



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

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## **User Manual Integrated Web Portal (IWP)**

### **Special Approval Medicine (Approval)**

<b>Version</b>	<b>: 12<sup>th</sup> Edition</b>
<b>Document ID</b>	<b>: HQ_U.MANUAL_IWP_KPK APPROVAL</b>



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*Reference ID : HQ\_U.MANUAL\_IWP\_KPK APPROVAL-12<sup>th</sup> E*

*Application reference: PhIS& CPS v2.5.1*



## Table of Contents

1.0	Introduction .....	1
1.1	Overview of PhIS .....	1
1.2	Purpose and Objectives .....	1
1.3	Organized Sections .....	1
2.0	Application Standard Features .....	2
2.1	PhIS Legend .....	2
3.0	KPK Approval .....	3
	Overview .....	3
	User Group .....	3
	Functional Diagram .....	3
	Functional Description .....	3
3.1	KPK Approval .....	4
3.1.1	KPK Special Drug Approval .....	4
3.1.2	KPK Special Drug Item Assign .....	17
4.0	Acronyms .....	20
5.0	Links to IWP Modules .....	20

## 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 excellent care. This implementation would transform most of the current manual process to electronic system would benefit facility end user in the health care sector.

There are 12 modules to assist service 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 Card(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 IWP (KPK Approval) sub-module and its key features and functionalities. The primary objective is to help guide users through the process of completing PhIS application process.

User will understand the following activities in details:

- KPK Drug Approval
- KPK Item Assign

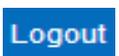
### 1.3 Organized Sections

These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Maintenance (General)
- Section 4 : Acronyms
- Section 5 : Link to IWP Modules

## 2.0 Application Standard Features

### 2.1 PhIS Legend

Standard Legend			
	Login		Reset Login screen
	Logout		Show Help
	Expand Menu		Add/Create New Record
	Collapse Menu		Calendar Icon
	Refresh Screen		Cancel Data Entry
	Search Icon		Mandatory Field
	Search Record		Edit Record
	Close Window		Save Record
	Close All Open Tabs		Delete Record
	Close Screen		Print Document
	Radio Button		Context Menu
	Checkbox		

**Note**

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

## 3.0 KPK Approval

### Overview

The module will provide a portal for configuration guide for the user which describe the basic and advance featured available on the system for KPK. This featured allow user to view, key in the relevant data and approve or reject the transaction.

### User Group

This module is intended for BPF users (subject to user assigned by the BPF)

### Functional Diagram

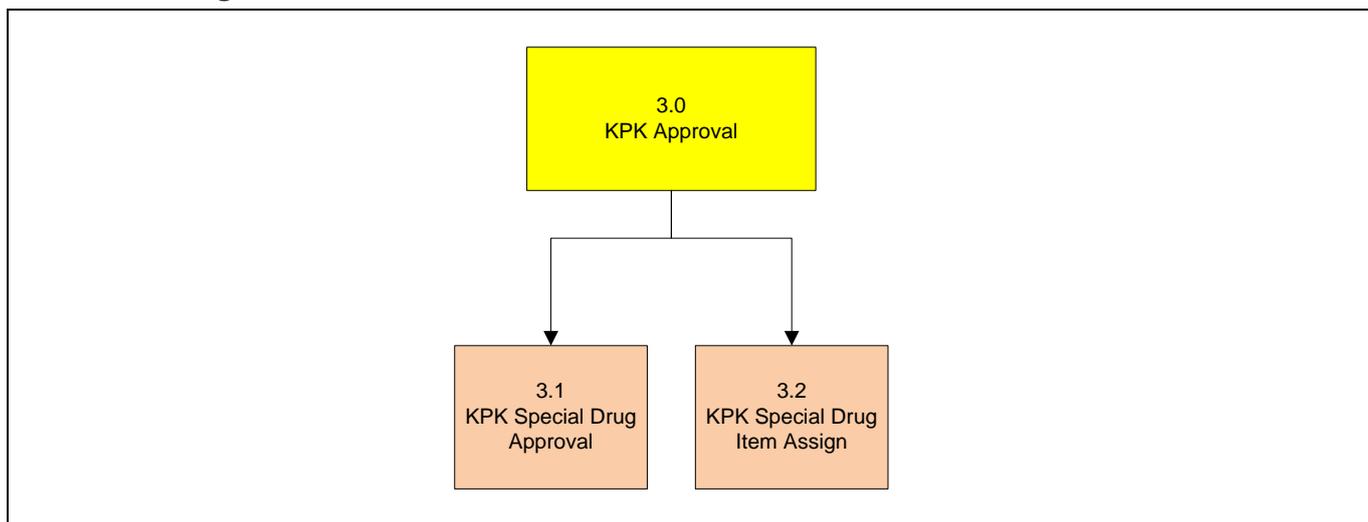


Figure 3.0-1

### Functional Description

KPK Approval module comprises of two (2) main sub modules:

- **KPK Special Drug Approval**

KPK Special Drug Approval screen allows user to approve and fill the approved quantity for KPK Drug Approval.

- **KPK Special Drug Item Assign**

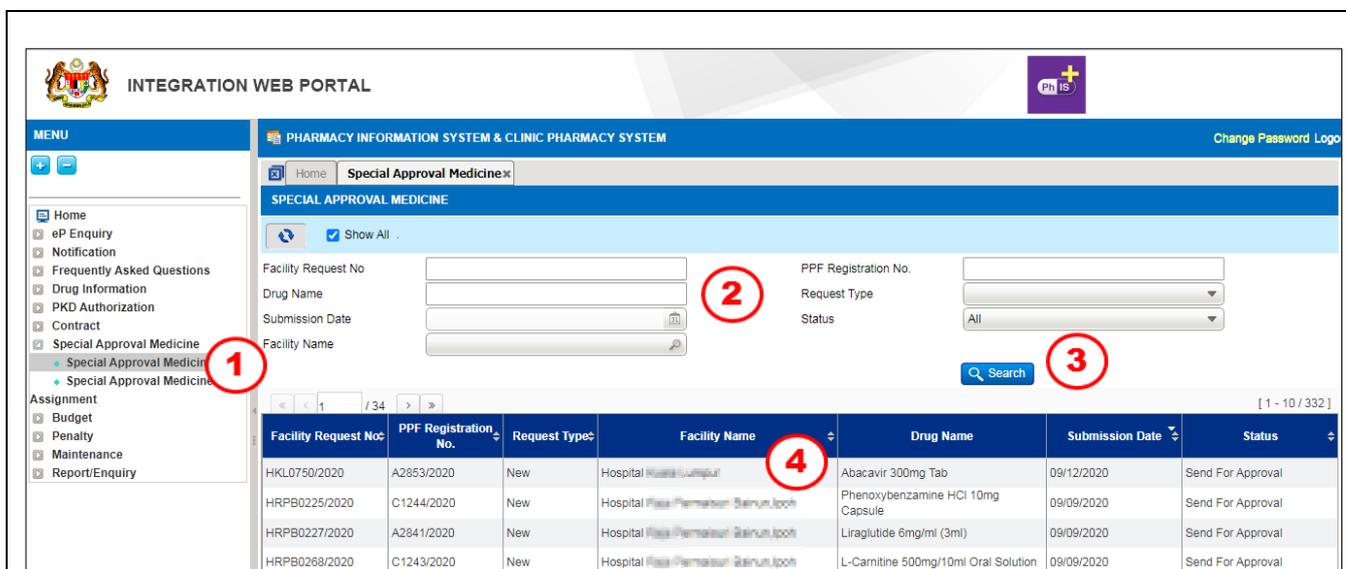
KPK Special Drug Item Assign screen allow user to choose the Item Code for KPK Drug that has been approved at KPK Special Drug Approval screen.

### 3.1 KPK Approval

This function is used to approve special drug request from the facility and recommend item code for the approved drug.

#### 3.1.1 KPK Special Drug Approval

This function is used to approve special drug request from the facility



**Integration Web Portal**

PHARMACY INFORMATION SYSTEM & CLINIC PHARMACY SYSTEM

SPECIAL APPROVAL MEDICINE

Facility Request No.  PPF Registration No.

Drug Name  Request Type

Submission Date  Status

Facility Name

Facility Request No.	PPF Registration No.	Request Type	Facility Name	Drug Name	Submission Date	Status
HKL0750/2020	A2853/2020	New	Hospital Kuala Lumpur	Abacavir 300mg Tab	09/12/2020	Send For Approval
HRPB0225/2020	C1244/2020	New	Hospital Raja Permaisuri Bainun, Ipoh	Phenoxylbenzamine HCl 10mg Capsule	09/09/2020	Send For Approval
HRPB0227/2020	A2841/2020	New	Hospital Raja Permaisuri Bainun, Ipoh	Liraglutide 6mg/ml (3ml)	09/09/2020	Send For Approval
HRPB0268/2020	C1243/2020	New	Hospital Raja Permaisuri Bainun, Ipoh	L-Carnitine 500mg/10ml Oral Solution	09/09/2020	Send For Approval

Figure 3.1.1-1 KPK Special Drug Approval List Page

#### STEP 1

Click on 'KPK Approval' followed by 'KPK Special Drug Approval'.

#### STEP 2

These search criteria can be used to search for existing KPK Special Drug Approval records:

- Facility Request No
- PPF Register No
- Drug Name
- Request Type
- Submission Date
- Status
- Facility Name

#### Note

It is recommended to set search 'Status' to 'Send for Approval' if there are too many search results

#### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

#### STEP 4

Double click on the selected record and the details of the KPK Special Drug Approval will be displayed as Figure 3.1.1-2.

SPECIAL APPROVAL MEDICINE			
Special Approval Medicine		Additional Document	
Facility Request No.	HKL0750/2020	PPF Registration No.	A2853/2020
Facility Name	Hospital Kuala Lumpur	JKN	HOSPITAL KUALA LUMPUR
Request Date	09/12/2020	Request By	<input checked="" type="radio"/> Batch <input type="radio"/> Patient
State	WP Kuala Lumpur	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat
Drug Name	Abacavir 300mg Tab	Status	Send For Approval
Create New Drug		Indication/reason for treatment for drug/product request	Test
		Approved Indication	
Drug Details			
Drug Description	Abacavir 300mg Tab	Item Code	
Status	PENDING	Packaging Description	
Registration Status with 'Pihak Berkuasa Kawalan Dadah'			
MOH Drug Formulary	<input checked="" type="radio"/> Yes <input type="radio"/> No	Indication approved by PBKD	<input checked="" type="radio"/> Yes <input type="radio"/> No
Registered MAL	<input checked="" type="radio"/> Yes <input type="radio"/> No MAL12345	Manufactured by	
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	
* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label			
Request Quantity	5000 tablet	Attachment 1 (Justification Report/Patient Monitoring Form)	Attachment JustificationReport.pdf View Attachment

Figure 3.1.1-2 KPK Special Drug Approval Edit Page

### STEP 5

Click on the  button to edit the KPK Special Drug Approval screen and fill all the criteria with mandatory flag 

### Note

- User is allowed to enter the value of drug assignment even request status not yet 'Approved by KPK/PKPF'. By default, status of drug assign as pending.
- If request is by existing drug name, drug name will be displayed in drug description. User is not allowed to change this value.
- If request is by 'new drug', user has to assign new drug name. Once assign and click on save button for request status as "Approved by KPK/PKPF", status will change to 'Completed'. This status will reflect in 'KPK Special Drug Item Assign' screen.
- Once completed, user is not allowed to change the drug and item. No changes for existing function in 'KPK Special Drug Item Assign'.
- 'Prepacking item' will be exclude from item code assignment list. User should not assign prepacking item as KPK item

### STEP 6

Enter the **Serial No** column.

### Note

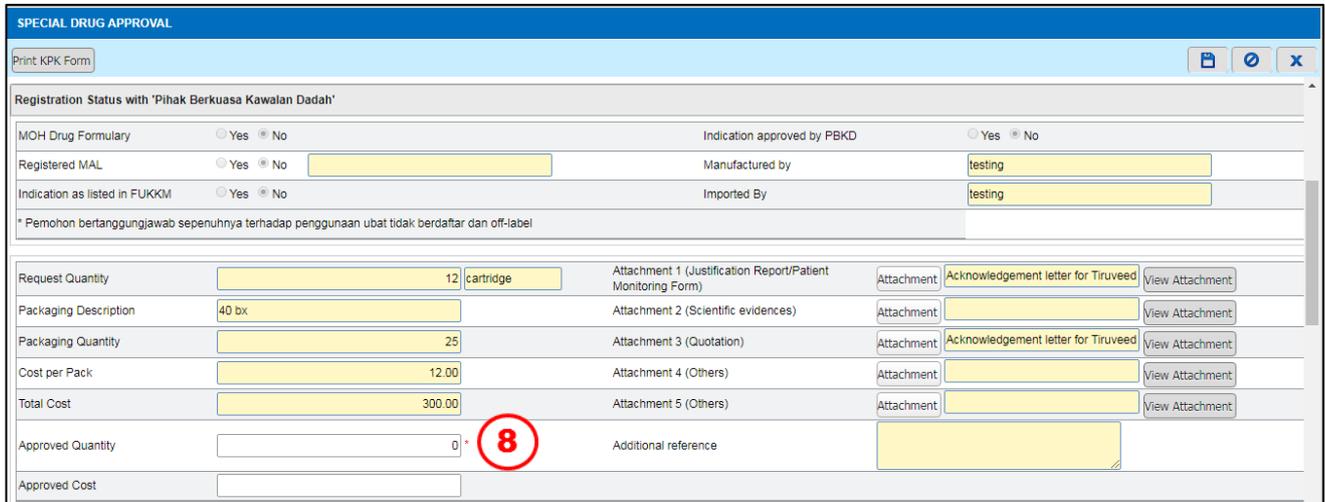
- User is allowed to enter the Serial No column, its free text with maximum 300 characters. This value will be maintained by HQ. Same fields will be displayed in Facility as read-only.

### STEP 7

Enter the **Approved Indication** column.

**Note**

User is allowed to enter the 'Approved Indication'. Free text with maximum 300 characters. This value will be maintained by HQ. Same fields will be displayed in Facility as read-only.

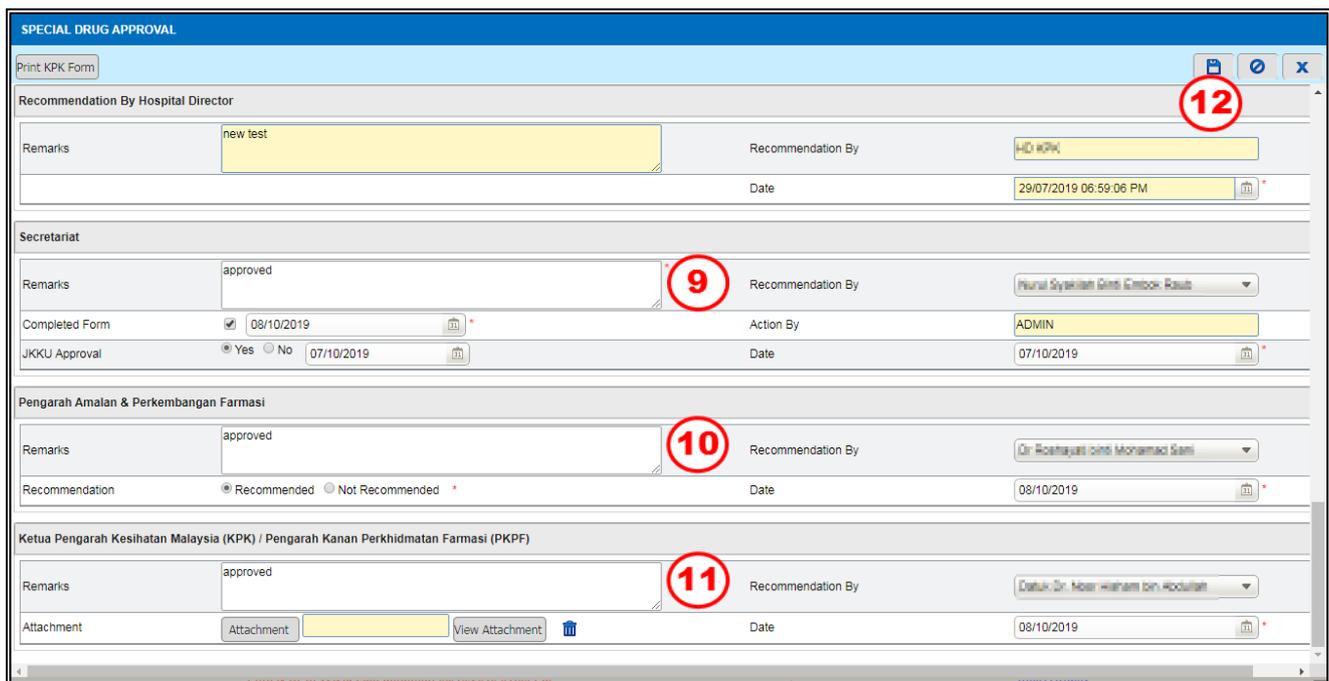


The screenshot shows the 'SPECIAL DRUG APPROVAL' form. The 'Request Quantity' is set to 12 cartridge. The 'Approved Quantity' field is currently empty and has a red circle with the number '8' next to it. Other fields include 'MOH Drug Formulary', 'Registered MAL', 'Indication as listed in FUKKM', 'Indication approved by PBKD', 'Manufactured by', and 'Imported By'. There are also sections for attachments and costs.

Figure 3.1.1-3 KPK Special Drug Approval

### STEP 8

Enter the **Approved Quantity** column



The screenshot shows the 'SPECIAL DRUG APPROVAL' form with the 'Recommendation By Hospital Director' section. The 'Remarks' field contains 'new test' and the 'Recommendation By' field has a value 'HD KPK' with a circled '12' next to it. The 'Date' is 29/07/2019. Below this is the 'Secretariat' section with 'Remarks' set to 'approved' and a circled '9' next to it. The 'Completed Form' is checked and dated 08/10/2019. The 'JKKU Approval' is 'Yes' and dated 07/10/2019. There are also sections for 'Pengaruh Amalan & Perkembangan Farmasi' and 'Ketua Pengarah Kesihatan Malaysia (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF)' with circled numbers 10 and 11 respectively.

Figure 3.1.1-4 KPK Special Drug Approval

### STEP 9

Fill all the criteria with 

- Fill the **Secretariat** section—**Remarks, Completed From, JKKU Approval** and **Date**

### STEP 10

Fill all the criteria with 

- Fill the **Pengarah Amalan & Perkembangan Farmasi** section - **Remarks, Recommendation, and Date**

### STEP 11

Fill all the criteria with 

- Fill the **Ketua Pengarah Kesihatan Malaysia (KPK)/ Pengarah Kanan Perkhidmatan Farmasi (PKPF)** section – **Remarks and Date**

### STEP 12

Click on the  button to save the record for KPK Special Drug Approval

#### Note

Record will save when user click on the  button as shown in Figure 3.1.1-5

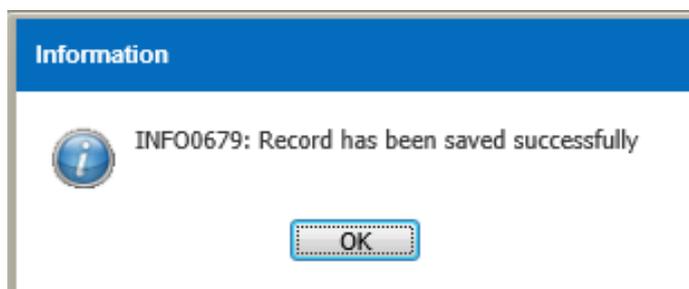
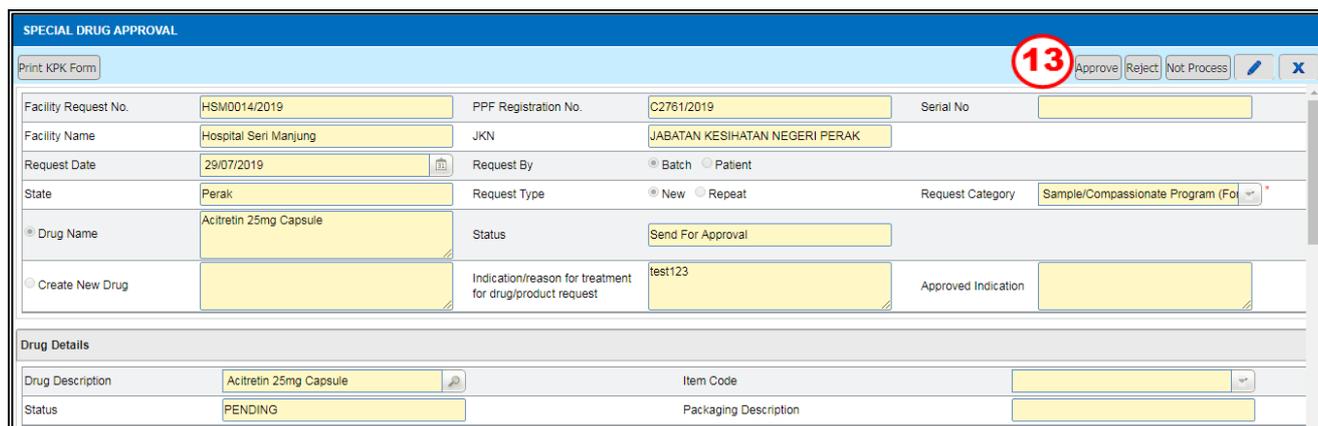


Figure 3.1.1-5 Information Message



The screenshot shows the "SPECIAL DRUG APPROVAL" form. At the top right, there is a red circle with the number "13" next to the "Approve" button. The form contains several fields for data entry, including Facility Request No., Facility Name, Request Date, State, Drug Name, and Status. The "Status" field is currently set to "Send For Approval".

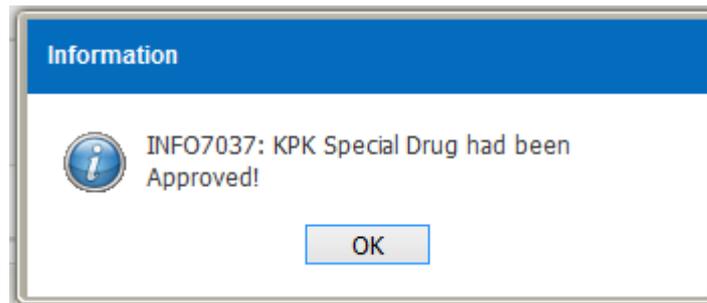
Figure 3.1.1-6 KPK Special Drug Approval

### STEP 13

Click on the  button to approve the record.

#### Note

- Record will approve when user click on the  button as shown in Figure 3.1.1-7



**Figure 3.1.1-7 Information Message**

- Click on the  button to print out the KPK Form as shown in Figure 3.1.1-8, 3.1.1-9 and 3.1.1-10

 <b>PERMOHONAN MEMPEROLEHI &amp; MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI</b>								
		<b>No. Siri</b> Fasiliti: HSM0014/2019 Prog. Perkhidmatan Farmasi: C2761/2019						
<b>PERHATIAN:</b> Permohonan yang tidak lengkap <b>TIDAK</b> akan diproses.								
1	Hospital yang memohon: Hospital Seri Manjung	5						
2	Negeri: Perak	6						
3	Jenis permohonan: Baru	Nama ubat / keluaran dimohon (nama generik): Acitretin 25mg Capsule						
4	Nama Pesakit:							
		7						
		Status pendaftaran Pihak Berkuasa Kawalan Dadah (PBKD: <a href="http://portal.bpfk.gov.my/">http://portal.bpfk.gov.my/</a> )  Tidak berdaftar dan tiada dalam FUKKM* <i>Indikasi seperti diluluskan oleh PBKD - Tidak Indikasi seperti terdapat dalam FUKKM - Tidak</i> Nama Pengilang: System Administrator Nama Pengimport: Tuberculin * Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label						
		Kuantiti dimohon (maksimum 12 bulan): 0 ampoule Saiz Bungkusan: capsule Kos/Pek: 200.00 Kos Sebenar:						
<b>A INDIKASI/TUJUAN RAWATAN BAGI UBAT/KELUARAN YANG DIMOHON</b>								
test123								
<b>B UBAT/KELUARAN ALTERNATIF SEDIA ADA DALAM FUKKM BAGI INDIKASI DIMOHON</b>								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">UBAT/KELUARAN</th> <th style="width: 20%;">TEMPOH PENGGUNAAN</th> <th style="width: 40%;">SEBAB-SEBAB TIDAK DAPAT DIGUNAKAN</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>			UBAT/KELUARAN	TEMPOH PENGGUNAAN	SEBAB-SEBAB TIDAK DAPAT DIGUNAKAN			
UBAT/KELUARAN	TEMPOH PENGGUNAAN	SEBAB-SEBAB TIDAK DAPAT DIGUNAKAN						
<b>C MAKLUMAT PAKAR YANG MEMOHON</b>								
Ulasan:		Nama: Pharmacist KPK Disiplin: Pharmacy Tarikh: 29/07/2019						
<b>D KETUA JABATAN</b>								
Ulasan:		Nama: KPF KPK Tarikh:						
<b>E KETUA PEGAWAI FARMASI</b>								
Ulasan: testing new		Peruntukan yang diperlukan: RM2,000.00 Peruntukan sedia ada: RM272.79						
		Nama: KPF KPK Tarikh: 29/07/2019						
<b>F PENGESAHAN PENGARAH HOSPITAL</b>								
Ulasan: new test		Nama: HD KPK Tarikh: 29/07/2019						
<b>G PENGESAHAN Pengerusi JKK Ubat-ubatan KKM (untuk permohonan ubat tidak berdaftar (tiada dalam FUKKM) dan permohonan ubat diluar indikasi/off-label)</b>								

BPF/103-KPK01 (Pindaan 4)

m/s 1

Figure 3.1.1-8 KPK Form

Ulasan:		Tandatangan, nama & cop:
<input type="checkbox"/> SOKONG	<input type="checkbox"/> TIDAK DISOKONG	Tarikh:

---

BPF/103-KPK01 (Pindaan 4) m/s 2

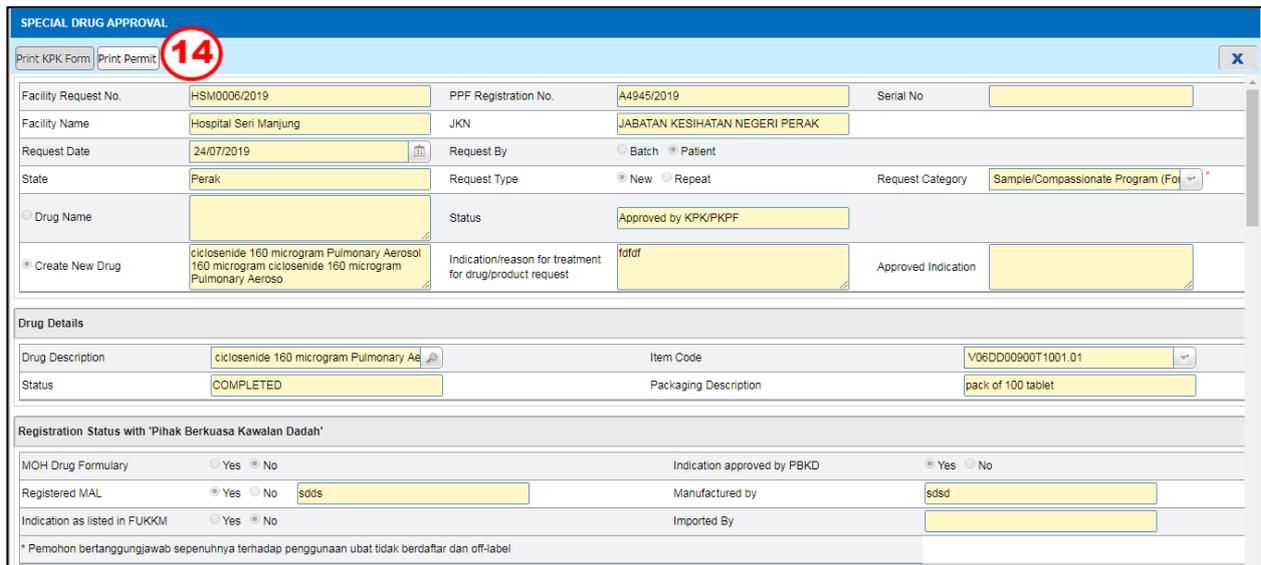
**Figure 3.1.1-9 KPK Form**

 <b>PERMOHONAN MEMPEROLEHI &amp; MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI</b>		
<b>Hospital</b>	Hospital Seri Manjung	<b>No. Siri:</b>
<b>Nama Ubat</b>	Acitretin 25mg Capsule	<b>No. Pen. PPF: C2761/2019</b>
<b>Indikasi</b>		
<b>Kuantiti Ubat</b>	0 ampoule	<b>Kos Ubat:</b>
<b>Nama Pesakit</b>		
<b>Nama Pemohon Jawatan (Pakar)</b>	Pharmacist KPK , Pegawai Farmasi UF52	
<b>H</b>	<b>SECRETARIAT</b>	
	Ulasan: approved	Nama: Nurul Syakilah Binti Embok Raub Tarikh: 07/10/2019
<b>I</b>	<b>PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>	
	Ulasan: approved  <input checked="" type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG	Tandatangan, nama & cop: Dr Roshayati binti Mohamad Sani Tarikh: 08/10/2019
<b>J</b>	<b>KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF)</b>	
	Sila maklum bahawa permohonan tuan/puan: <input type="checkbox"/> LULUS <input type="checkbox"/> TIDAK LULUS Ulasan: approved	Tandatangan, nama & cop: Datuk Dr. Noor Hisham bin Abdullah Tarikh: 08/10/2019

**Peringatan :**

1. Urusan perolehan bagi setiap permohonan yang telah diluluskan hendaklah mengikut tatacara perolehan tertakluk kepada Arahan Perbendaharaan yang telah ditetapkan.
2. Peruntukan bagi proses perolehan hendaklah menggunakan peruntukan semasa yang telah diberikan dan bukan sebagai alasan untuk memohon peruntukan tambahan.

Figure 3.1.1-10 KPK Form



**SPECIAL DRUG APPROVAL**

Print KPK Form | **Print Permit** (14) | X

Facility Request No.	HSM0006/2019	PPF Registration No.	A4945/2019	Serial No	
Facility Name	Hospital Seri Manjung	JKN	JABATAN KESIHATAN NEGERI PERAK		
Request Date	24/07/2019	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Perak	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Sample/Compassionate Program (Fo...)
<input type="radio"/> Drug Name		Status	Approved by KPK/PKPF		
<input checked="" type="radio"/> Create New Drug	ciclesonide 160 microgram Pulmonary Aerosol 160 microgram ciclesonide 160 microgram Pulmonary Aerosol	Indication/reason for treatment for drug/product request	fdfdf	Approved Indication	

**Drug Details**

Drug Description	ciclesonide 160 microgram Pulmonary Ae...	Item Code	V06DD00900T1001.01
Status	COMPLETED	Packaging Description	pack of 100 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

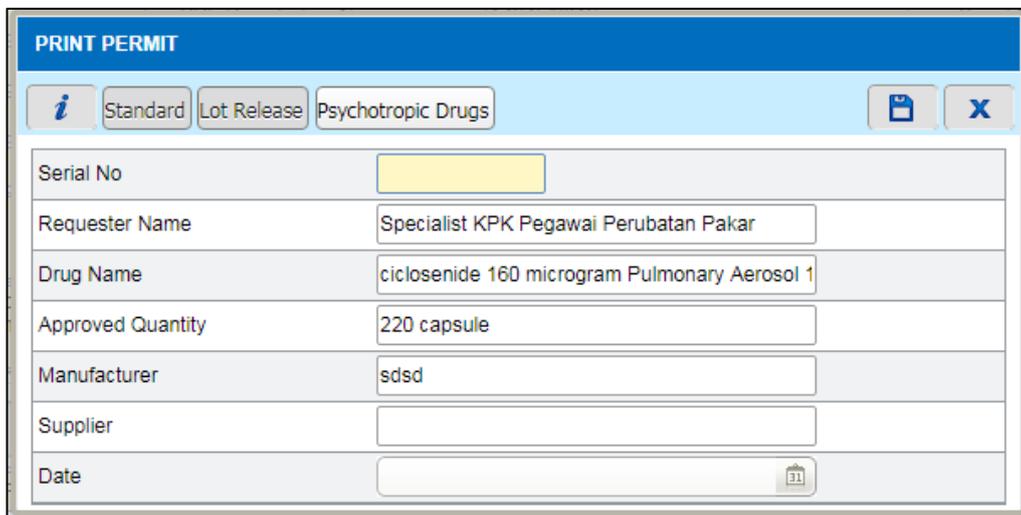
MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input checked="" type="radio"/> Yes <input type="radio"/> No
Registered MAL	<input checked="" type="radio"/> Yes <input type="radio"/> No sdsd	Manufactured by	sdsd
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

**Figure 3.1.1-11 KPK Approval Screen**

**STEP 14**

Click on the **Print Permit** button to print out the KPK Permit



**PRINT PERMIT**

Serial No	
Requester Name	Specialist KPK Pegawai Perubatan Pakar
Drug Name	ciclesonide 160 microgram Pulmonary Aerosol 1
Approved Quantity	220 capsule
Manufacturer	sdsd
Supplier	
Date	

**Figure 3.1.1-12 Print Permit Screen**

**Note**

- To print permit user able to choose three type of permit as shown in figure3.1.1-12
- User able edit or change Requester Name, Drug Name, Approved Quantity, Manufacturer, Supplier and Date. All the details will appear in the permit after save it.
- Click on the **Standard** button to print standard permit as shown in figure3.1.1-13 below.



AKTA JUALAN DADAH 1952  
PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984  
(Peraturan 15(6))

**PENGECUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN  
PENYAKIT YANG MENGANCAM NYAWA (No.Siri :)**

KKM-600-34/4/

Pengecualian ini diberikan kepada:

Nama Pemohon : **Specialist KPK Pegawai Perubatan Pakar,**  
Hospital/Institusi : **Hospital Seri Manjung**  
Nama Produk : **ciclosenide 160 microgram Pulmonary Aerosol 160 microgram**  
Kuantiti : **220 capsule**

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

- (1) Pengimportan ini dikhaskan bagi kegunaan pemohon ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
- (2) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk tersebut tidak melanggar mana-mana hak milik paten atau/dan data exclusivity.
- (3) Tatacara yang berkaitan dengan pengimportan, penyimpanan serta pembekalan hendaklah dipatuhi. Segala rekod dan dokumen hendaklah disimpan bagi tujuan audit.
- (4) Aduan produk dan kesan advers akibat dari penggunaan produk tidak berdaftar tersebut adalah dibawah tanggungjawab pemohon sepenuhnya. Laporan aduan produk dan kesan advers hendaklah dikemukakan kepada Bahagian Amalan dan Perkembangan Farmasi.
- (5) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah;
  - a) memulangkan semula permit import ini; dan
  - b) menghantar sesalinan borang import Kastam.kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- (6) Pengecualian ini sah untuk pengimportan dalam **tempoh satu (1) tahun** dari tarikh ia dikeluarkan. Walaubagaimanapun, permit import ini terbatal apabila produk yang berdaftar telah berada di pasaran.
- (7) **Dokumen ini merupakan hak kerajaan Malaysia. Kehilangan dokumen ini perlu dilaporkan kepada pihak polis.**

Tarikh:

Pengarah Kanan Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia.

**Figure 3.1.1-13 KPK Permit - Standard**

- Click on the  button to print Lot Release as shown in figure 3.1.1-14 below.

  
**AKTA JUALAN DADAH 1952**  
**PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984**  
(Peraturan 15(6))

**PENGECCUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN**  
**PENYAKIT YANG MENGANCAM NYAWA (No.Siri :)**

KKM-600-34/4/  
Pengecualian ini diberikan kepada:

Nama Pemohon : **Specialist KPK Pegawai Perubatan Pakar,**  
Hospital/Institusi : **Hospital Seri Manjung**  
Nama Produk : **ciclosenide 160 microgram Pulmonary Aerosol 160 microgram**  
Kuantiti : **220 capsule**  
Nama Pembekal : **sdsd**  
Nama Pengilang :

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

- (1) Syarat-syarat khusus untuk produk **vaksin dan plasma:**
  - a. Keluaran-keluaran tersebut hanya dibenarkan untuk diimport melalui Lapangan Terbang Antarabangsa Kuala Lumpur (KLIA), Sepang, Selangor dan Lapangan Terbang Antarabangsa Pulau Pinang, Pulau Pinang sahaja.
  - b. Pengimportan keluaran-keluaran tersebut hendaklah dilakukan oleh pengimport yang mempunyai Lesen Racun Jenis A yang sah di bawah Akta Racun 1952 (Akta 366) iaitu ..... (perlu tambah).
  - c. Pengimportan keluaran-keluaran tersebut adalah tertakluk kepada **penilaian dokumentasi** dan **pemeriksaan rangkaian sejuk** oleh pihak Bahagian Regulatori Farmasi Negara.
- (2) Pengimportan ini dihaskan bagi kegunaan pemohon ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
- (3) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk tersebut tidak melanggar mana-mana hak milik paten atau/dan *data exclusivity*.
- (4) Tatacara yang berkaitan dengan pengimportan, penyimpanan serta pembekalan hendaklah dipatuhi. Segala rekod dan dokumen hendaklah disimpan bagi tujuan audit.
- (5) Aduan produk dan kesan advers akibat dari penggunaan produk tidak berdaftar tersebut adalah dibawah tanggungjawab pemohon sepenuhnya. Laporan aduan produk dan kesan advers hendaklah dikemukakan kepada Bahagian Amalan dan Perkembangan Farmasi.
- (6) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah;
  - a) memulangkan semula permit import ini; dan
  - b) menghantar sesalinan borang import Kastam. kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- (7) Pengecualian ini sah untuk pengimportan dalam **tempoh satu (1) tahun** dari tarikh ia dikeluarkan. Walaubagaimanapun, permit import ini terbatal apabila produk yang berdaftar telah berada di pasaran.
- (8) **Dokumen ini merupakan hak kerajaan Malaysia. Kehilangan dokumen ini perlu dilaporkan kepada pihak polis.**

Tarikh: \_\_\_\_\_  
Pengarah Kanan Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia.

**Figure 3.1.1-14 KPK Permit -Lot Release**

- Click on the **Psychotropic Drugs** button to print Psychotropic Drugs as shown in figure 3.1.1-15 below.



**AKTA JUALAN DADAH 1952**  
**PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984**  
(Peraturan 15(6))

**PENGEUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN**  
**PENYAKIT YANG MENGANCAM NYAWA (No.Siri :)**

KKM-600-34/4/  
Pengecualian ini diberikan kepada:

Nama Pemohon : **Specialist KPK Pegawai Perubatan Pakar,**  
Hospital/Institusi : **Hospital Seri Manjung**  
Nama Produk : **ciclosenide 160 microgram Pulmonary Aerosol 160 microgram**  
Kuantiti : **220 capsule**

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

- (1) Pengimportan ini dikhaskan bagi kegunaan pemohon ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
- (2) **Pengimport perlu memohon kebenaran import DADAH BERBAHAYA kerana bahan ini dikawal di bawah Akta Dadah Berbahaya 1952**
- (3) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk tersebut tidak melanggar mana-mana hak milik paten atau/dan data exclusivity.
- (4) Tatacara yang berkaitan dengan pengimportan, penyimpanan serta pembekalan hendaklah dipatuhi. Segala rekod dan dokumen hendaklah disimpan bagi tujuan audit.
- (5) Aduan produk dan kesan advers akibat dari penggunaan produk tidak berdaftar tersebut adalah dibawah tanggungjawab pemohon sepenuhnya. Laporan aduan produk dan kesan advers hendaklah dikemukakan kepada Bahagian Amalan dan Perkembangan Farmasi.
- (6) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah;
  - a) memulangkan semula permit import ini; dan
  - b) menghantar sesalinan borang import Kastam.kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- (7) Pengecualian ini sah untuk pengimportan dalam **tempoh satu (1) tahun** dari tarikh ia dikeluarkan. Walaubagaimanapun, permit import ini terbatal apabila produk yang berdaftar telah berada di pasaran.
- (8) **Dokumen ini merupakan hak kerajaan Malaysia. Kehilangan dokumen ini perlu dilaporkan kepada pihak polis.**

Tarikh:

Pengarah Kanan Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia.

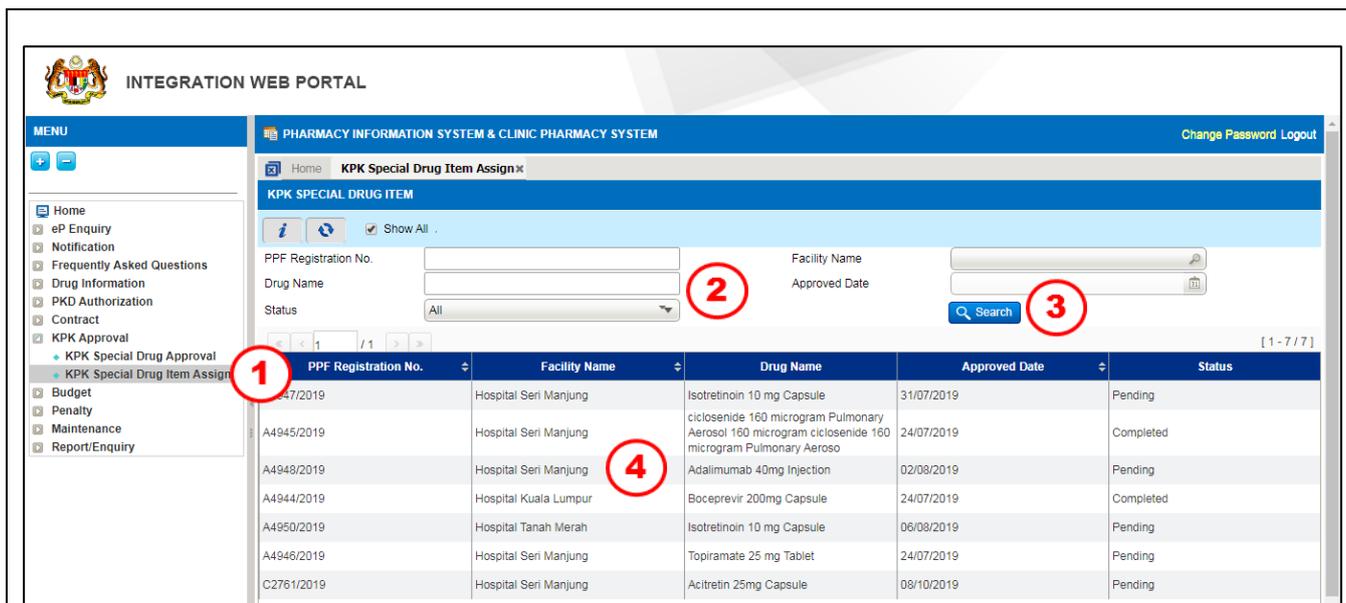
**Figure 3.1.1-15 KPK Permit - Psychotropic Drugs**

**Note**

- Click on the  button to reject the record. **Status will change to *Rejected By KPK/PKPF***
- Click on the  button to cancel process the record. **Status will change to *Not Processed***

### 3.1.2 KPK Special Drug Item Assign

This function is used to assign KPK Drug Item



INTEGRATION WEB PORTAL

PHARMACY INFORMATION SYSTEM & CLINIC PHARMACY SYSTEM

Home KPK Special Drug Item Assign

KPK SPECIAL DRUG ITEM

PPF Registration No.  Facility Name

Drug Name  Approved Date

Status

PPF Registration No.	Facility Name	Drug Name	Approved Date	Status
A4947/2019	Hospital Seri Manjung	Isotretinoin 10 mg Capsule	31/07/2019	Pending
A4945/2019	Hospital Seri Manjung	ciclosenide 160 microgram Pulmonary Aerosol 160 microgram ciclosenide 160 microgram Pulmonary Aerosol	24/07/2019	Completed
A4948/2019	Hospital Seri Manjung	Adalimumab 40mg Injection	02/08/2019	Pending
A4944/2019	Hospital Kuala Lumpur	Boceprevir 200mg Capsule	24/07/2019	Completed
A4950/2019	Hospital Tanah Merah	Isotretinoin 10 mg Capsule	06/08/2019	Pending
A4946/2019	Hospital Seri Manjung	Topiramate 25 mg Tablet	24/07/2019	Pending
C2761/2019	Hospital Seri Manjung	Acitretin 25mg Capsule	08/10/2019	Pending

Figure 3.1.2-1 KPK Special Drug Item Assign List Page

#### STEP 1

Click on 'Maintenance' followed by 'KPK Special Drug Item Assign'.

#### STEP 2

These search criteria can be used to search for existing KPK Special Drug Item Assign:

- a) **BPF Register No**
- b) **Facility Name**
- c) **Drug Name**
- d) **Approve Date**
- e) **Status**

#### Note

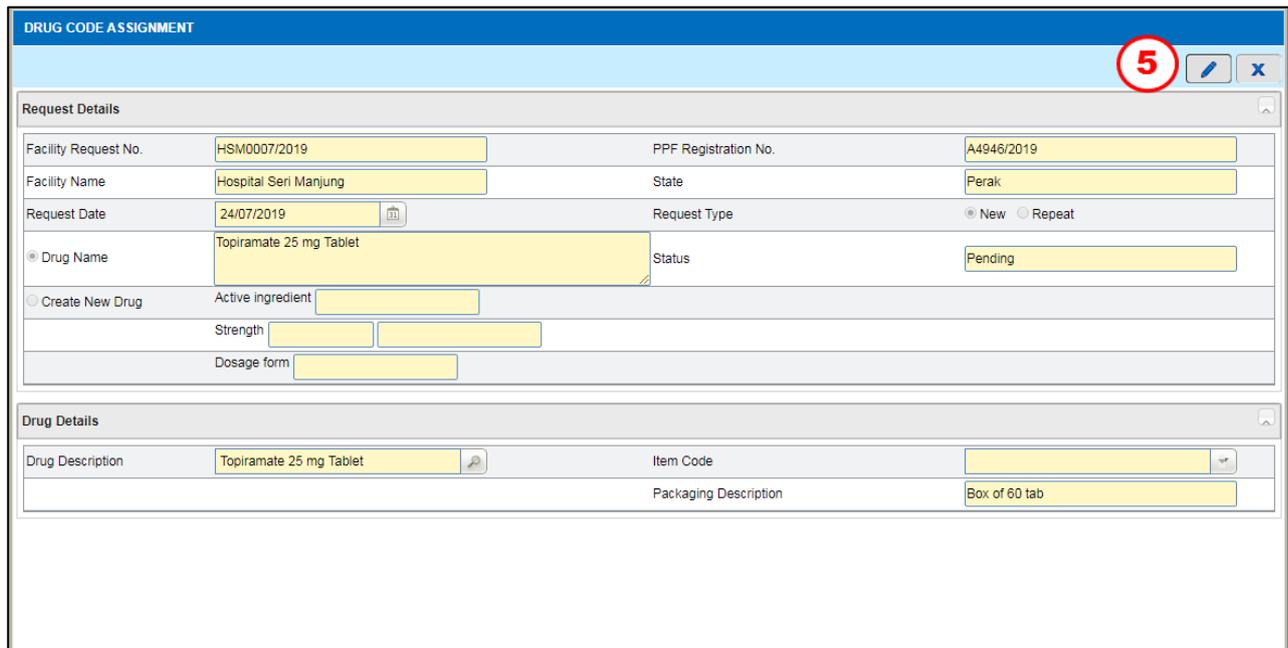
*It is recommended to set 'Status' to 'Pending' if there are too many search results*

#### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

#### STEP 4

Double click on the selected record and the details of the KPK Special Drug Item Assign will be displayed as Figure 3.1.2-2.



**DRUG CODE ASSIGNMENT**

Request Details

Facility Request No.	HSM0007/2019	PPF Registration No.	A4946/2019
Facility Name	Hospital Seri Manjung	State	Perak
Request Date	24/07/2019	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat
<input checked="" type="radio"/> Drug Name	Topiramate 25 mg Tablet	Status	Pending
<input type="radio"/> Create New Drug	Active ingredient		
	Strength		
	Dosage form		

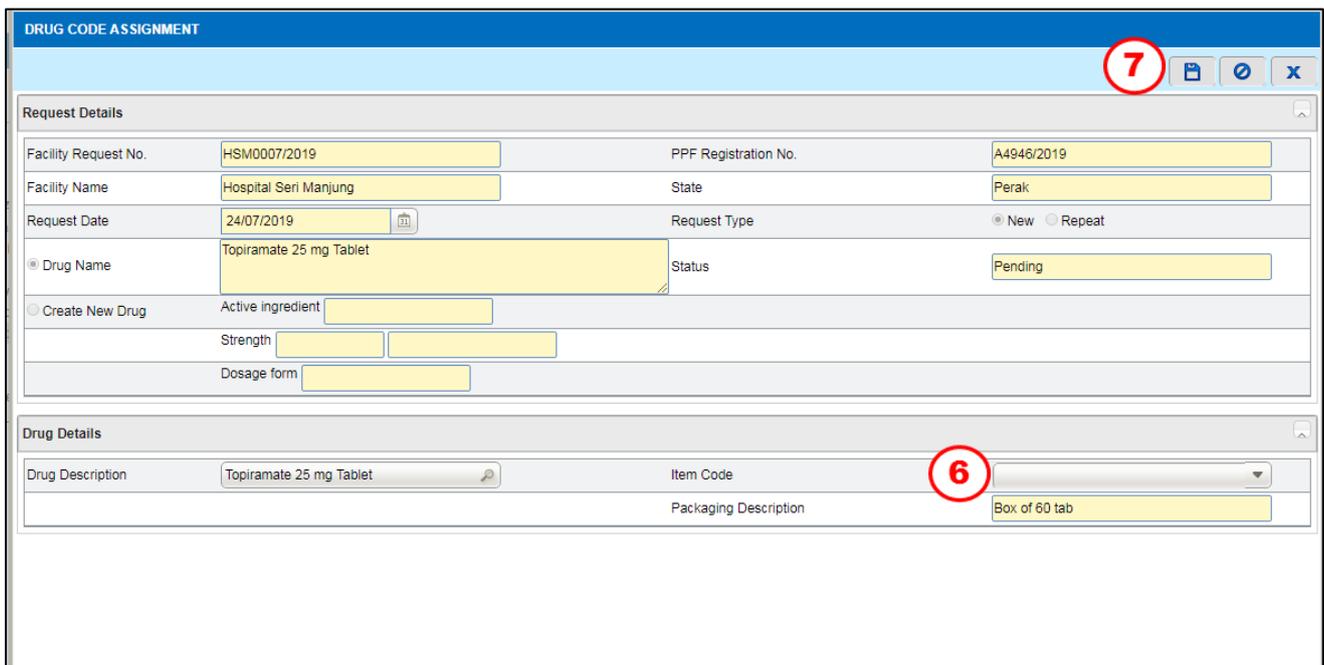
Drug Details

Drug Description	Topiramate 25 mg Tablet	Item Code	
		Packaging Description	Box of 60 tab

Figure 3.1.2-2 Drug Code Assignment

**STEP 5**

Click on the  button to edit the KPK Special Drug Item Assign screen and fill the compulsory



**DRUG CODE ASSIGNMENT**

Request Details

Facility Request No.	HSM0007/2019	PPF Registration No.	A4946/2019
Facility Name	Hospital Seri Manjung	State	Perak
Request Date	24/07/2019	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat
<input checked="" type="radio"/> Drug Name	Topiramate 25 mg Tablet	Status	Pending
<input type="radio"/> Create New Drug	Active ingredient		
	Strength		
	Dosage form		

Drug Details

Drug Description	Topiramate 25 mg Tablet	Item Code	
		Packaging Description	Box of 60 tab

Figure 3.1.2-3 Drug Code Assignment

**STEP 6**

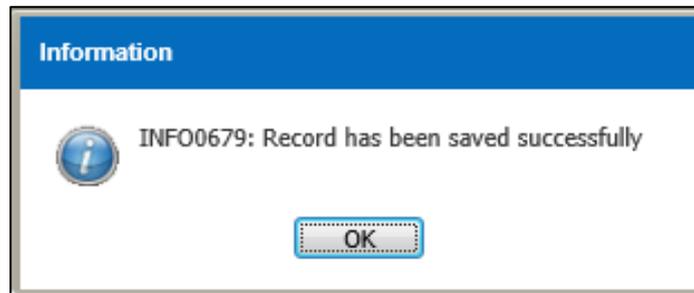
Click on the dropdown box to choose **Item Code** for Drug Description and click on the selected **Item Code**.

## STEP 7

Click on the  button to save the record for the KPK Special Drug Item Assign

### **Note**

- *After saved, the status will be updated to Completed. Once completed, status will be sent to facility with updated drug information.*
- *Record will save when user click on the  button as shown in Figure 3.1.2-4*



**Figure 3.1.2-4 Information Message**

- *Click on the  button to close the KPK Special Drug Item Assign screen.*

## 4.0 Acronyms

Abbreviation	Definition
MOH	Ministry of Health
KKM	Kementerian Kesihatan Malaysia
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
PKU	Packaging Keeping Unit
SKU	Store Keeping Unit
BPF	BahagianPerkhidmatanFarmasi
NPRA	National Pharmaceutical Regulatory Agency

## 5.0 Links to IWP Modules

No	Module	PDF Links
1	<i>Notification</i>	<a href="#">Click Here</a>
2	<i>Frequency Asked Question</i>	<a href="#">Click Here</a>
3	<i>Drug Information</i>	<a href="#">Click Here</a>
4	<i>Contract</i>	<a href="#">Click Here</a>
5	<i>KPK Approval</i>	<a href="#">Click Here</a>
6	<i>Maintenance – Pharmacy</i>	<a href="#">Click Here</a>
7	<i>Maintenance – Inventory</i>	<a href="#">Click Here</a>
8	<i>Maintenance – General</i>	<a href="#">Click Here</a>
9	<i>Maintenance – HQ Security</i>	<a href="#">Click Here</a>