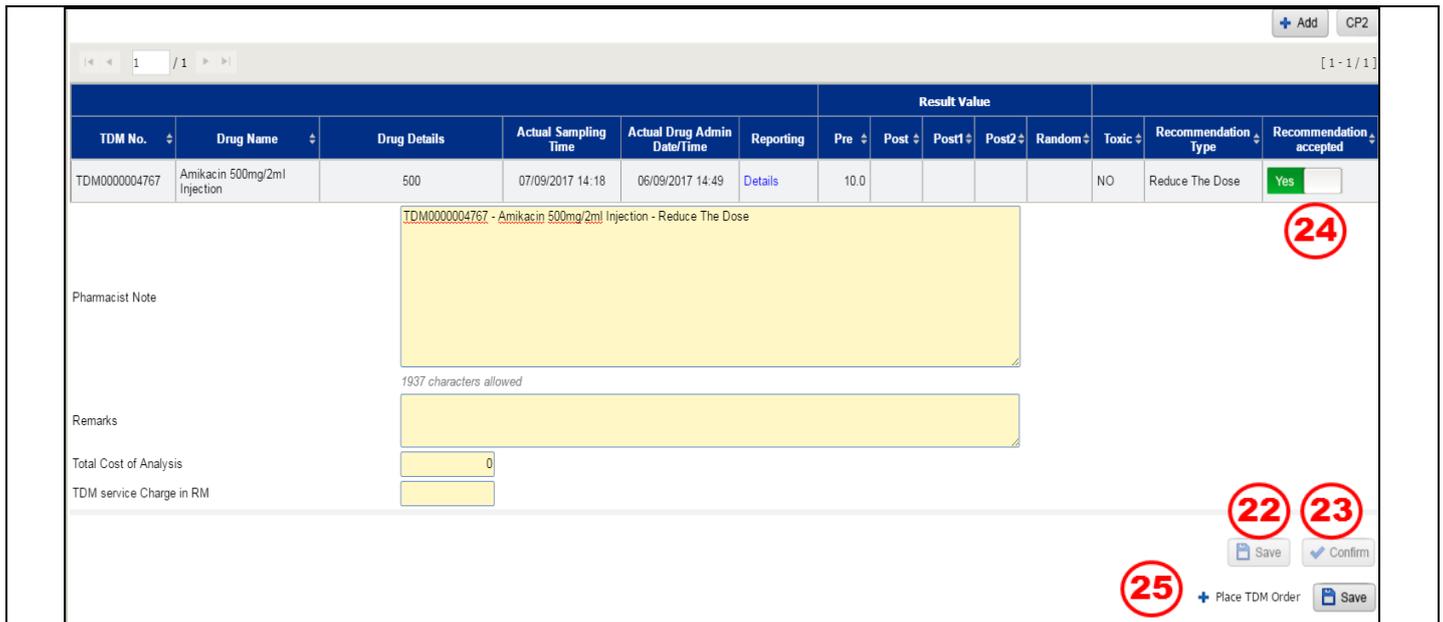


Figure 3.3-21 TDM Reporting

**STEP 22**

Click on the  button to save report

**STEP 23**

Click on the  button to confirm report

**Note**

The  button and  button will be enabled.

**STEP 24**

Click 'Yes' or 'No' at the  button under **Recommendation accepted**

**STEP 25**

Click on the  button to authorize the report

**Note**

- The status will change to "Result Viewed".
- Click on the  button to place new TDM order.
- Click on the  button to print TDM Report



**CLINICAL PHARMACOKINETICS SERVICES**  
**Therapeutic Drug Monitoring (TDM) Report**  
**Hospital Pakar Sultanah Fatimah, Muar**

Report No: RPT0000002341

**PATIENT DETAILS**

Name: [Redacted] IL MRN NO : HPSF00137158 IC : [Redacted]  
Age : 25 Years 08 Months 25 Days Sex : Female Race : Malay  
Weight : 80 Kg Height : 155 Cm Ward/Unit : WAD 9 (MED - P)

No	TDM No	Drug Name	Drug Details	Indication Request	Recommendation Type	Recommendation Accepted	Toxic
1	TDM0000004684	Phenytoin Sodium 100 mg Capsule	300 mg, ON (every night), Oral Capsule, Oral, 26/03/2017 (7 Days), Start Date: 26/03/2017 End Date: 02/04/2017	Therapeutic Monitoring		Yes	No

Sampling Id	Sample Type	Actual Sampling Date Time	Actual Drug Admin Date Time	Result Value	Therapeutic Range
HPSF/SM/0000004848	RANDOM	3/27/17 12:00 AM	3/27/17 3:28 PM		TROUGH : 10 – 20 mcg /ml

**Pharmacist Note:** DRUG REGIMEN MEASURED LEVEL (mcg/ml) Adjusted level (mcg/ml)  
LOADING DOSE IV PHENYTOIN 1G +5.7 14.61  
100mg TDS  
\*Adjusted level was calculated due to patient on dialysis and hypoalbumin  
DESIRED THERAPEUTIC RANGE:  
Phenytoin: 10-20 mcg/ml

**Comments:**  
Adjusted level of phenytoin is WITHIN the therapeutic range.  
May continue with maintenance of IV Phenytoin 100mg TDS.  
Kindly monitor patient's liver function and albumin level.  
Please repeat TDM (pre dose) only if patient fits.  
Thank you.

Printed Date : 05/09/2017 Printed By : [Redacted] Unit Name : STOR FARMASI Source : PhIS

Figure 3.3-22 TDM Report

### 3.4 External TDM

#### 3.4.1 External TDM Online

External TDM module is for user to record external TDM resulting (Outsource) via online or offline. It will be recorded online if both facilities use PhIS to perform TDM processes.

External Notification	
External TDM Request Received:	<input type="text" value="1"/>
External TDM Result Received:	<input type="text" value="0"/>
Online SPUB R1 Request Received:	<input type="text" value="0"/>

Figure 3.4.1-1 External Notification

#### STEP 1

Click on the **External TDM Result Received**  button to view Outsource information

OUTSOURCE LISTING							
Hosp/Clinic	Mrn No	Patient Name	Patient ID	TDM Drug	Sample Type	Date/Time	Register
<input type="checkbox"/> Hospital Pakar Sultanah Fatimah, Muar	HPSF00007006	[Redacted]	[Redacted]	carBAMAZepine 200mg Tablet	RANDOM	22/07/2014 13:26	Register
<input type="checkbox"/> Hospital Pakar Sultanah Fatimah, Muar	HPSF00017231	[Redacted]	[Redacted]	Sodium Valproate 200 mg Tablet	PRE	22/09/2014 15:48	Register

Figure 3.4.1-2 Outsource Listing

#### STEP 2

Click on **Register** hyperlink to register the patient in the system

#### Note

The status will change to 'Registered' as per Figure 3.4.1-2

OUTSOURCE LISTING							
Hosp/Clinic	Mrn No	Patient Name	Patient ID	TDM Drug	Sample Type	Date/Time	Register
<input type="checkbox"/> Hospital Pakar Sultanah Fatimah, Muar	HPSF00007006	[Redacted]	910801126176	carBAMAZepine 200mg Tablet	RANDOM	22/07/2014 13:26	Register
<input checked="" type="checkbox"/> Hospital Pakar Sultanah Fatimah, Muar	HPSF00017231	[Redacted]	790719015422	Sodium Valproate 200 mg Tablet	PRE	22/09/2014 15:48	Registered

Figure 3.4.1-3 Outsource Listing – Registered Patient

#### STEP 3

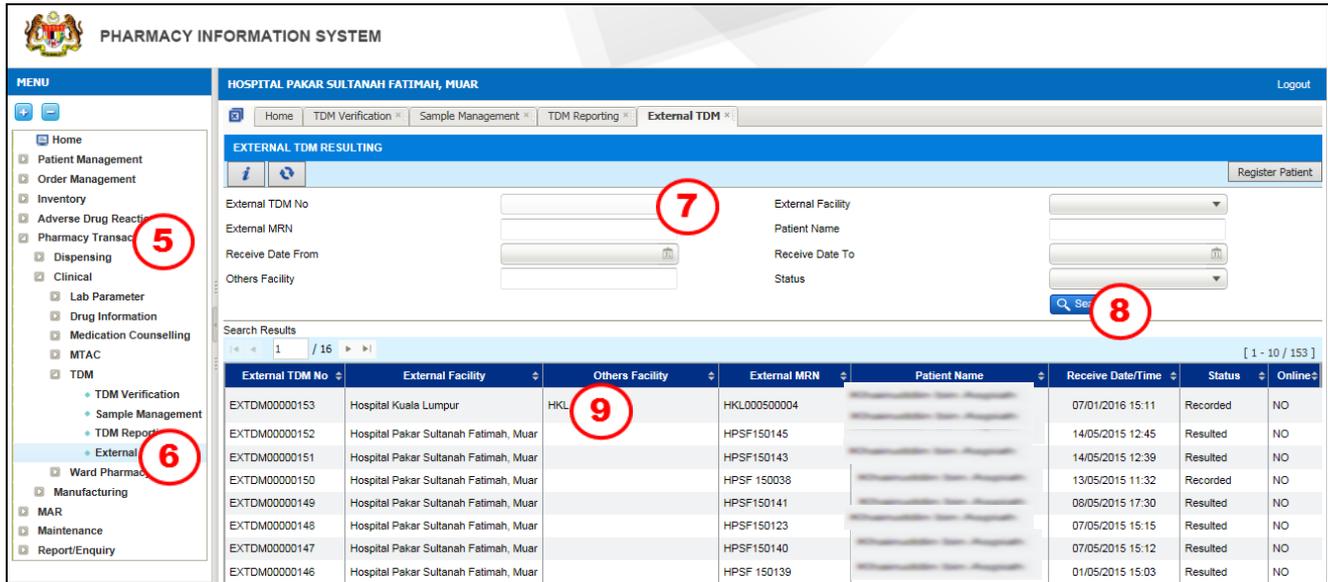
Click on the  checkbox for selected patient

#### STEP 4

Click on the  button to save the record

#### Note

Registered patient will be uploaded to the External TDM listing page.



**PHARMACY INFORMATION SYSTEM**

HOSPITAL PAKAR SULTANAH FATIMAH, MUAR

Home | TDM Verification | Sample Management | TDM Reporting | **External TDM** | Logout

**EXTERNAL TDM RESULTING** Register Patient

External TDM No:  **7**

External Facility:

External MRN:

Receive Date From:

Receive Date To:

Others Facility:

Status:

**8** Search

Search Results: 1 / 16 [ 1 - 10 / 153 ]

External TDM No	External Facility	Others Facility	External MRN	Patient Name	Receive Date/Time	Status	Online
EXTDM00000153	Hospital Kuala Lumpur	HKL <b>9</b>	HKL000500004		07/01/2016 15:11	Recorded	NO
EXTDM00000152	Hospital Pakar Sultanah Fatimah, Muar		HPSF150145		14/05/2015 12:45	Resulted	NO
EXTDM00000151	Hospital Pakar Sultanah Fatimah, Muar		HPSF150143		14/05/2015 12:39	Resulted	NO
EXTDM00000150	Hospital Pakar Sultanah Fatimah, Muar		HPSF 150038		13/05/2015 11:32	Recorded	NO
EXTDM00000149	Hospital Pakar Sultanah Fatimah, Muar		HPSF150141		08/05/2015 17:30	Resulted	NO
EXTDM00000148	Hospital Pakar Sultanah Fatimah, Muar		HPSF150123		07/05/2015 15:15	Resulted	NO
EXTDM00000147	Hospital Pakar Sultanah Fatimah, Muar		HPSF150140		07/05/2015 15:12	Resulted	NO
EXTDM00000146	Hospital Pakar Sultanah Fatimah, Muar		HPSF 150139		01/05/2015 15:03	Resulted	NO

**Figure 3.4.1-4 External TDM Listing Page**

**STEP 5**

Click on 'Pharmacy Transaction' menu follow by 'Clinical' sub-menu

**STEP 6**

Click on 'TDM' and click on 'External TDM' function

**STEP 7**

Search for patient records by:

- External TDM No.
- External Facility
- External MRN
- Patient Name
- Receive Date From
- Receive Date To
- Others Facility
- Status
  - Recorded
  - Rejected
  - Resulted

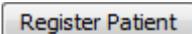
**STEP 8**

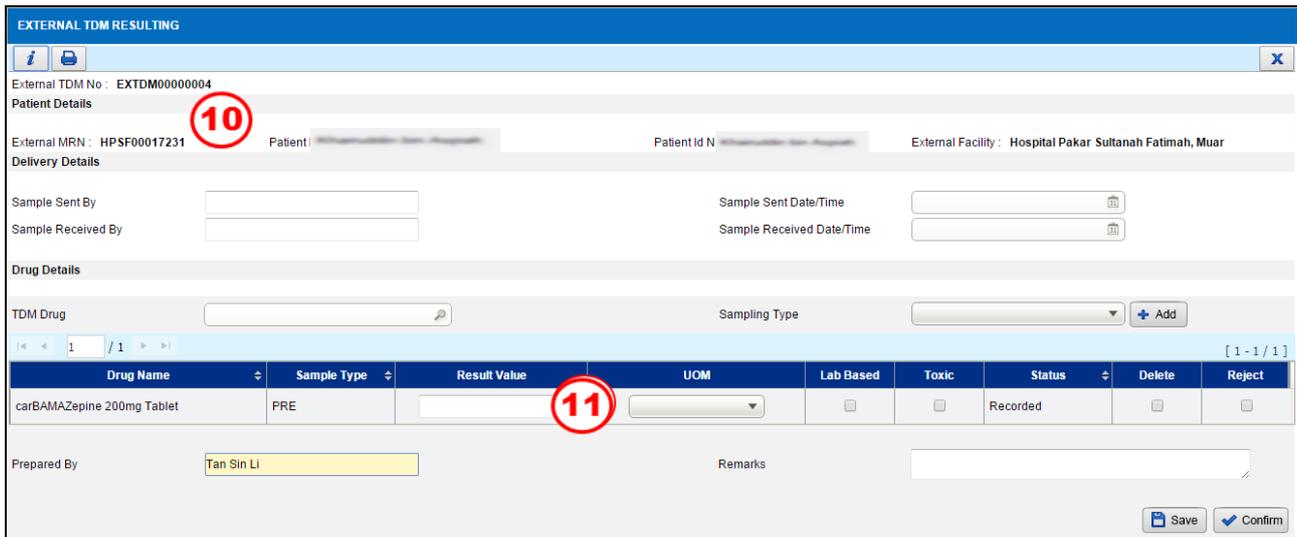
Click on the  button to search for patient records

**STEP 9**

Double-click on the selected patient and External TDM Resulting screen will be displayed as per Figure 3.4.1-5

**Note**

 button is for offline External TDM (refer to [section 3.4.2 External TDM Offline](#))



**EXTERNAL TDM RESULTING**

External TDM No : EXTDM00000004

**Patient Details**

External MRN : HPSF00017231 Patient: [Redacted] Patient Id N: [Redacted] External Facility : Hospital Pakar Sultanah Fatimah, Muar

**Delivery Details**

Sample Sent By: [Text Box] Sample Sent Date/Time: [Text Box]

Sample Received By: [Text Box] Sample Received Date/Time: [Text Box]

**Drug Details**

TDM Drug: [Text Box] Sampling Type: [Dropdown] + Add

Drug Name	Sample Type	Result Value	UOM	Lab Based	Toxic	Status	Delete	Reject
carBAMAZepine 200mg Tablet	PRE	[Text Box]	[Dropdown]	<input type="checkbox"/>	<input type="checkbox"/>	Recorded	<input type="checkbox"/>	<input type="checkbox"/>

Prepared By: Tan Sin Li Remarks: [Text Box]

Save Confirm

Figure 3.4.1-5 External TDM Resulting

**STEP 10**

Enter **Delivery Details** as below:

- Sample Sent By
- Sample Sent Date/Time
- Sample Received By
- Sample Received Date/Time

**STEP 11**

Enter **Result Value** and select **UOM** from dropdown box :

- mcg/ml
- mg/dl
- mmol/l
- ng/ml

**Note**

- Select on  **Lab Based** checkbox if TDM resulting process is done at a laboratory.
- Select on  **Toxic** checkbox if TDM results show toxicity for selected patient.
- Select on  **Reject** checkbox to reject sampling received.
- Select on  **Delete** checkbox to delete TDM order.
- Enter **Remarks** if applicable.

**Figure 3.4.1-6 External TDM Resulting**

**STEP 12**

Click on the Save button to save external TDM resulting

**STEP 13**

Click on the Confirm button to confirm external TDM resulting

**Note**

- The status will change to “Resulted”.
- Outsource TDM Resulting will be sent back to the requester.

To receive an **External TDM Result Received**:

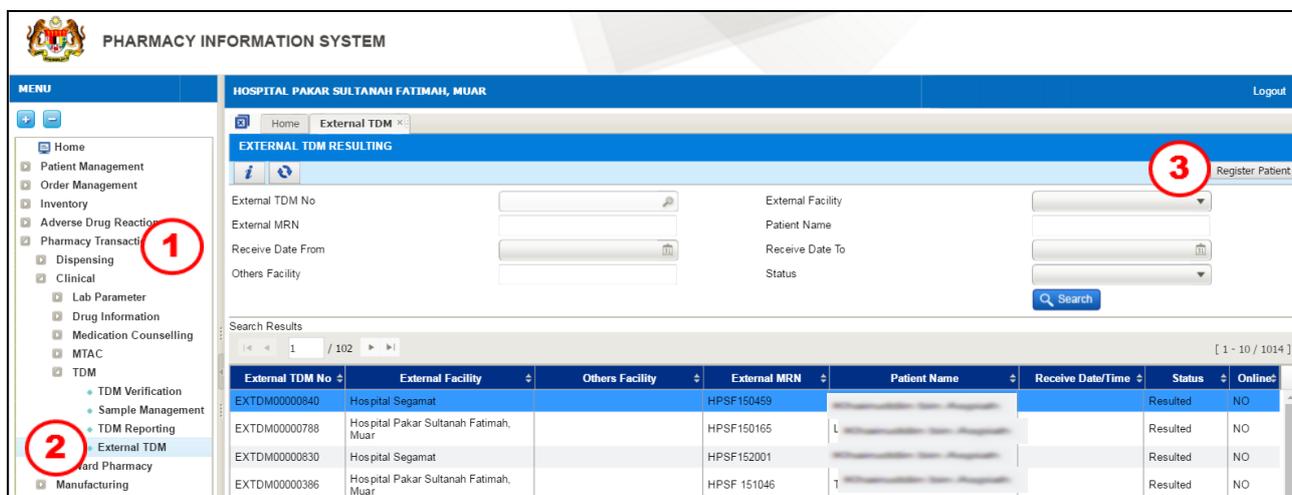
- Click on the **External TDM Result Received** button to view the outsource listing.
- Select on  checkbox(es) on selected outsource request.
- Click on the button to upload the patient record in order to proceed with TDM Reporting processes. (refer to [section 3.3 Therapeutic Drug Monitoring \(TDM\) Order](#) )

**Figure 3.4.1-7 External Notification**

TDM Order No	Mrn No	Patient Name	Patient ID	TDM Drug	Sample Type	Result	UOM	Date/Time
<input checked="" type="checkbox"/>	EXTDM00000001	HPSF00017231	790719015422	Sodium Valproate 200 mg Tablet	PRE	13.3	mcg/ml	22/09/2014 16:22

**Figure 3.4.1-8 Outsource Listing**

### 3.4.2 External TDM Offline



External TDM No	External Facility	Others Facility	External MRN	Patient Name	Receive Date/Time	Status	Online
EXTDM00000840	Hospital Segamat		HPSF150459			Resulted	NO
EXTDM00000788	Hospital Pakar Sultanah Fatimah, Muar		HPSF150165			Resulted	NO
EXTDM00000830	Hospital Segamat		HPSF152001			Resulted	NO
EXTDM00000386	Hospital Pakar Sultanah Fatimah, Muar		HPSF 151046			Resulted	NO

Figure 3.4.2-1 External TDM Listing Page

External TDM module is for user to record external TDM resulting (Outsource) via online and offline. It is recorded offline if one of the facility used PhIS to perform TDM processes.

#### STEP 1

Click on 'Pharmacy Transaction' menu follow by 'Clinical' sub-menu

#### STEP 2

Click on 'TDM' and click on 'External TDM' function

#### STEP 3

Click on the **Register Patient** button to register external patient

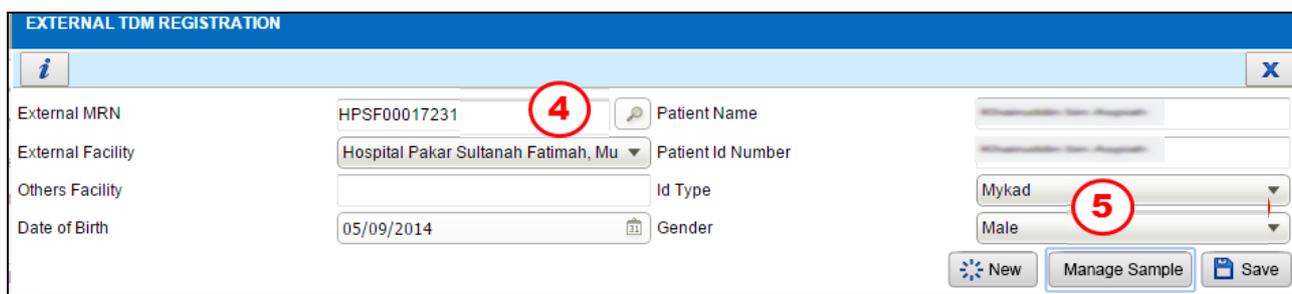


Figure 3.4.2-2 External TDM Registration

#### STEP 4

Enter details in the fields below:

- External MRN
- Patient Name
- External Facility
- Patient Id Number
- Other Facility  
(If the sample come from private sector or facility which is not listed under MOH facilities)
- Id Type

#### Note

Click on the External MRN  button to search for registered patient and all fields will be automatically retrieved.

### STEP 5

Click on the **Manage Sample** button and External TDM Resulting screen will be displayed as per Figure 3.4.2-3

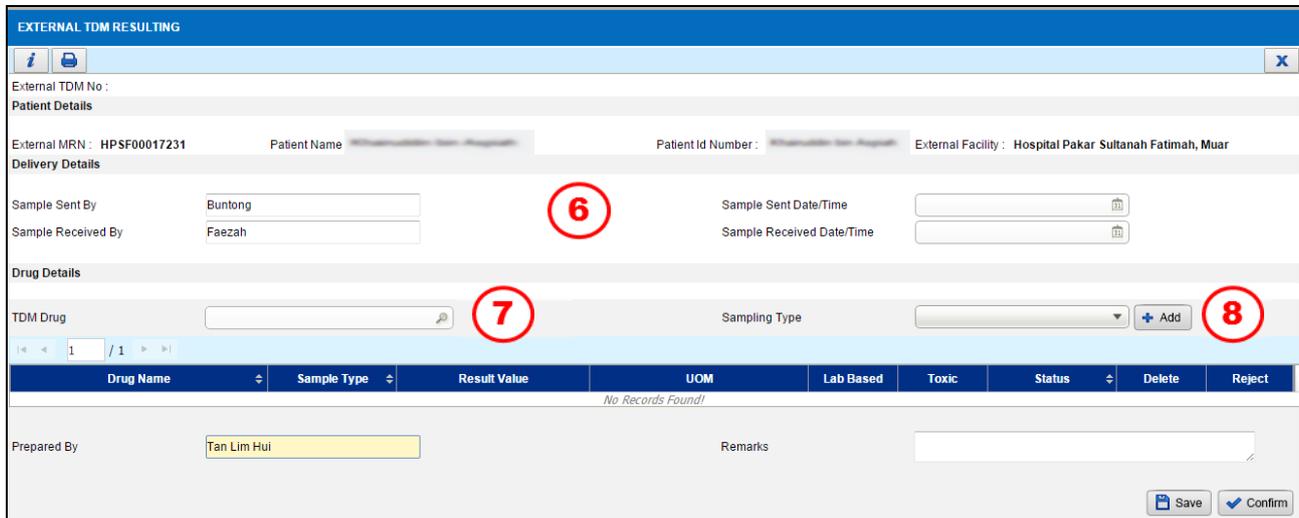


Figure 3.4.2-3 External TDM Resulting

### STEP 6

Enter **Delivery Details** as below:

- Sample Sent By
- Sample Sent Date/Time
- Sample Received By
- Sample Received Date/Time

### STEP 7

Click on the **TDM Drug**  button to search for drug

### STEP 8

Select **Sampling Type** from dropdown box:

- Pre
- Post
- Random

and click on the  button to add the information

**EXTERNAL TDM RESULTING**

External TDM No :  
Patient Details

External MRN : HPSF00017231    Patient Name : [Redacted]    Patient Id Num : [Redacted]    External Facility : Hospital Pakar Sultanah Fatimah, Muar

Delivery Details

Sample Sent By : Buntong    Sample Sent Date/Time : 05/11/2014 11:55  
Sample Received By : Faedah    Sample Received Date/Time : 05/11/2014 11:55

Drug Details

TDM Drug : [Search Box]    Sampling Type : [Dropdown]    + Add

Drug Name	Sample Type	Result Value	UOM	Lab Based	Toxic	Status	Delete	Reject
Theophylline 250 mg Long Acting Tablet	PRE	100	mg/dL	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Prepared By : Tan Lim Hui    Remarks : [Text Box]

[Save] [Confirm]

Figure 3.4.2-4 External TDM Resulting

**STEP 9**

Enter **Result Value** and select **UOM** from dropdown box:

- mcg/ml
- mg/dl/ml

**Note**

- Select on  **Lab Based** checkbox if TDM resulting process is done at a laboratory.
- Select on  **Toxic** checkbox if TDM results show toxicity for selected patient.
- Select on  **Reject** checkbox to reject sampling received.
- Select on  **Delete** checkbox to delete TDM order.
- Enter **Remarks** if applicable.

**STEP 10**

Click on the  button to save external TDM resulting

**STEP 11**

Click on the  button to confirm external TDM resulting

## 4.0 Acronyms

Abbreviation	Definition
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
MOH	Ministry Of Health
TDM	Therapeutic Drug Monitoring

## 5.0 Links to Clinical Modules

No	Module	PDF Links	No	Module	PDF Links
1	Inpatient	<a href="#">Click Here</a>	12	CDR Dispensing	<a href="#">Click Here</a>
2	CDR Order	<a href="#">Click Here</a>	13	Methadone Dispensing	<a href="#">Click Here</a>
3	TDM Order	<a href="#">Click Here</a>	14	PN Dispensing	<a href="#">Click Here</a>
4	PN Order	<a href="#">Click Here</a>	15	Order Management	<a href="#">Click Here</a>
5	IV Order	<a href="#">Click Here</a>	16	Patient Management	<a href="#">Click Here</a>
6	Prepacking	<a href="#">Click Here</a>	17	Radiopharmaceuticals	<a href="#">Click Here</a>
7	Galenical	<a href="#">Click Here</a>	18	Outpatient	<a href="#">Click Here</a>
8	MTAC	<a href="#">Click Here</a>	19	Special Drug Request	<a href="#">Click Here</a>
9	ADR & DAC	<a href="#">Click Here</a>	20	MAR	<a href="#">Click Here</a>
10	Medication Counselling	<a href="#">Click Here</a>	21	DICE	<a href="#">Click Here</a>
11	Ward Pharmacy	<a href="#">Click Here</a>	22		