



National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

USER MANUAL

QUEST 3+ System

Module: **PRODUCT REGISTRATION**
(Front-End)

Document No.: Q3+/User Manual/M2/1

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INTRODUCTION

This user manual will serve to guide the applicants from the industry to conduct transactions in QUEST 3+ for:

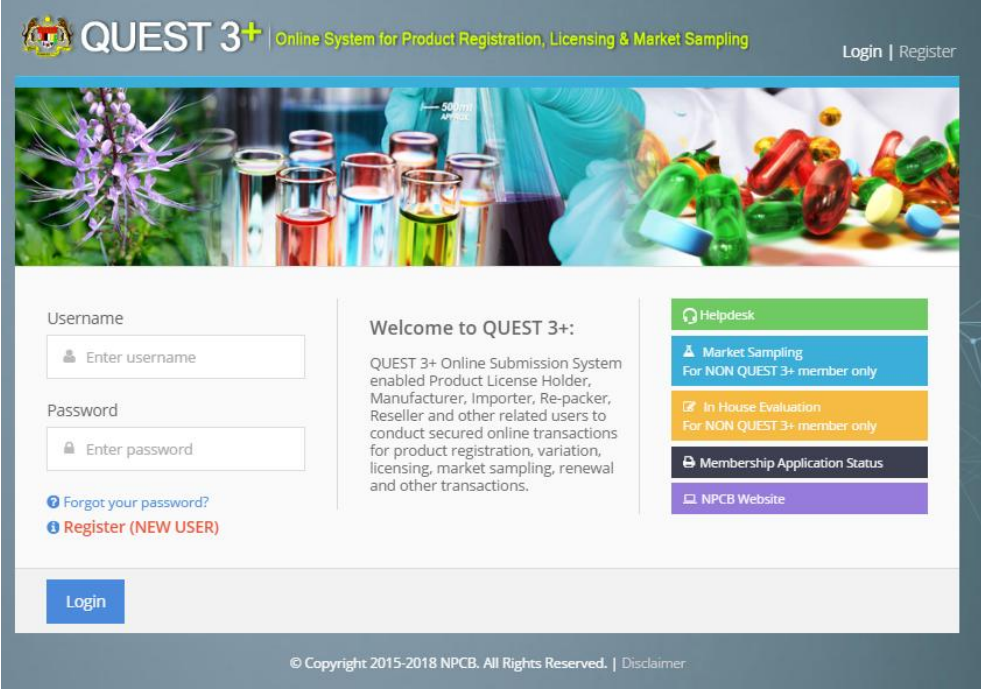
1. Application / Registration Evaluation New Products
2. Application / Product Evaluation Combos
3. Application / Additional Rate Indications
4. Appeal for Product Registration
5. Application for Certificate of Pharmaceutical Product (CPP)
6. Application for Change of Holder (COH)
7. Application for Product Re-Registration

Pre-requisite:

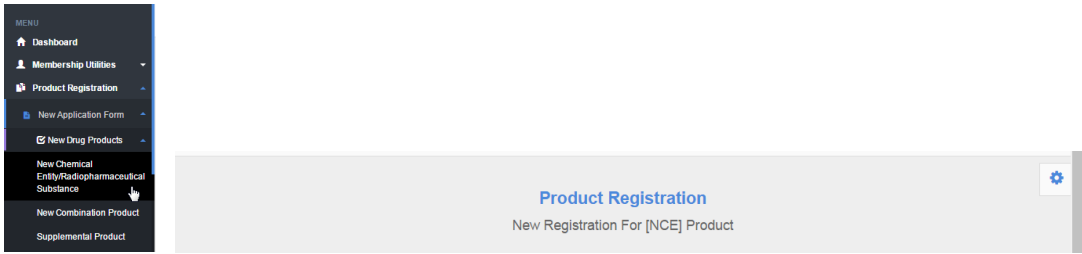
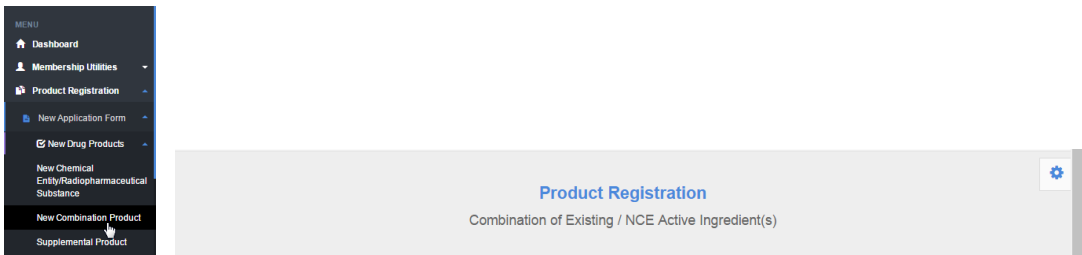
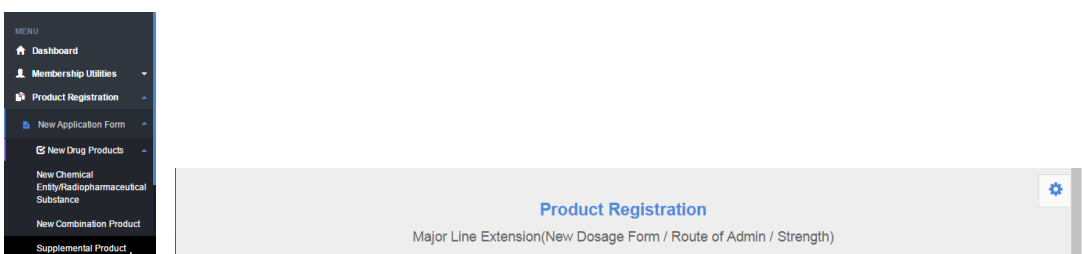
The application / registration process by the applicants will be conducted completely online including payments. The following are the pre-requisites before conducting the transactions in QUEST 3+:

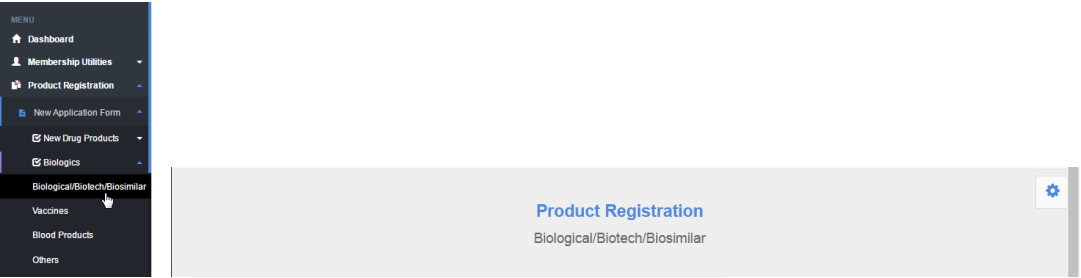
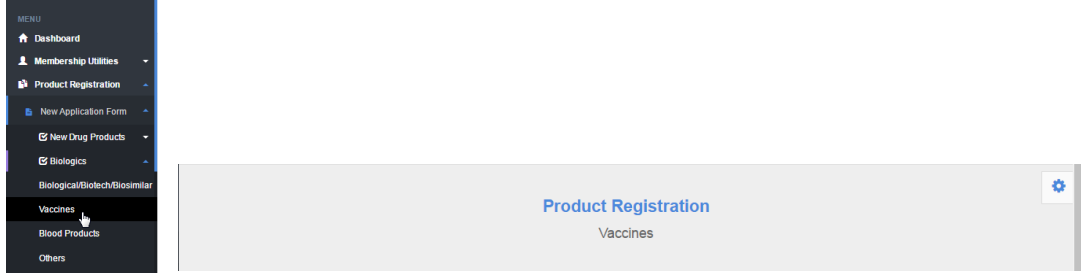
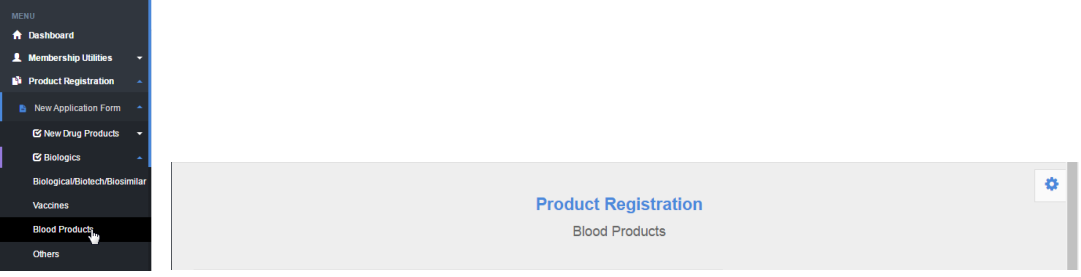
1. Internet Ready PC
2. Broadband Internet connection
3. Google Chrome latest version (recommended) or other internet explorer
4. Valid Digital Certificate (USB Token) – To be purchased online during Membership Application
5. Scanner
6. PDF Reader/Writer Software
7. Photo editor to edit (crop, resize or other editing functions) your attachments in jpg format
8. Valid email account for correspondences and system notifications
9. Online banking account (Personal or Business) or credit card to conduct payment transactions via FPX (Financial Process Exchange). FPX is a payment channel that allows you to make payment via online real-time through your current or savings account. All you need is an Internet banking account with any of FPX participating banks.

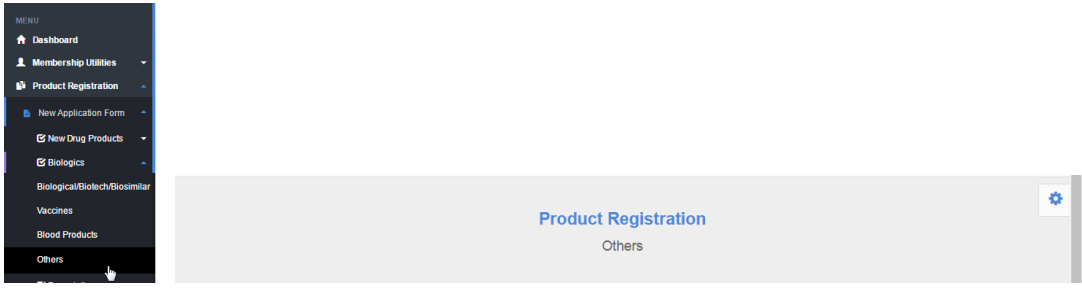
1.0 QUEST3+ Front-end login

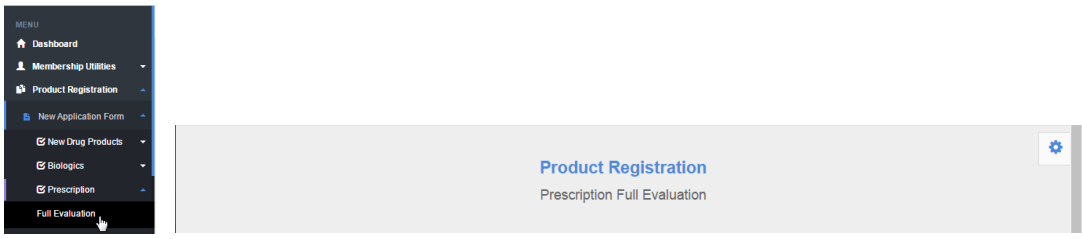
#	SCREENSHOTS / EXPLANATION
1	Login
FG1	
EX1	<p>Explanation:</p> <p>To access the Quest 3+ system, user need to use the URL as below: https://quest3plus.bpfk.gov.my/front-end</p> <p>Figure 1 as the above will appear and the user will need to enter the following information:</p> <ol style="list-style-type: none">1. User Name: User ID2. Password: Enter Password.3. Click Login

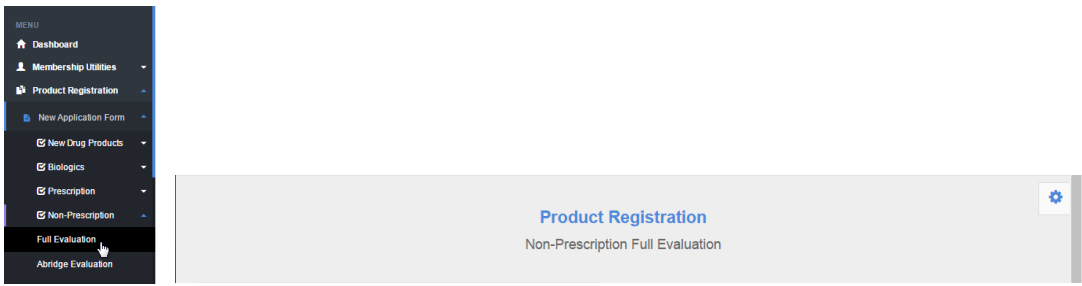
2.0 NEW APPLICATION FORM

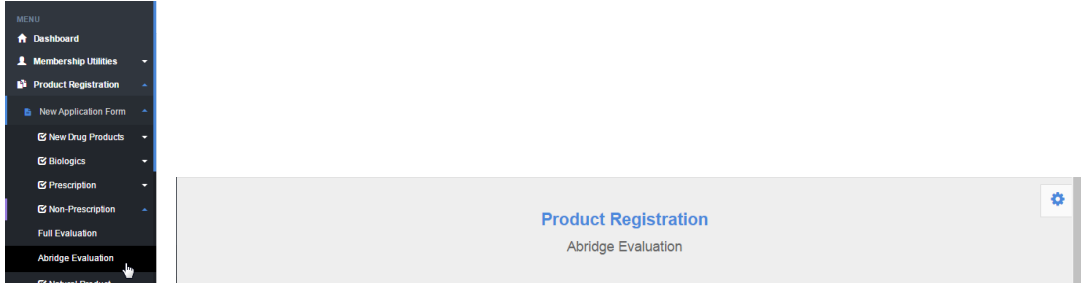
#	SCREENSHOTS / EXPLANATION
2.1	New Drug Products
2.1.1	New Chemical Entity / Radiopharmaceutical Substance
FG2	 <p>The screenshot shows a side menu on the left with the following items: Dashboard, Membership Utilities, Product Registration, New Application Form, New Drug Products, New Chemical Entity/Radiopharmaceutical Substance (highlighted with a mouse cursor), New Combination Product, and Supplemental Product. The main content area displays 'Product Registration' and 'New Registration For [NCE] Product'.</p>
EX2	<p>Explanation: Click on side menu 'New Chemical Entity / Radiopharmaceutical Substance'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.1.2	New Combination Product
FG3	 <p>The screenshot shows the same side menu as FG2, but with 'New Combination Product' highlighted by the mouse cursor. The main content area displays 'Product Registration' and 'Combination of Existing / NCE Active Ingredient(s)'.</p>
EX3	<p>Explanation: Click on side menu 'New Combination Product'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.1.3	Supplemental Product
FG4	 <p>The screenshot shows the same side menu as FG2, but with 'Supplemental Product' highlighted by the mouse cursor. The main content area displays 'Product Registration' and 'Major Line Extension(New Dosage Form / Route of Admin / Strength)'.</p>
EX4	<p>Explanation: Click on side menu 'Supplemental Product'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>

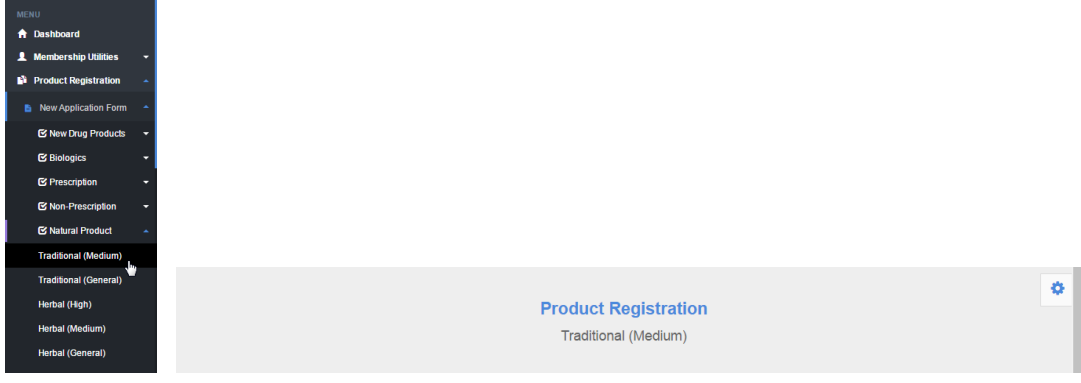
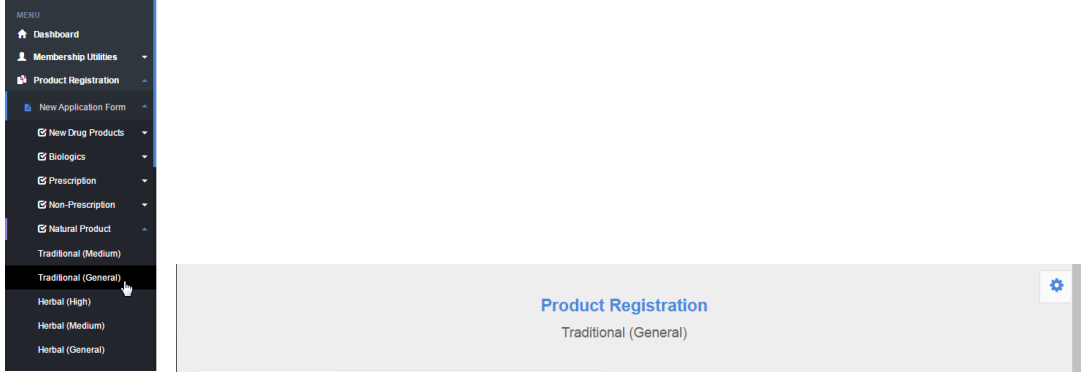
2.2	Biologics
2.2.1	Biological/Biotech/Bio similar
FG5	
EX5	<p>Explanation: Click on side menu 'Biological/Biotech/Bio similar'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.2.2	Vaccines
FG6	
EX6	<p>Explanation: Click on side menu 'Vaccines'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.2.3	Blood Products
FG7	
EX7	<p>Explanation: Click on side menu 'Blood Products'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.2.4	Others

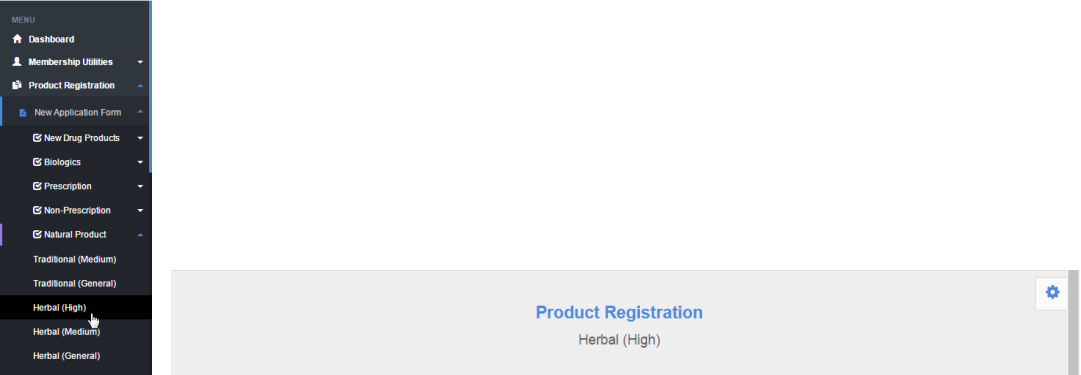
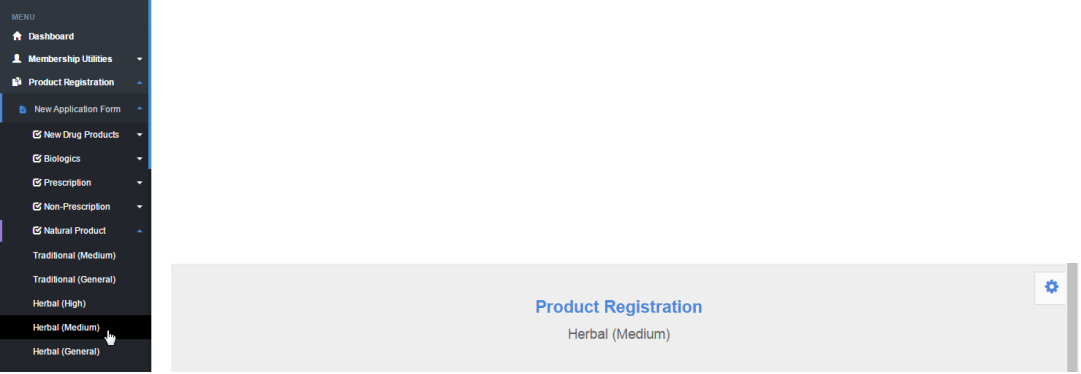
FG8	
EX8	<p>Explanation: Click on side menu 'Others'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>

2.3	Prescription
2.3.1	Full Evaluation
FG9	
EX9	<p>Explanation: Click on side menu 'Full Evaluation'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>

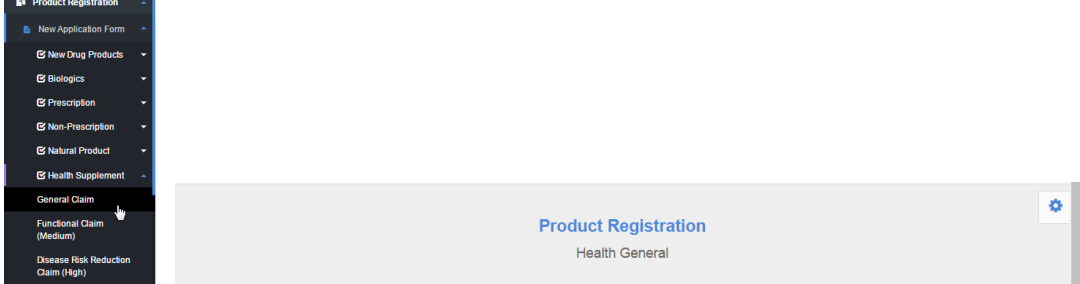
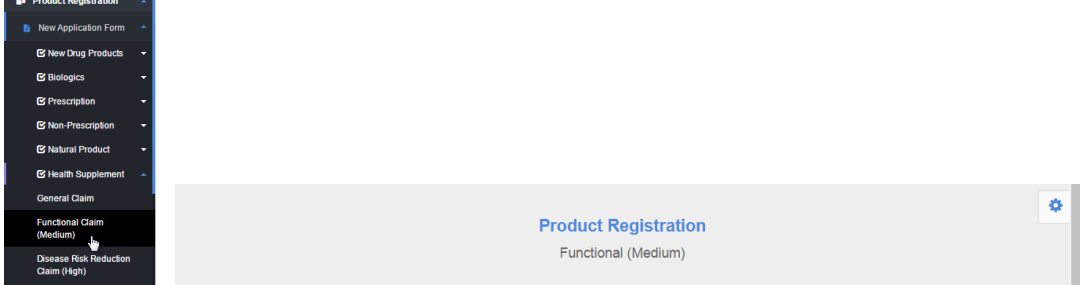
2.4	Non-Prescription
2.4.1	Full Evaluation
FG10	
EX10	<p>Explanation: Click on side menu 'Full Evaluation'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>

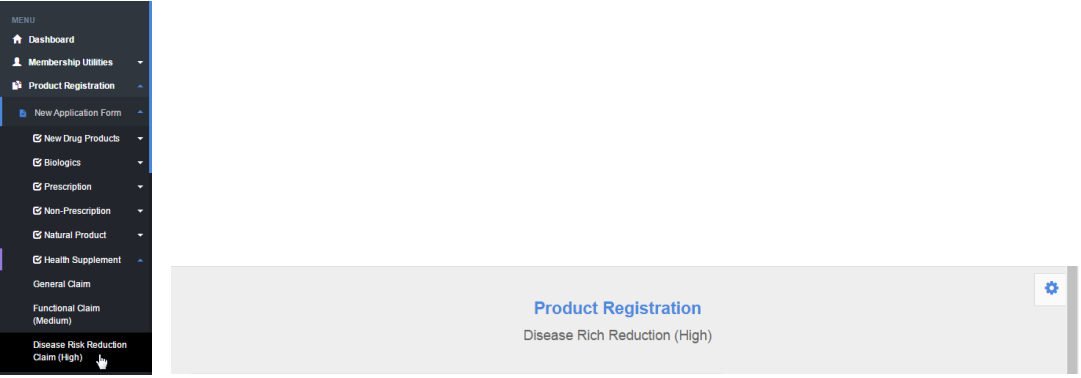
2.4.2	Abridge Evaluation
FG11	
EX11	<p>Explanation: Click on side menu 'Abridge Evaluation'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>

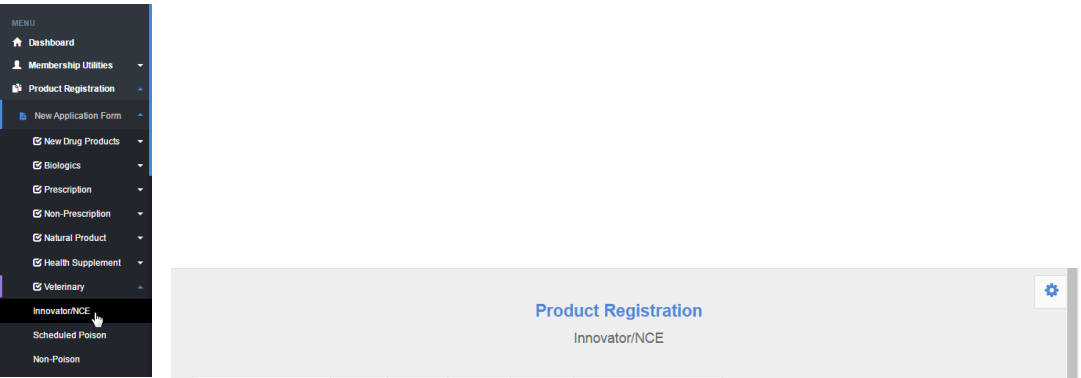
2.5	Natural Product
2.5.1	Traditional (Medium)
FG12	
EX12	<p>Explanation: Click on side menu 'Traditional (Medium)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>
2.5.2	Traditional (General)
FG13	

EX13	<p>Explanation: Click on side menu 'Traditional (General)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>
2.5.3	Herbal (High)
FG14	
EX14	<p>Explanation: Click on side menu 'Herbal (High)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.5.4	Herbal (Medium)
FG15	
EX15	<p>Explanation: Click on side menu 'Herbal (Medium)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.5.5	Herbal (General)

<p>FG16</p>	 <p>The screenshot shows a dark sidebar menu on the left with the following items: Dashboard, Membership Utilities, Product Registration, New Application Form, New Drug Products, Biologics, Prescription, Non-Prescription, Natural Product, Traditional (Medium), Traditional (General), Herbal (High), Herbal (Medium), and Herbal (General). The 'Herbal (General)' item is highlighted with a mouse cursor. The main content area on the right is a light gray box with the text 'Product Registration' in blue and 'Herbal (General)' in black below it. A settings gear icon is in the top right corner of the main area.</p>
<p>EX16</p>	<p>Explanation: Click on side menu 'Herbal (General)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>

<p>2.6</p>	<p>Health Supplement</p>
<p>2.6.1</p>	<p>General Claim</p>
<p>FG17</p>	 <p>The screenshot shows the same dark sidebar menu as in FG16, but with 'Health Supplement' highlighted. The main content area on the right displays 'Product Registration' in blue and 'Health General' in black below it. A settings gear icon is in the top right corner.</p>
<p>EX17</p>	<p>Explanation: Click on side menu 'Health (General)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>
<p>2.6.2</p>	<p>Functional Claim (Medium)</p>
<p>FG18</p>	 <p>The screenshot shows the same dark sidebar menu, but with 'Functional Claim (Medium)' highlighted. The main content area on the right displays 'Product Registration' in blue and 'Functional (Medium)' in black below it. A settings gear icon is in the top right corner.</p>
<p>EX18</p>	<p>Explanation: Click on side menu 'Functional (Medium)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 6</p>

2.6.3	Disease Risk Reduction Claim (High)
FG19	 <p>The screenshot shows a dark sidebar menu on the left with the following items: Dashboard, Membership Utilities, Product Registration, New Application Form, New Drug Products, Biologics, Prescription, Non-Prescription, Natural Product, Health Supplement, General Claim, Functional Claim (Medium), and Disease Risk Reduction Claim (High). The 'Disease Risk Reduction Claim (High)' item is highlighted with a mouse cursor. The main content area on the right is a light gray box with the text 'Product Registration' in blue and 'Disease Rich Reduction (High)' in black below it. A settings gear icon is in the top right corner of the main area.</p>
EX19	<p>Explanation: Click on side menu 'Disease Risk Reduction Claim (High)'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>

2.7	Veterinary
2.7.1	Innovator/NCE
FG20	 <p>The screenshot shows the same dark sidebar menu as in the previous example. The 'Innovator/NCE' item is highlighted with a mouse cursor. The main content area on the right is a light gray box with the text 'Product Registration' in blue and 'Innovator/NCE' in black below it. A settings gear icon is in the top right corner of the main area.</p>
EX20	<p>Explanation: Click on side menu 'Innovator/NCE'</p> <p>Refer content number 13.0</p> <p>Follow instructions: TAB 1 -> TAB 2 -> TAB 3 -> TAB 4 -> TAB 5 -> TAB 6</p>
2.7.2	Scheduled Poison

FG21

The screenshot shows a dark sidebar menu on the left with the following items: Dashboard, Membership Utilities, Product Registration (expanded), New Application Form, New Drug Products, Biologics, Prescription, Non-Prescription, Natural Product, Health Supplement, Veterinary, Innovator/NCE, Scheduled Poison (highlighted), and Non-Poison. The main content area is a light gray box with the text 'Product Registration' in blue and 'Scheduled Poison' below it. A settings gear icon is in the top right corner.

EX21

Explanation:
Click on side menu 'Scheduled Poison'

Refer content number 13.0

Follow instructions: [TAB 1](#) -> [TAB 2](#) -> [TAB 3](#) -> [TAB 6](#)

2.7.3 Non-Poison

FG22

The screenshot shows the same sidebar menu as FG21, but with 'Non-Poison' highlighted. The main content area shows 'Product Registration' in blue and 'Non-Poison' below it. A settings gear icon is in the top right corner.

EX22

Explanation:
Click on side menu 'Non-Poison'

Refer content number 13.0

Follow instructions: [TAB 1](#) -> [TAB 2](#) -> [TAB 3](#) -> [TAB 6](#)

2.9 **Combination Product**

FG28

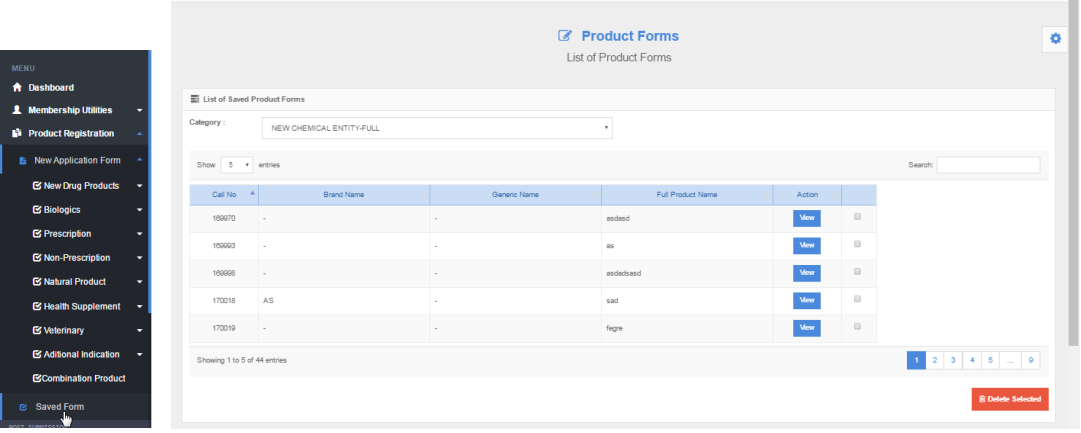
The screenshot shows the sidebar menu with 'Combination Product' highlighted. The main content area is a form titled 'Combo Product'. It features a 'Category' dropdown menu set to 'NEW CHEMICAL ENTITY-FULL', a search bar, and a table with columns: #, Product Name, Ref. No., Reg. No., and Action. The table is currently empty with the message 'No data available in table'. Below the table, it says 'Showing 0 to 0 of 0 entries' and has 'Previous' and 'Next' buttons. A 'Submit' button is at the bottom left. A settings gear icon is in the top right corner.

EX28

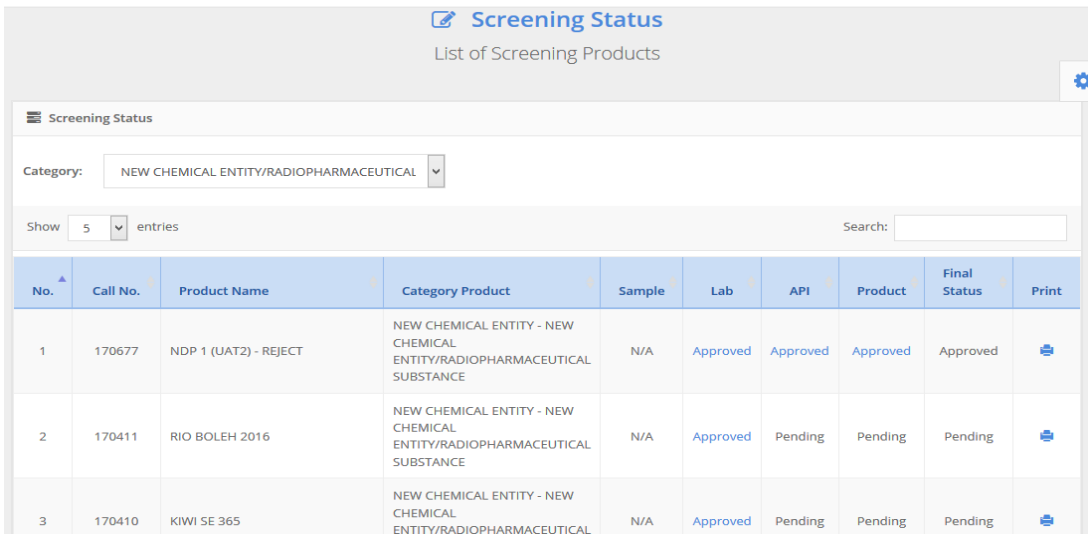
Explanation:
Click on side menu 'Combination Product'


Search related **Combination** product via selecting **Category**

3.0 SAVED FORM

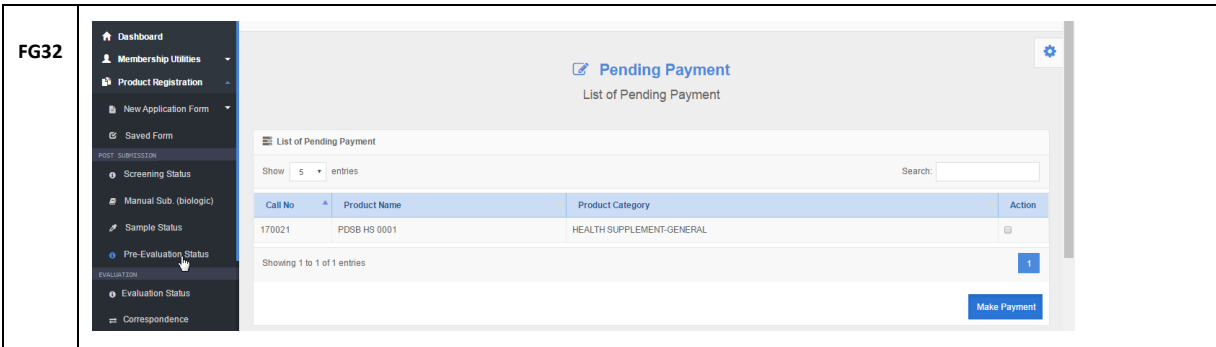
#	SCREENSHOTS / EXPLANATION																														
3.1	List of Product Form																														
FG29	 <p>The screenshot shows the 'List of Product Forms' page. On the left, a dark sidebar menu has 'Saved Form' highlighted. The main area has a header 'Product Forms' and 'List of Product Forms'. Below is a filter for 'Category' set to 'NEW CHEMICAL ENTITY-FULL'. A table lists product forms with columns: Call No., Brand Name, Generic Name, Full Product Name, and Action. The table contains 5 rows of data. At the bottom, there is a pagination bar showing 'Showing 1 to 5 of 44 entries' and a 'Delete Selected' button.</p> <table border="1" data-bbox="454 499 1145 656"> <thead> <tr> <th>Call No.</th> <th>Brand Name</th> <th>Generic Name</th> <th>Full Product Name</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>160070</td> <td>-</td> <td>-</td> <td>esdod</td> <td>View</td> </tr> <tr> <td>102003</td> <td>-</td> <td>-</td> <td>as</td> <td>View</td> </tr> <tr> <td>160008</td> <td>-</td> <td>-</td> <td>esdodband</td> <td>View</td> </tr> <tr> <td>170018</td> <td>AS</td> <td>-</td> <td>sad</td> <td>View</td> </tr> <tr> <td>170019</td> <td>-</td> <td>-</td> <td>fyge</td> <td>View</td> </tr> </tbody> </table>	Call No.	Brand Name	Generic Name	Full Product Name	Action	160070	-	-	esdod	View	102003	-	-	as	View	160008	-	-	esdodband	View	170018	AS	-	sad	View	170019	-	-	fyge	View
Call No.	Brand Name	Generic Name	Full Product Name	Action																											
160070	-	-	esdod	View																											
102003	-	-	as	View																											
160008	-	-	esdodband	View																											
170018	AS	-	sad	View																											
170019	-	-	fyge	View																											
EX29	<p>Explanation: Click on side menu 'Save Form'</p> <p>User can view/update form any registered product</p>																														

4.0 POST SUBMISSION

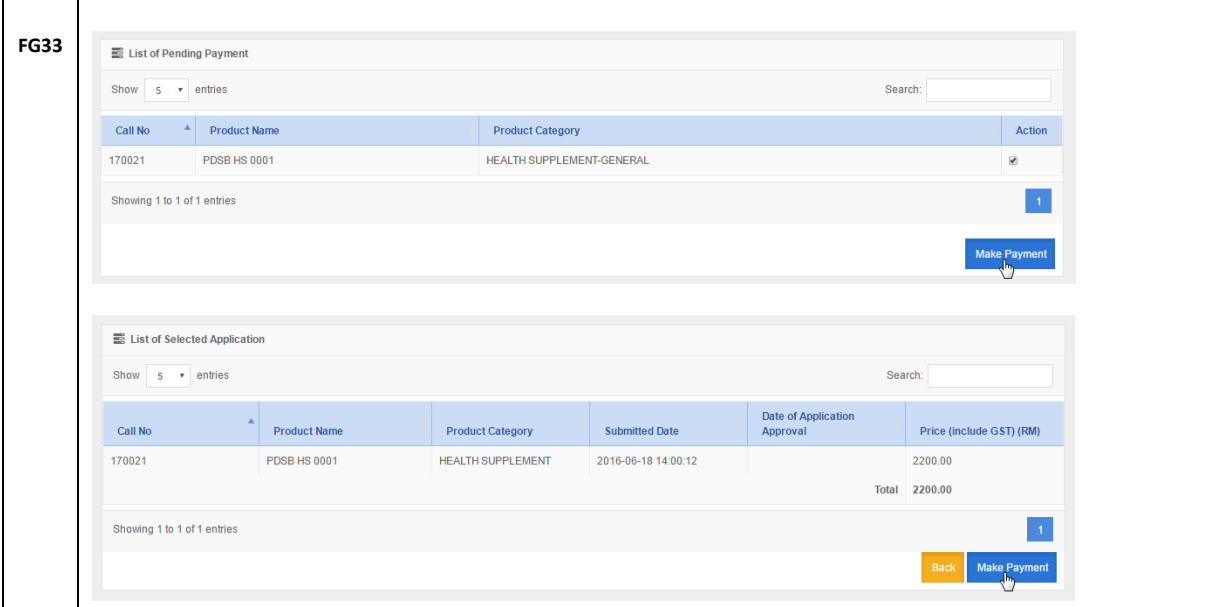
#	SCREENSHOTS / EXPLANATION																																								
4.1	SCREENING STATUS																																								
FG30	 <p>The screenshot displays the 'Screening Status' interface. At the top, it says 'Screening Status' and 'List of Screening Products'. Below this, there is a filter for 'Category' set to 'NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL'. A 'Show' dropdown is set to '5' entries, and there is a search bar. The main content is a table with the following data:</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Call No.</th> <th>Product Name</th> <th>Category Product</th> <th>Sample</th> <th>Lab</th> <th>API</th> <th>Product</th> <th>Final Status</th> <th>Print</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>170677</td> <td>NDP 1 (UAT2) - REJECT</td> <td>NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE</td> <td>N/A</td> <td>Approved</td> <td>Approved</td> <td>Approved</td> <td>Approved</td> <td></td> </tr> <tr> <td>2</td> <td>170411</td> <td>RIO BOLEH 2016</td> <td>NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE</td> <td>N/A</td> <td>Approved</td> <td>Pending</td> <td>Pending</td> <td>Pending</td> <td></td> </tr> <tr> <td>3</td> <td>170410</td> <td>KIWI SE 365</td> <td>NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL</td> <td>N/A</td> <td>Approved</td> <td>Pending</td> <td>Pending</td> <td>Pending</td> <td></td> </tr> </tbody> </table>	No.	Call No.	Product Name	Category Product	Sample	Lab	API	Product	Final Status	Print	1	170677	NDP 1 (UAT2) - REJECT	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE	N/A	Approved	Approved	Approved	Approved		2	170411	RIO BOLEH 2016	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE	N/A	Approved	Pending	Pending	Pending		3	170410	KIWI SE 365	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL	N/A	Approved	Pending	Pending	Pending	
No.	Call No.	Product Name	Category Product	Sample	Lab	API	Product	Final Status	Print																																
1	170677	NDP 1 (UAT2) - REJECT	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE	N/A	Approved	Approved	Approved	Approved																																	
2	170411	RIO BOLEH 2016	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE	N/A	Approved	Pending	Pending	Pending																																	
3	170410	KIWI SE 365	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL	N/A	Approved	Pending	Pending	Pending																																	
EX30	<p>Explanation: User can know updates status for Screening Product.</p>																																								

4.2	MANUAL SUB. (BIOLOGIC)
FG31	 <p>The screenshot shows the 'Manual Submission for Biologics' interface. On the left is a navigation menu with options like Dashboard, Membership Utilities, Product Registration, and Manual Sub. (biologic). The main area is titled 'Manual Submission for Biologics' and 'List of Manual Submission for Biologics'. It includes a 'Show' dropdown set to '5' entries and a search bar. Below this is a table with columns: Call No., Product Name, Product Category, and Manufacturer. The table is empty, with the message 'No data available in table' displayed. At the bottom, it says 'Showing 0 to 0 of 0 entries'.</p>
EX31	<p>Explanation: User can know updates status for Manual Submission.</p>

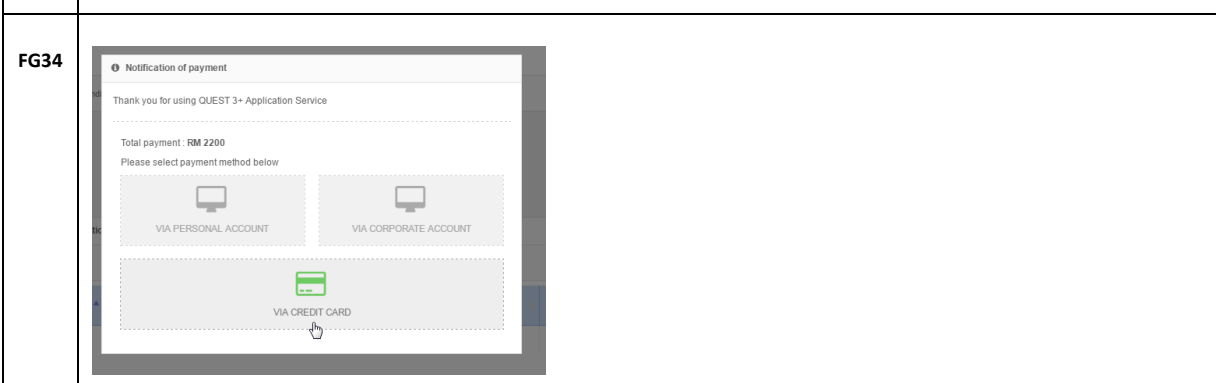
4.3	PRE-EVALUATION STATUS
-----	-----------------------

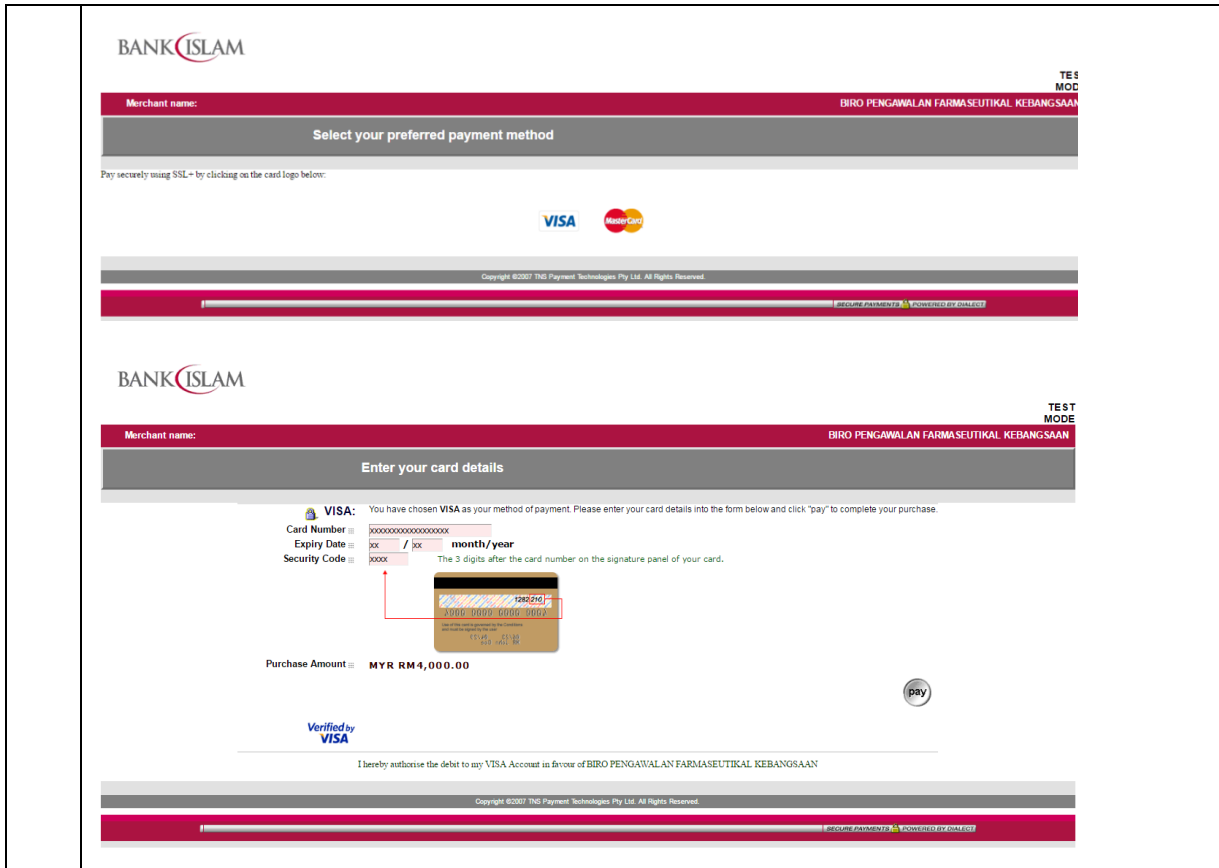


EX32 **Explanation:**
 User can know updates status for **Pre-Evaluation**.
 User can proceed payment when evaluation is success.



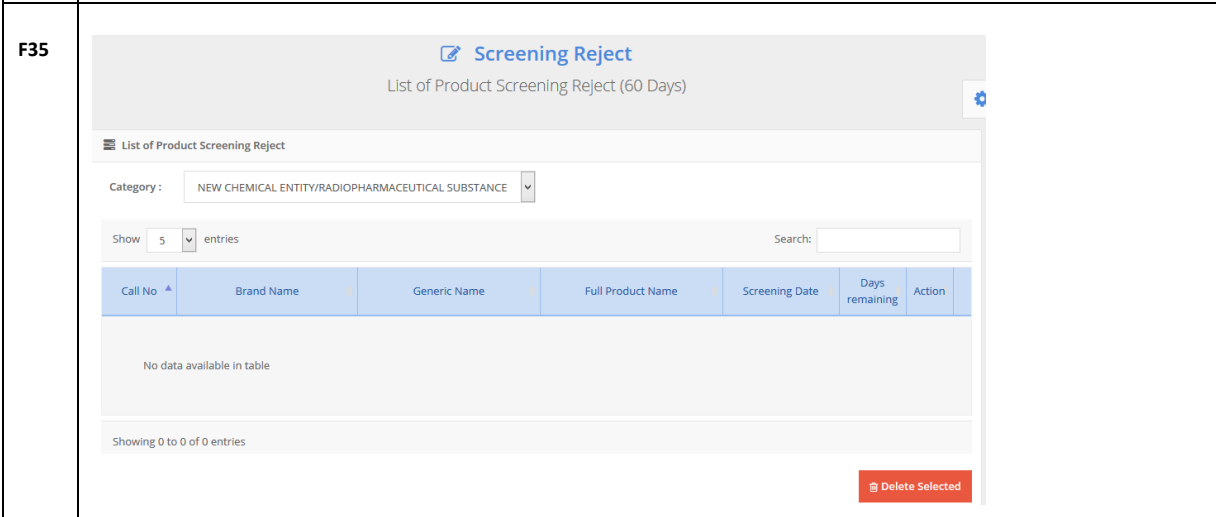
EX33 **Explanation:**
 Click on **'Make Payment'** button.
 User can see list of selected Application, then one more time click on **'Make Payment'** button.





EX34 **Explanation:**
 Window will pop up selection of how to pay .
 If using credit card, follow above instruction.

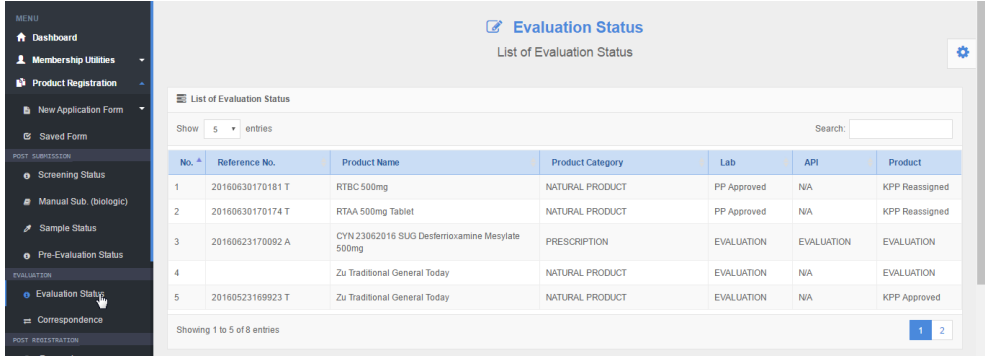
4.4 **Screening Rejected (60 Days)**

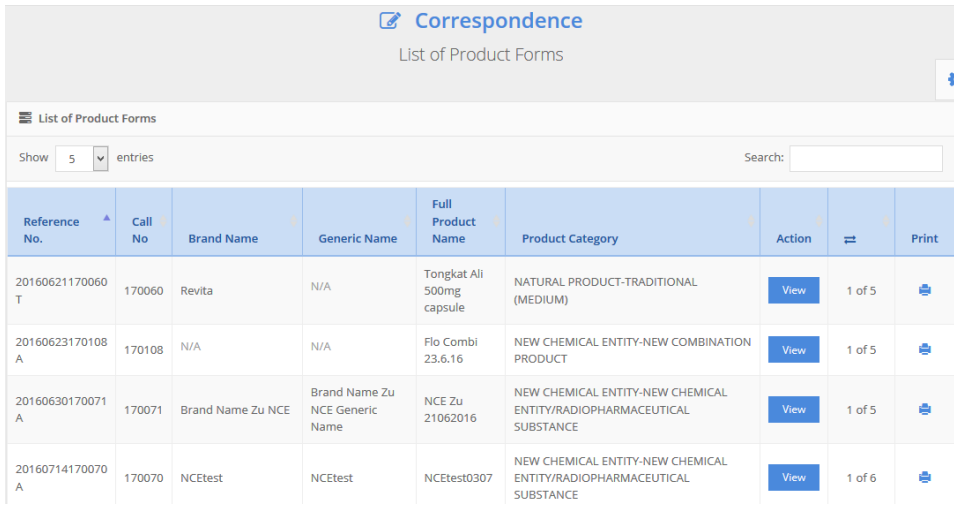



EX35 **Explanation:**
 User can know updates status for **List of product screening rejected**.

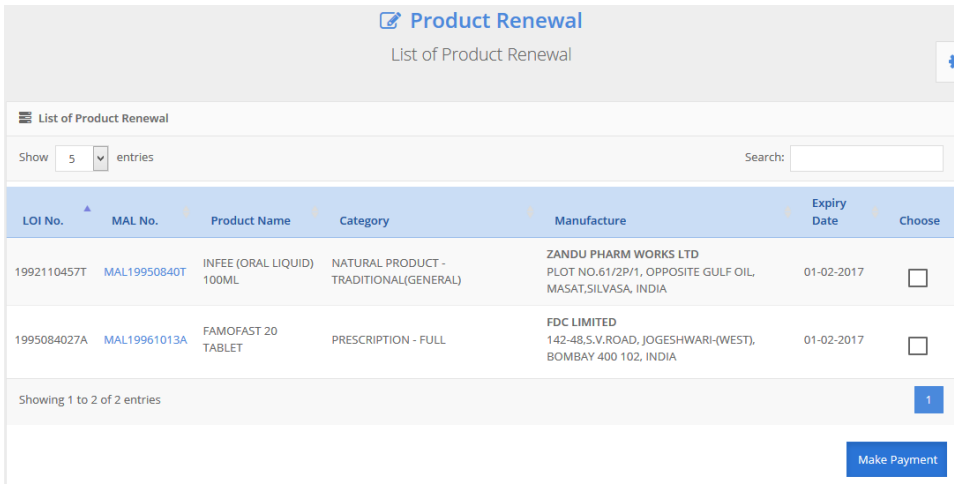
5.0 EVALUATION

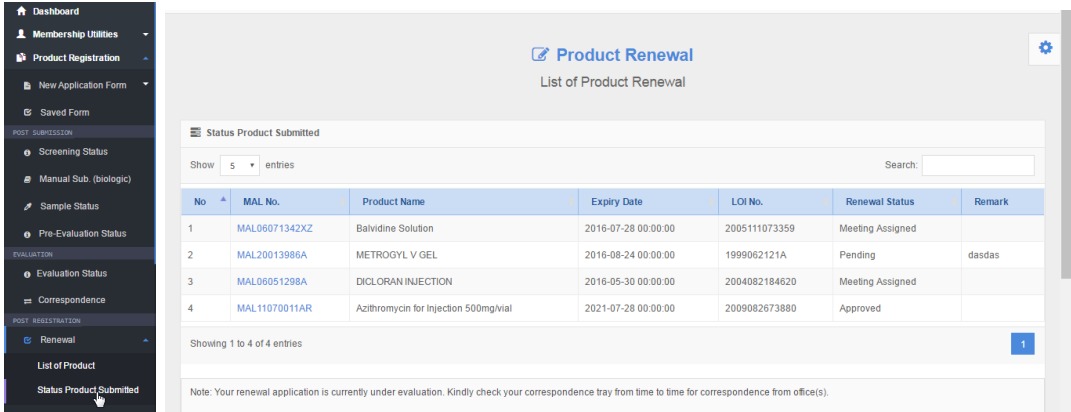
#	SCREENSHOTS / EXPLANATION
---	---------------------------

5.1	EVALUATION STATUS
FG36	
EX36	<p>Explanation: User can know updates for Evaluation Status</p>

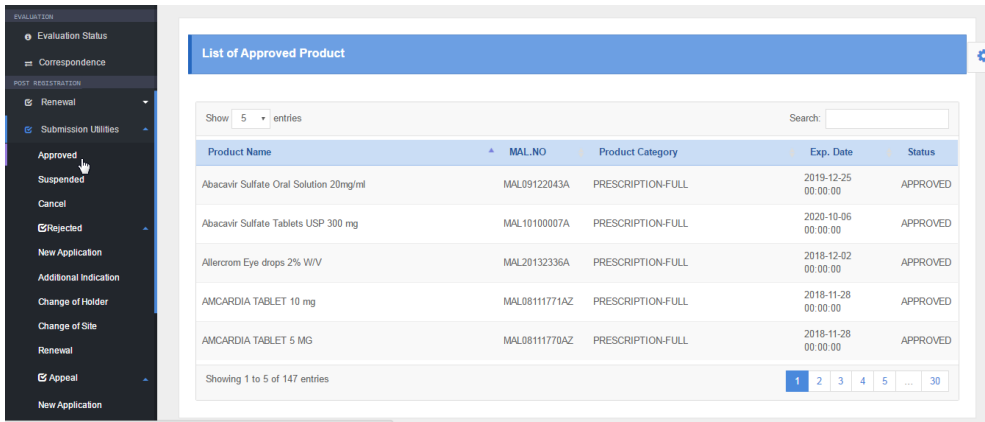
5.2	CORRESPONDENCE
FG37	
EX37	<p>Explanation:</p> <ul style="list-style-type: none"> - Click on “view” button to open correspondence form. -  shown the total number of correspondence have been done.

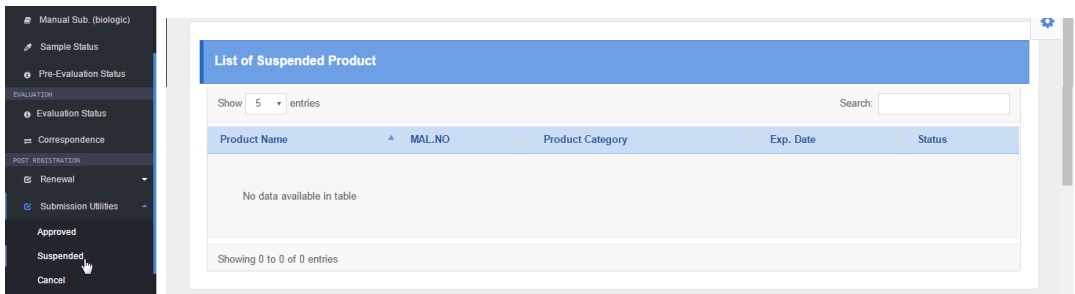
6.0 RENEWAL

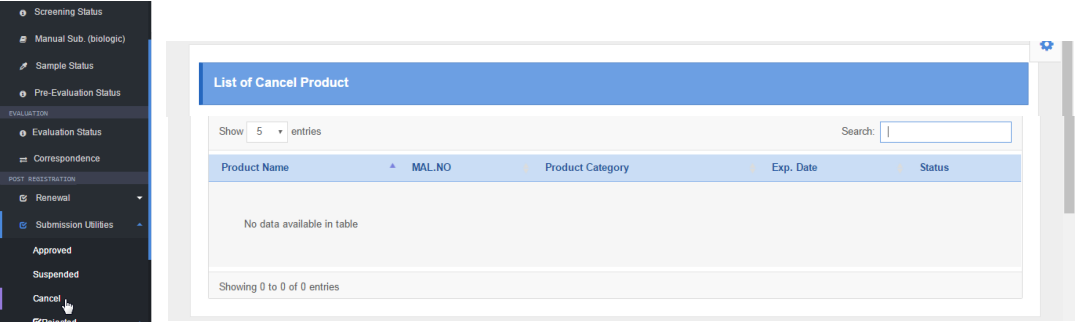
#	SCREENSHOTS / EXPLANATION
6.1	List of Product
FG38	
EX38	<p>Explanation: Only registered products that are due for re-registration (within 6 months from product registration expiry date) shall appear under List of Renewal Products.</p> <p>User can select product for Renewal submission and proceed to make payment</p>

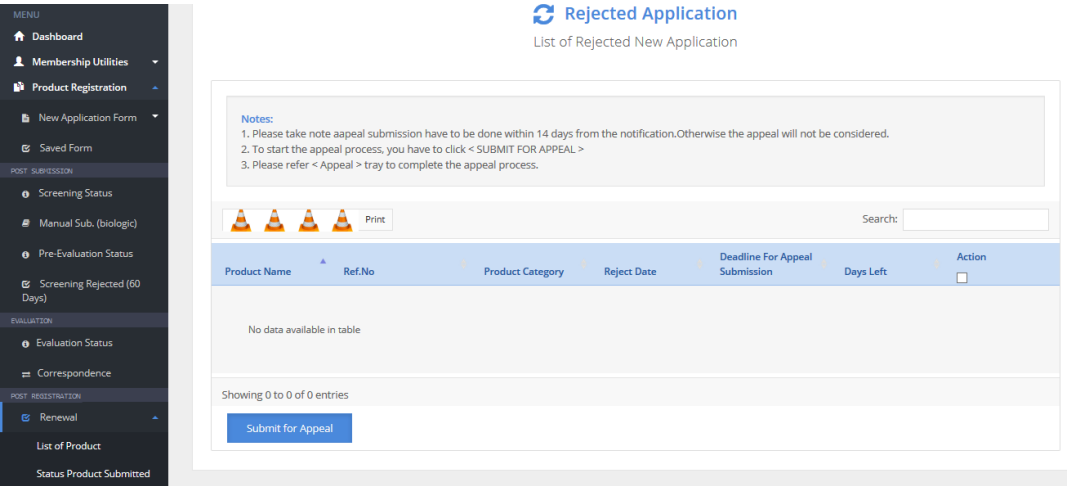
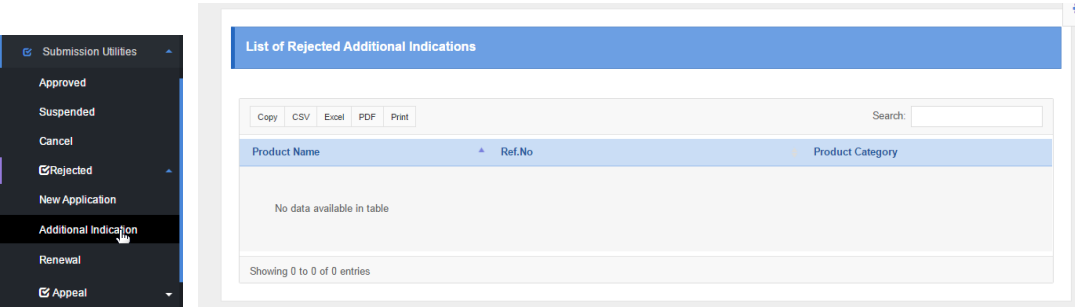
6.2	Status Product Submitted
FG39	
EX39	<p>Explanation:</p> <ul style="list-style-type: none"> - User can check Renewal Status under “Status Renewal Submitted” . - User can view the remarks from officer - Description of the status - For products approved for Renewal, the product registration expiry date shall be updated.

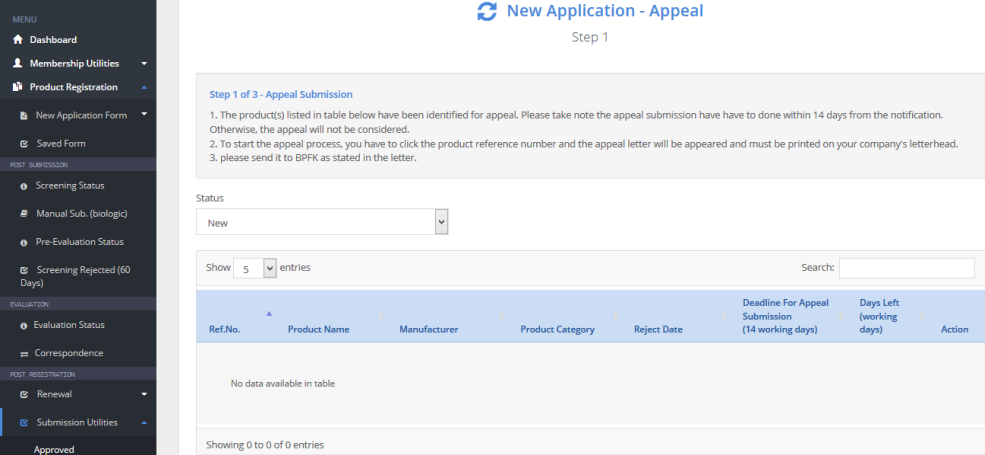
7.0 SUBMISSION UTILITIES

#	SCREENSHOTS / EXPLANATION																														
7.1	Approved																														
FG40	 <p>List of Approved Product</p> <p>Show 5 entries Search:</p> <table border="1"> <thead> <tr> <th>Product Name</th> <th>MAL.NO</th> <th>Product Category</th> <th>Exp. Date</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>Abacavir Sulfate Oral Solution 20mg/ml</td> <td>MAL09122043A</td> <td>PRESCRIPTION-FULL</td> <td>2019-12-25 00:00:00</td> <td>APPROVED</td> </tr> <tr> <td>Abacavir Sulfate Tablets USP 300 mg</td> <td>MAL10100007A</td> <td>PRESCRIPTION-FULL</td> <td>2020-10-06 00:00:00</td> <td>APPROVED</td> </tr> <tr> <td>Allercrom Eye drops 2% W/V</td> <td>MAL20132336A</td> <td>PRESCRIPTION-FULL</td> <td>2018-12-02 00:00:00</td> <td>APPROVED</td> </tr> <tr> <td>AMCARDIA TABLET 10 mg</td> <td>MAL08111771AZ</td> <td>PRESCRIPTION-FULL</td> <td>2018-11-28 00:00:00</td> <td>APPROVED</td> </tr> <tr> <td>AMCARDIA TABLET 5 MG</td> <td>MAL08111770AZ</td> <td>PRESCRIPTION-FULL</td> <td>2018-11-28 00:00:00</td> <td>APPROVED</td> </tr> </tbody> </table> <p>Showing 1 to 5 of 147 entries</p>	Product Name	MAL.NO	Product Category	Exp. Date	Status	Abacavir Sulfate Oral Solution 20mg/ml	MAL09122043A	PRESCRIPTION-FULL	2019-12-25 00:00:00	APPROVED	Abacavir Sulfate Tablets USP 300 mg	MAL10100007A	PRESCRIPTION-FULL	2020-10-06 00:00:00	APPROVED	Allercrom Eye drops 2% W/V	MAL20132336A	PRESCRIPTION-FULL	2018-12-02 00:00:00	APPROVED	AMCARDIA TABLET 10 mg	MAL08111771AZ	PRESCRIPTION-FULL	2018-11-28 00:00:00	APPROVED	AMCARDIA TABLET 5 MG	MAL08111770AZ	PRESCRIPTION-FULL	2018-11-28 00:00:00	APPROVED
Product Name	MAL.NO	Product Category	Exp. Date	Status																											
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Abacavir Sulfate Tablets USP 300 mg	MAL10100007A	PRESCRIPTION-FULL	2020-10-06 00:00:00	APPROVED																											
Allercrom Eye drops 2% W/V	MAL20132336A	PRESCRIPTION-FULL	2018-12-02 00:00:00	APPROVED																											
AMCARDIA TABLET 10 mg	MAL08111771AZ	PRESCRIPTION-FULL	2018-11-28 00:00:00	APPROVED																											
AMCARDIA TABLET 5 MG	MAL08111770AZ	PRESCRIPTION-FULL	2018-11-28 00:00:00	APPROVED																											
EX40	<p>Explanation: User can check any product that already Approved.</p>																														

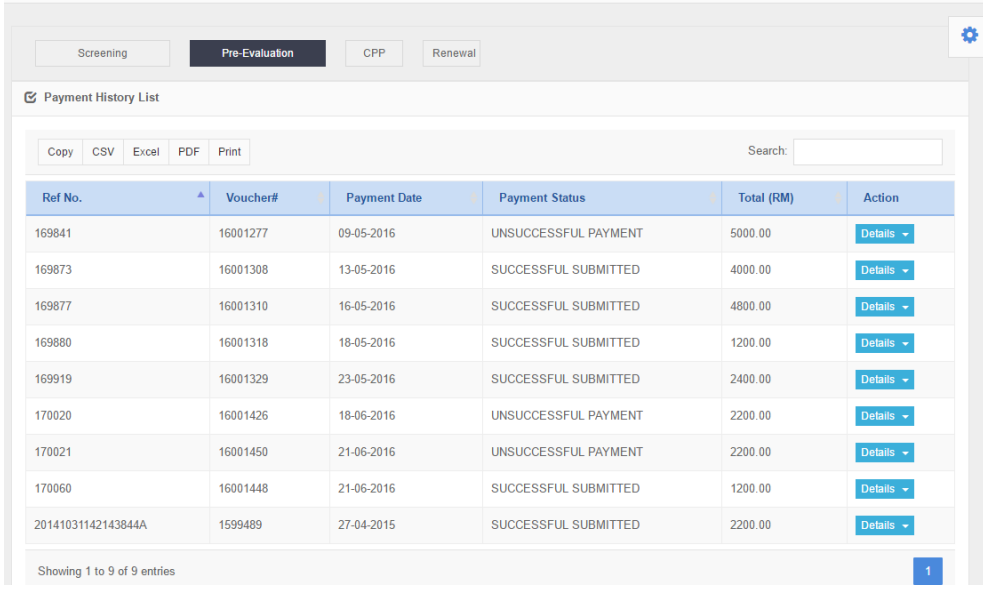
7.2	Suspended										
FG41	 <p>List of Suspended Product</p> <p>Show 5 entries Search:</p> <table border="1"> <thead> <tr> <th>Product Name</th> <th>MAL.NO</th> <th>Product Category</th> <th>Exp. Date</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td colspan="5">No data available in table</td> </tr> </tbody> </table> <p>Showing 0 to 0 of 0 entries</p>	Product Name	MAL.NO	Product Category	Exp. Date	Status	No data available in table				
Product Name	MAL.NO	Product Category	Exp. Date	Status							
No data available in table											
EX41	<p>Explanation: User can check any product that has been Suspended.</p>										

7.3	Cancel
FG42	
EX42	Explanation: User can check any product that has been Canceled .

7.4	Rejected
7.4.1	New Application
FG43	
EX43	Explanation: User can submit for appeal for product that has been Rejected
7.4.2	Additional Indication
FG44	
EX44	Explanation: User can know any Rejected Indication

7.5	Appeal
7.5.1	New Application
FG48	
EX48	<p>Explanation: User can apply New Application for Appeal product under product rejected menu. Click on rejected then new application to continue apply for appeal.</p> <p>View by Status :- New , Appeal , Appeal Reply</p> <p>Appeal can be done in 14 days.</p>

8.0 PAYMENT

#	SCREENSHOTS / EXPLANATION
8.1	History
FG65	
EX65	<p>Explanation: Display Payment History List for:-</p> <ol style="list-style-type: none"> 1. Screening 2. Pre-Evaluation 3. CPP 4. Renewal <p>Action Details: - Voucher / Repay</p>

9.0 APPLICATION STATUS

#	SCREENSHOTS / EXPLANATION
9.1	List of Application status

FG66

Application Status
List of Application Status

List of Application

Show 5 entries Search:

Call No.	Full Product Name	Product Category	Registration Date	Status	#
79816	MYDRON Amiodarone Hydrochloride Injection 50mg/ml	PRESCRIPTION	01-01-1970	APPROVED PAYMENT	Letter of Consent Sample Manufacturing
79829	REDUPROST (DUTASTERIDE SOFT GELATIN CAPSULES 0.5MG)	PRESCRIPTION	01-01-1970	APPROVED PAYMENT	Letter of Consent Sample Manufacturing
79910	MEROGRAM 500 (Meropenem powder for Injection USP 500mg)	PRESCRIPTION	01-01-1970	APPROVED PAYMENT	Letter of Consent Sample Manufacturing
80028	PANZAL Pantoprazole Sodium for Injection 40mg/Vial, 10mL, Lyo Vial	PRESCRIPTION	01-01-1970	APPROVED PAYMENT	Letter of Consent Sample Manufacturing
80180	UNIMOL PARACETAMOL TABLET 500MG	NON PRESCRIPTION(FULL)	01-01-1970	ASSIGNED TO ASSESSOR	Letter of Consent Sample Manufacturing

Showing 1 to 5 of 434 entries

1 2 3 4 5 ... 87

EX66

Explanation:
User can view status of All application of product

10.0 CORRESPONDENCE

#	SCREENSHOTS / EXPLANATION
10.1	List of Product

FG63

Correspondence
List of Product Forms

List of Product Forms

Show 5 entries Search:

Call No	Brand Name	Generic Name	Full Product Name	Product Category	Action
170184	N/A	N/A	PDSB TRAD MED 3006	NATURAL PRODUCT-TRADITIONAL (MEDIUM)	View
170109	NDP1 - HASYA	AMLODIPINE 20MG CAPSULE	NDP 1 - HASYA AMLODIPINE 20MG CAPSULE	NEW CHEMICAL ENTITY-FULL	View
170108	N/A	N/A	Flo Combi 23.6.16	NEW CHEMICAL ENTITY-NEW COMBINATION PRODUCT	View
170071	Brand Name Zu NCE	Brand Name Zu NCE Generic Name	NCE Zu 21062016	NEW CHEMICAL ENTITY-FULL	View

Showing 1 to 4 of 4 entries 1

EX63 **Explanation:**
User can view remark/status update from correspondence regarding of product application

10.2 Additional Indication

FG64

List of registered product (Correspondence)

Search:

#	Product Name	Registration No.	Reference No.	Submitted Date
No data available in table				

Showing 0 to 0 of 0 entries Previous Next

EX64 **Explanation:**
user can view any additional indication applying by user

11.0 PRODUCT REGISTRATION / NEW APPLICATION FORM (COMMON TABS)

#	SCREENSHOTS / EXPLANATION
11.1	Product Registration
FG67	
EX67	Explanation: Please read all term and condition before start fill in form for registration product.

11.2	TAB-1 Product Validation
11.2.1	Product Name
FG68	
EX68	Explanation: Key-in the followings:-

	<p>1.1 Brand Name</p> <p>1.2 Generic Name</p> <p>1.3 Full Product Name</p>
<p>11.2.2</p>	<p>Dosage Form</p>
<p>FG69</p>	<div style="text-align: center; border-bottom: 1px solid #ccc; margin-bottom: 10px;"> <p>Product Information</p> </div> <p>Product Name : <input type="text" value="Product Name Test"/></p> <p>Call Number : <input type="text" value="170114"/></p> <div style="text-align: center; border-bottom: 1px solid #ccc; margin-bottom: 10px;"> <p>Product Validation - Dosage Form</p> </div> <p>2.1 Dosage Form <input type="text" value="--"/> Not Listed</p> <p>2.2 Dosage Form Description <input type="text" value="-"/></p> <div style="text-align: right; margin-top: 20px; border: 1px solid #ccc; padding: 5px; display: inline-block;"> Back Next </div>
<p>EX69</p>	<p>Explanation: Product Name & Call Number is automated displayed.</p> <p>Key-in the followings:-</p> <p>2.1 Dosage Form</p> <p>2.2 Dosage Form Description</p>
<p>11.2.3</p>	<p>Active Ingredient</p>
<p>FG70</p>	<div style="text-align: center; border-bottom: 1px solid #ccc; margin-bottom: 10px;"> <p>Product Validation - Active Ingredient</p> </div> <div style="border: 1px solid #ccc; padding: 10px; margin-bottom: 10px;"> <p style="text-align: center; margin: 0;">Important Notes</p> <p style="font-size: small; margin: 5px 0;">Click "ADD" button after filling in fields 3.1-3.6. Repeat these steps if there is more than one(1) Active Ingredients.</p> <p style="font-size: small; margin: 5px 0;">To delete an entry from the list, click on the "DELETE" button</p> </div> <p>3.1 Active Ingredient <input type="text"/></p> <p>3.2 Salt Form <input type="text" value="--"/></p> <p>3.3 Strength of Active Ingredient <input type="text" value="Type Here..."/> Unit <input type="text" value="--"/> IN</p> <p>3.4 Strength of Active Ingredient (Salt-Free Equivalent) <input type="text" value="Type Here..."/> Unit <input type="text" value="--"/></p> <p>3.5 Source of Active Ingredient <input checked="" type="checkbox"/> Synthetic <input type="checkbox"/> Plant <input type="checkbox"/> Animal <input type="checkbox"/> Others *</p> <p>3.7 Remarks (if any) <input style="width: 100%; height: 30px;" type="text"/></p> <div style="margin-top: 10px; text-align: left;"> Add </div>

List of Active Ingredient

#	Active Ingredient	Salt Form	Strength	Strength Salt-Free	Source	Remarks	
							Back Next

EX70

Explanation:
Key-in the followings:-

3.1 Active Ingredient
3.2 Salt Form
3.3 Strength of Active Ingredient
3.4 Strength of Active Ingredient (Salt-Free Equivalent)
3.5 Source of Active Ingredient
3.6 Form of Substance
3.7 Remarks (if any)

11.2.4

Excipient

Product Validation - Excipient

Note to Applicant

- Click "ADD" button after filling in fields 4.1-4.5. Repeat these steps if there is more than one(1) excipient(s).
- To delete an entry from the list, click on the "DELETE" button.

4.1 Excipient

4.2 Strength of Excipient Unit

4.3 Function of Excipient

4.4 Source of Excipient Synthetic Plant Animal Others

4.5 Remarks(if any)

[Add](#)

List of Excipient

#	Excipient	Strength	Function	Source	Remarks	Action

[Back](#) [Next](#)

EX71

Explanation:
Key-in the followings:-

4.1 Excipient
4.2 Strength of Excipient
4.3 Function of Excipient

	4.4 Source of Excipient 4.5 Remarks (if any)
11.2.5	Other Information
FG72	<p style="text-align: center;">Product Validation - Other Information</p> <p>5. Ingredients of Human or Animal Origin (Active Ingredient, Excipient and / or Capsule Shell) <input type="radio"/> Yes <input checked="" type="radio"/> No Not Listed</p> <hr/> <p>6. Manufacturer <input type="radio"/> <input type="text" value=""/> Not Listed</p> <hr/> <p>7. Is there any Contract Manufacturer Involved? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>8. Is this Product a Second Source Product? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>9. Is there any Repacker Involved? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>11. Is the Product Under Patent Protection? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>12. Is this an Imported Product? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>15. Does this product need Priority Review? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>16. Request for Data Exclusivity (DE)? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p>18. Does this product contain a medical device component? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <hr/> <p style="text-align: right;"><input type="button" value="Back"/> <input type="button" value="Next"/></p>
EX72	<p>Explanation: Key-in the followings:- 5 to 18 – please answer yes or no.</p>

11.3	TAB-2 Part I
11.3.1	Section A - A1 to A10

	A1-A10	A11-A21
--	--------	---------

A1. Active Ingredient

#	Active Ingredient	Salt Form	Strength	Strength Salt-Free	Source	Remarks
---	-------------------	-----------	----------	--------------------	--------	---------


A2. Excipients


#	Excipient	Strength	Function	Source	Remarks
---	-----------	----------	----------	--------	---------


A3. Dosage Form

Dosage Form	Dosage Form Description	Source of Capsule Shell	Certificate to verify the Source of Capsule Shell	Colouring Agent used in capsule	Certificate Analysis of Capsule Shell
-------------	-------------------------	-------------------------	---	---------------------------------	---------------------------------------





A4. Product Description 

A5. Pharmacodynamics 

A6. Pharmacokinetics 

A7. Indication 

A8. Recommended Dose 

	<p>A9. Route of Administration </p> <p>-- Not Listed</p> <hr/> <p>A10. Contraindications </p> <div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div> <div style="text-align: right; margin-top: 20px;"> Back Next </div>
<p>EX73</p>	<p>Explanation: Key-in the followings:-</p> <p>A1 capture from “product validation” tab active ingredient. A2 capture from “product validation” tab excipient. A3 capture from “product validation” tab dosage form. A4 Fill in data if applicable A5 Fill in data if applicable A6 Fill in data if applicable A7 Fill in data if applicable A8 Fill in data if applicable A9 select from dropdown list. A10 Fill in data if applicable</p>
<p>11.3.2</p>	<p>Section A - A11 to A21</p>
<p>FG74</p>	<p style="text-align: center; color: #0070C0;">Part I - Section A: Product Particulars</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> A1-A10 A11-A21  </div> <p>A11. Warnings and Precautions </p> <div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div> <div style="text-align: right; margin-top: 5px;"><></div>

A12. Interactions with Other Medicaments *



A13. Pregnancy and Lactation *

A14. Side Effects *



A15. Symptoms and Treatment of Overdose *

A16. Effects on Ability to Drive and Use Machine



A17. Preclinical Safety Data



A18. Instructions for Use *

A19. Storage Conditions *

A20. Shelf Life *

A21. ATC Code *

1st Level:

2st Level:

3rd Level:

4th Level:

5th Level:

ATC CODE:

◀ Back Next ▶

EX74

Explanation:

Key-in the followings:-

- A11 Fill in data if applicable
- A12 Fill in data if applicable
- A13 Fill in data if applicable
- A14 Fill in data if applicable
- A15 Fill in data if applicable
- A16 Fill in data if applicable
- A17 Fill in data if applicable
- A18 Fill in data if applicable
- A19 Fill in data if applicable
- A20 Fill in data if applicable

	A21 select from dropdown list (1 st level until 5 th level).																																
11.3.3	Section B																																
FG75	<p style="text-align: center;">Part 1 - Section B: Product Formula</p> <p>B1. Batch Manufacturing Formula</p> <p>B1.1 Batch size(*) <input type="text" value="Type Here..."/> Unit <input type="text"/></p> <p>B1.2 Batch Formula</p> <p>List of Active Ingredient</p> <table border="1"> <thead> <tr> <th>#</th> <th>Active Ingredient</th> <th>Overage</th> <th>Salt Form</th> <th>Strength</th> <th>Strength Salt-Free</th> <th>Source</th> <th>Form of Substance</th> <th>Remarks</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>List of Excipient</p> <table border="1"> <thead> <tr> <th>#</th> <th>Excipient</th> <th>Overage</th> <th>Strength</th> <th>Function</th> <th>Source</th> <th>Remarks</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>B2. Attachment of Batch Manufacturing Formula *</p> <p><input type="button" value="Choose File"/> Please Select File <input type="button" value="🗑️"/></p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p style="text-align: right;"><input type="button" value="⏪ Back"/> <input type="button" value="Next ⏩"/></p>	#	Active Ingredient	Overage	Salt Form	Strength	Strength Salt-Free	Source	Form of Substance	Remarks										#	Excipient	Overage	Strength	Function	Source	Remarks							
#	Active Ingredient	Overage	Salt Form	Strength	Strength Salt-Free	Source	Form of Substance	Remarks																									
#	Excipient	Overage	Strength	Function	Source	Remarks																											
EX75	<p>Explanation: Key-in the followings:-</p> <p>B1 fill in data if applicable</p> <p>B2 fill in data if applicable</p>																																
11.3.4	Section C																																
FG76	<p style="text-align: center;">Part 1 - Section C: Particulars of packing</p> <p>C1. Pack Size* : <input type="text" value="Type Here..."/> Unit <input type="text"/></p> <p>C2. Immediate Container Type* : <input type="text" value="-"/></p> <p>C3. Container Type Description* : <input type="text"/></p> <p>C4. Barcode / Serial No. (if applicable) : <input type="text" value="Type Here..."/></p> <p>C5. Recommended Distributor's Price(RM)* : <input type="text" value="Type Here..."/></p> <p>C6. Recommended Retail Price(RM)* : <input type="text" value="Type Here..."/></p> <p style="text-align: center;"><input type="button" value="Add"/></p> <p>List of Pack Size</p> <table border="1"> <thead> <tr> <th>#</th> <th>Pack Size</th> <th>Immediate Container Type</th> <th>Container Type Description</th> <th>Barcode / Serial No.</th> <th>Recommended Distributor's Price(RM)</th> <th>Recommended Retail Price(RM)</th> <th>🗑️</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p style="text-align: right;"><input type="button" value="⏪ Back"/> <input type="button" value="Next ⏩"/></p>	#	Pack Size	Immediate Container Type	Container Type Description	Barcode / Serial No.	Recommended Distributor's Price(RM)	Recommended Retail Price(RM)	🗑️																								
#	Pack Size	Immediate Container Type	Container Type Description	Barcode / Serial No.	Recommended Distributor's Price(RM)	Recommended Retail Price(RM)	🗑️																										
EX76	<p>Explanation: Key-in the followings:-</p> <p>C1 fill in data if applicable</p> <p>C2 select from dropdown list</p> <p>C3 fill in data if applicable</p> <p>C4 fill in data if applicable</p>																																

	C5 fill in data																																								
11.3.5	Section D																																								
FG77	<p style="text-align: center;">Part 1 - Section D: Label (Mock-up) For Immediate Container, Outer Carton, Proposed Package Insert & PIL/RIMUP</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>D1. Label (mock-up) for Immediate Container: *</p> <p><input type="button" value="Choose File"/> Please Select File <-></p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Attachment File(s)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>D2. Label (mock-up) for Outer Carton: *</p> <p><input type="button" value="Choose File"/> Please Select File 📎</p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Attachment File(s)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>D3. Proposed Package Insert: *</p> <p><input type="button" value="Choose File"/> Please Select File 📎</p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Attachment File(s)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>D4. Patient Information Leaflet (PIL) / Risalah Maklumat Ubat Pesakit (RIMUP):</p> <p><input type="button" value="Choose File"/> Please Select File 📎</p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Attachment File(s)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>D5. Label (Mock-up) for Diluent:</p> <p><input type="button" value="Choose File"/> Please Select File 📎</p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Attachment File(s)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div style="text-align: right; margin-top: 10px;"> <input type="button" value="Back"/> <input type="button" value="Next"/> </div>	#	Attachment	Date of Attach	Action					#	Attachment	Date of Attach	Action					#	Attachment	Date of Attach	Action					#	Attachment	Date of Attach	Action					#	Attachment	Date of Attach	Action				
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#	Attachment	Date of Attach	Action																																						
EX77	<p>Explanation: Key-in the followings:-</p> <p>D1 upload attachment file if applicable</p> <p>D2 upload attachment file if applicable</p> <p>D3 upload attachment file if applicable</p> <p>D4 upload attachment file if applicable</p> <p>D5 upload attachment file if applicable</p>																																								
11.3.6	Section E – E1 to E2																																								

FG78

Part 1 - Section E: Supplementary Documentation

E1-E2 E3 E4 E5 E6-E12 E13 E14-E17

E1.1. Product Owner

Role of Product Owner

E1.2. Letter of Authorization from Product Owner:

Please Select File

▲ Attachment file size limit 5 MB

List of Attachment File(s)

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

E2. Contract Manufacturer and Repacker

E2.1. Letter of Appointment of the Contract Manufacturer from the Product Owner:

Please Select File

▲ Attachment file size limit 5 MB

List of Attachment File(s)

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

E2.2. Letter of Acceptance from the Contract Manufacturer:

Please Select File

▲ Attachment file size limit 5 MB

List of Attachment File(s)

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

E2.3. Letter of Appointment of the Repacker from the Product Owner:

Please Select File

▲ Attachment file size limit 5 MB

List of Attachment File(s)

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

E2.4. Letter of Acceptance from the Repacker:

Please Select File

▲ Attachment file size limit 5 MB

List of Attachment File(s)

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

EX78

Explanation:

Key-in the followings:-

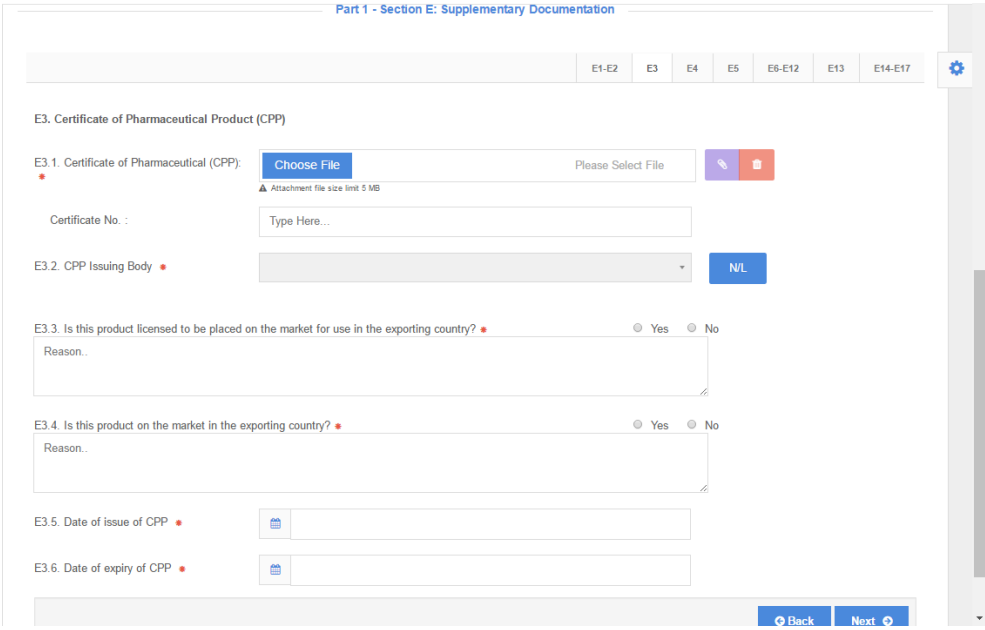
E1.1 Select from dropdown list. Please key in minimum three characters to search.

E1.2 upload attachment file if applicable

E2 upload attachment file if applicable

11.3.7

Section E – E3

<p>FG79</p>	
<p>EX79</p>	<p>Explanation: Key-in the followings:-</p> <p>E3.1 upload attachment file and key in certificate number.</p> <p>E3.2 fill in issuing body</p> <p>E3.3 fill in reason if select yes.</p> <p>E3.4 fill in reason if select yes</p> <p>E3.5 fill in date</p> <p>E3.6 fill in date</p>
<p>11.3.8</p>	<p>Section E – E4</p>
<p>FG80</p>	
<p>EX80</p>	<p>Explanation: Key-in the followings:-</p> <p>E4.1 upload attachment file and key in certificate number.</p> <p>E4.2 fill in issuing body</p> <p>E4.3 fill in date</p> <p>E4.4 fill in date</p>

11.3.9	Section E – E5
FG81	<p style="text-align: center;">Part 1 - Section E: Supplementary Documentation</p> <p style="text-align: right;">E1-E2 E3 E4 E5 E6-E12 E13 E14-E17</p> <p>E5. Certificate of Good Manufacturing Practice (GMP) </p> <p>E5.1. Certificate of Good Manufacturing Practice (GMP) Choose File Please Select File </p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>Certificate No. : <input type="text" value="Type Here..."/></p> <p>E5.2. GMP Issuing Body <input type="text" value="--"/> N/L</p> <p>E5.3. Date of issue of GMP <input type="text" value="--"/></p> <p>E5.4. Date of expiry of GMP <input type="text" value="--"/></p> <p style="text-align: right;">Back Next</p>

EX81	<p>Explanation: Key-in the followings:-</p> <p>E5.1 upload attachment file and key in certificate number.</p> <p>E5.2 fill in issuing body</p> <p>E5.3 fill in date</p> <p>E5.4 fill in date</p>
------	---

11.3.9	Section E – E6 to E12												
FG82	<p style="text-align: center;">Part 1 - Section E: Supplementary Documentation</p> <p style="text-align: right;">E1-E2 E3 E4 E5 E6-E12 E13 E14-E17 </p> <p>E6. Manufacturer : <input type="text" value="Type Here..."/></p> <p>E7. Other Manufacturer(s) Involved : <input type="text" value="--"/> N/L</p> <p>Address : <input type="text" value="--"/></p> <p>Processing Step : <input type="text" value="--"/></p> <p>GMP Certificate : Choose File Please Select File Cancel</p> <p style="text-align: center;">ADD</p> <p>List of Other Manufacturer(s)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e1eef6;"> <th>No</th> <th>Manufacturer Name</th> <th>Manufacturer Address</th> <th>Processing Step</th> <th>GMP Certificate</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>E8. Importer: <input type="text" value="--"/> N/L</p>	No	Manufacturer Name	Manufacturer Address	Processing Step	GMP Certificate	Action						
No	Manufacturer Name	Manufacturer Address	Processing Step	GMP Certificate	Action								

	<p>The screenshot displays a web-based form interface. At the top, there is a dropdown menu for 'Address' with a green 'ADD' button below it. Below this is a table titled 'List of Importer' with columns for 'No', 'Importer Name', 'Importer Address', and 'Action'. A form section for 'E9. Store Address' includes a dropdown for 'Store Address', a blue 'N/L' button, and another 'Address' dropdown with a green 'ADD' button. Below that is a table titled 'List of Store Address' with columns for 'No', 'Store Name', 'Store Address', and 'Action'. The interface then shows three sections for file uploads: 'E10. Summary of Product Characteristics / Product Data Sheet', 'E11. Company Core Data Sheet (CCDS)', and 'E12. Analysis Protocol'. Each section has a 'Choose File' button, a 'Please Select File' prompt, and a 5 MB attachment size limit warning. Below each upload section is a table with columns for '#', 'Attachment', 'Date of Attach', and 'Action'. At the bottom right, there are 'Back' and 'Next' navigation buttons.</p>
<p>EX82</p>	<p>Explanation: Key-in the followings:-</p> <p>E6 display data from “product validation” tab others. (manufacturer)</p> <p>E7 Select manufacturer, address and processing step from dropdown list and upload GMP Certificate attachment then click “add” button.</p> <p>E8 Select importer name and address from dropdown list then click “add” button.</p> <p>E9 Select store name and address from dropdown list then click “add” button.</p> <p>E10 upload attachment file if applicable</p> <p>E11 upload attachment file if applicable</p> <p>E12 upload attachment file if applicable</p>
<p>11.3.10</p>	<p>Section E – E13</p>

<p>FG83</p>	<div data-bbox="327 156 1364 728"> <h3>E13. Protocol Analysis & Data Validation</h3> <p>1. Please add at least one test before submitting form 2. * required field</p> <p>Test Category : <input type="text" value="-- Please Select --"/></p> <p>Method : <input type="text" value="-- Please Select --"/> <input type="button" value="+ Add"/></p> <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Summary of method validation * <input type="button" value="Choose File"/> <input type="button" value="📎"/> <input type="button" value="🗑️"/> <small>▲ Attachment file size limit 5 MB</small></td> </tr> <tr> <td>2.</td> <td>Protocol Validation, Other Documents <input type="button" value="Choose File"/> <input type="button" value="📎"/> <input type="button" value="🗑️"/> <small>▲ Attachment file size limit 5 MB</small></td> </tr> </tbody> </table> <p>QUEST3+ Product Registration</p> <p><input type="button" value="←"/> <input type="button" value="→"/></p> </div>	#	Attachment	1.	Summary of method validation * <input type="button" value="Choose File"/> <input type="button" value="📎"/> <input type="button" value="🗑️"/> <small>▲ Attachment file size limit 5 MB</small>	2.	Protocol Validation, Other Documents <input type="button" value="Choose File"/> <input type="button" value="📎"/> <input type="button" value="🗑️"/> <small>▲ Attachment file size limit 5 MB</small>										
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<p>EX83</p>	<p>Explanation: Key-in the followings:-</p> <p>E13</p> <ul style="list-style-type: none"> - Add at least one test before submitting form. - upload attachment file if applicable 																
<p>11.3.11</p>	<p>Section E – E14 to E17</p>																
<p>FG84</p>	<div data-bbox="327 1097 1284 1590"> <p>Part 1 - Section E: Supplementary Documentation</p> <p>E1-E2 E3 E4 E5 E6-E12 E13 E14-E17 <input type="button" value="⚙️"/></p> <div data-bbox="335 1220 1212 1400"> <p>E14. Other Supporting Documents : <input type="button" value="🔍"/></p> <p><input type="button" value="Choose File"/> <input type="text" value="Please Select File"/> <input type="button" value="📎"/></p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Other Supporting Documents</p> <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> <div data-bbox="335 1422 1212 1579"> <p>E15. Worldwide Registration Status : <input type="button" value="🔍"/> *</p> <p><input type="button" value="Choose File"/> <input type="text" value="Please Select File"/> <input type="button" value="📎"/></p> <p><small>▲ Attachment file size limit 5 MB</small></p> <p>List of Worldwide Registration Status</p> <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div> </div>	#	Attachment	Date of Attach	Action					#	Attachment	Date of Attach	Action				
#	Attachment	Date of Attach	Action														
#	Attachment	Date of Attach	Action														

E16. Post-Approval Commitment(s) :

Choose File Please Select File

▲ Attachment file size limit: 5 MB

List of Post-Approval Commitment(s)

#	Attachment	Date of Attach	Action

E17. TSE Risk-Free Commitment :

Choose File Please Select File

▲ Attachment file size limit: 5 MB

List of TSE Risk-Free Commitment(s)

#	Attachment	Date of Attach	Action

Back **Next**

EX84 **Explanation:**
 Key-in the followings:-

E14 upload attachment file if applicable

E15 upload attachment file if applicable

E16 upload attachment file if applicable

E17 upload attachment file if applicable

11.4 **TAB-3 Part II**

11.4.1 **Section P - P1 to P2**

FG85

Part II - Section P

Section P P1-P2 P3 P4 P5 P6-P9

SECTION A : QUALITY OVERALL SUMMARY *

Choose File Please Select File

▲ Attachment file size limit: 5 MB

SECTION B : TABLE OF CONTENTS *

Choose File Please Select File

▲ Attachment file size limit: 5 MB

SECTION C : BODY OF DATA *

Choose File Please Select File

▲ Attachment file size limit: 5 MB

P1. Description and Composition

P1. Description and Composition *

List of Description and Composition

Choose File

Please Select File



▲ Attachment file size limit 5 MB



P2. Pharmaceutical Development

P2.1 Information on Development Studies

List of Information on Development

Choose File

Please Select File



▲ Attachment file size limit 5 MB

P2.2 Components of drug product



List of Component of drug product

Choose File

Please Select File



▲ Attachment file size limit 5 MB

P2.3 Finished product

List of Finished product

Choose File

Please Select File



▲ Attachment file size limit 5 MB

P2.4 Manufacturing Process Development



List of Manufacturing Process Development

Choose File



Please Select File



▲ Attachment file size limit 5 MB

P2.5 Container Closure System



List of Container Closure System

Choose File Please Select File  

▲ Attachment file size limit 5 MB

P2.6 Microbiological Attributes •



List of Microbiological Attributes

Choose File Please Select File  

▲ Attachment file size limit 5 MB

P2.7 Compatibility •

List of Compatibility

Choose File Please Select File  

▲ Attachment file size limit 5 MB

[Back](#) [Next](#)

EX85

Explanation:
Key-in the followings:-

P1 Fill in data and upload attachment file

P2.1 Fill in data and upload attachment file

P2.2 Fill in data and upload attachment file

P2.3 Fill in data and upload attachment file

P2.4 Fill in data and upload attachment file

P2.5 Fill in data and upload attachment file

P2.6 Fill in data and upload attachment file

P2.7 Fill in data and upload attachment file

11.4.2 Section P - P3

FG86

P3. Manufacturer Information

P3.1 : Batch Formula

#	Active Ingredient	Salt Form	Strength	Strength Salt-Free	Source	Form of Substance	Remarks
---	-------------------	-----------	----------	--------------------	--------	-------------------	---------

#	Excipient	Strength	Function	Source	Remarks
---	-----------	----------	----------	--------	---------

P3.2 Manufacturing Process and Process Control

Manufacturing Process and Process Control

Please Select File

▲ Attachment file size limit 5 MB

P3.2.1 Manufacturing Process Flowchart

Please Select File

▲ Attachment file size limit 5 MB

P3.3 Control of Critical Steps and Intermediate

List of Control of Critical Steps and Intermediates

Please Select File

▲ Attachment file size limit 5 MB

P3.4 Process Validation and/or Evaluation

Please Select File

▲ Attachment file size limit 5 MB

EX86


Explanation:
Key-in the followings:-
P3.1 Capture data from “product validation” tab. (Active ingredient and excipient).
P3.2 Fill in data and upload attachment file
P3.3 Fill in data and upload attachment file
P3.4 Upload attachment file

11.4.3


Section P - P4

FG87



Part II - Section P

Section P P1-P2 P3 P4 P5 P6-P9 

P4. Control of Excipients



P4.1 : Specification 

List of Specification



▲ Attachment file size limit 5 MB

P4.2 Analytical Protocol

▲ Attachment file size limit 5 MB



P4.3 Validation of Analytical Protocol

▲ Attachment file size limit 5 MB

P4.4 Justification of Specification



List of Justification of Specification

▲ Attachment file size limit 5 MB

P4.5 Excipients of Human and Animal Origin



List of Excipients of Human and Animal Origin

▲ Attachment file size limit 5 MB

P4.6 Novel Excipients(if applicable)

List of Novel Excipients

▲ Attachment file size limit 5 MB

EX87

Explanation:

Key-in the followings:-

P4.1 Fill in data and upload attachment file

P4.2 upload attachment file

P4.3 upload attachment file

P4.4 Fill in data and upload attachment file

P4.5 Fill in data and upload attachment file

P4.6 Fill in data and upload attachment file

11.4.4

Section P - P5

FG88

Part II - Section P

Section P P1-P2 P3 P4 P5 P6-P9

P5. Control of Finished Product

P5.1 : Specification

List of Specification

Please Select File

▲ Attachment file size limit 5 MB

P5.2 Analytical Protocol

Please Select File

▲ Attachment file size limit 5 MB

P5.3 Validation of Analytical Protocol

Please Select File

▲ Attachment file size limit 5 MB

P5.4 Batch Analysis

Please Select File

▲ Attachment file size limit 5 MB

P5.4.1 Certificates of Analysis (COA)

Batch 1

Please Select File

▲ Attachment file size limit 5 MB

List of Batch 1

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

Batch 2

Please Select File

▲ Attachment file size limit 5 MB

List of Batch 2

#	Attachment	Date of Attach	Action
---	------------	----------------	--------

P5.5 Characterisation of Impurities

List of Characterisation of Impurities

Please Select File

▲ Attachment file size limit 5 MB

P5.6 Justification of Specification

List of Justification of Specification

Please Select File

▲ Attachment file size limit 5 MB

EX88

Explanation:
Key-in the followings:-

P5.1 Fill in data and upload attachment file

P5.2 upload attachment file

P5.3 upload attachment file

P5.4 upload attachment file

P5.5 Fill in data and upload attachment file

P5.6 Fill in data and upload attachment file

11.4.5 Section P - P6 to P9

Part II - Section P

Section P P1-P2 P3 P4 P5 P6-P9

P6 Reference Standards of Materials

Please Select File

Attachment file size limit 5 MB

P7 Container Closure System

Please Select File

Attachment file size limit 5 MB

P8 Stability Data

Please Select File

Attachment file size limit 5 MB

P9 Product Interchangeability/Equivalence Evidence(if applicable)

Please Select File

Attachment file size limit 5 MB

EX89

Explanation:
Key-in the followings:-

P6 upload attachment file

P7 upload attachment file

P8 upload attachment file

P9 upload attachment file

11.4.6 Section S

Part II - Section S: Active Pharmaceutical Ingredient

Section S: List of Active Pharmaceutical Ingredients

No.	Active Ingredient	Fields	Details	Remarks		
1	clypon	Salt Form Strength Strength(Salt Free Equivalent) Source Form of Substance	Salt 1 12 gm 45 ml ANIMAL -	test	-	<input type="button" value="Details"/>

EX90
Explanation:
 Key-in the followings:-
 Select from list below to confirm ingredients by click on “details” button.

FG90.1 **Active Pharmaceutical Ingredient Manufacturer[clpyon]**

: Has This API Approved by NPCB Yes No

: Same API manufacturer? Yes No

: Same synthesis route? Yes No

This Unapproved API Manufacturer are Local Foreign
 Local or Foreign

ADDING MANUFACTURER : SEARCH UNAPPROVED FOREIGN API MANUFACTURER

Copy CSV Excel PDF Print Search:

Add. ^	No.	Manufacturer	Manufacturer Address
<input type="checkbox"/>	1	Novacyl	
<input type="checkbox"/>	2	BIZEN CHEMICAL CO., LTD.	363, Tokutomi, Akaiwa-shi, Okayama
<input type="checkbox"/>	3	CHARAK PHARMA PVT. LTD.	M/S LEAMAK HEALTHCARE PVT. LTD., SARKHEJ-BAVLA HIGHWAY,
<input type="checkbox"/>	4	DOW CORNING CORPORATION	Corporate Center,
<input type="checkbox"/>	5	DOW CORNING CORPORATION	HEALTHCARE IND MATERIALS SITE, 1635 N. GLEANER RD

Showing 1 to 5 of 9 entries 1 2

Add Unapproved Foreign Manufacturer

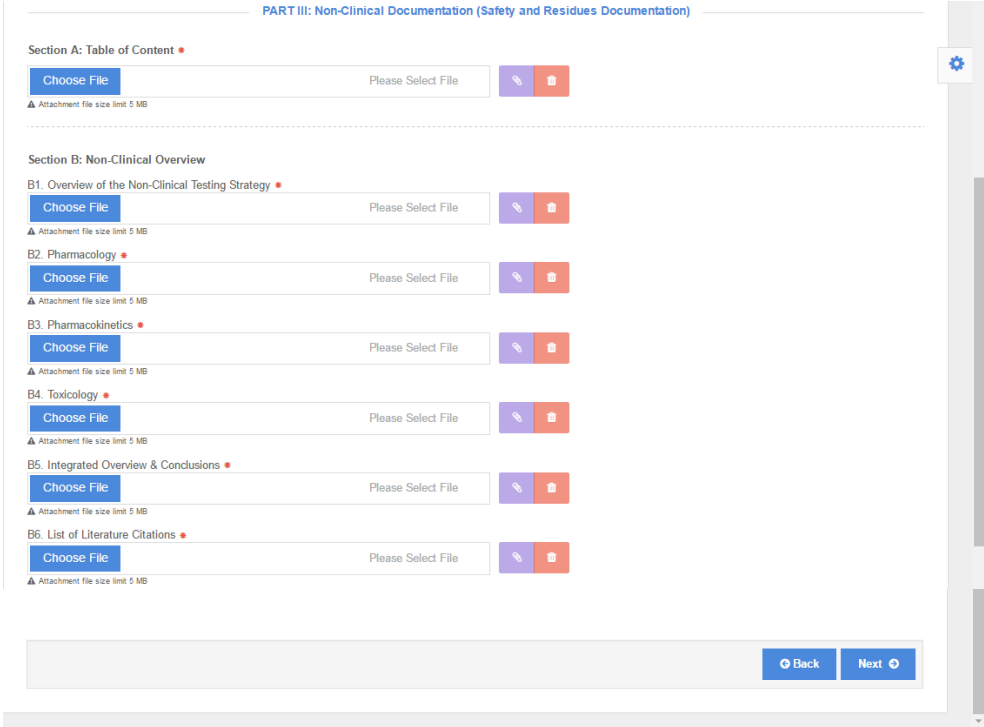
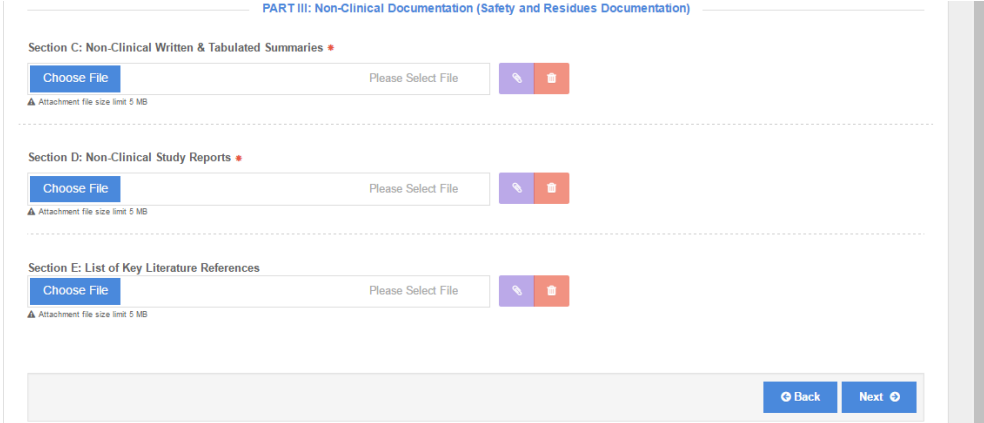
clpyon

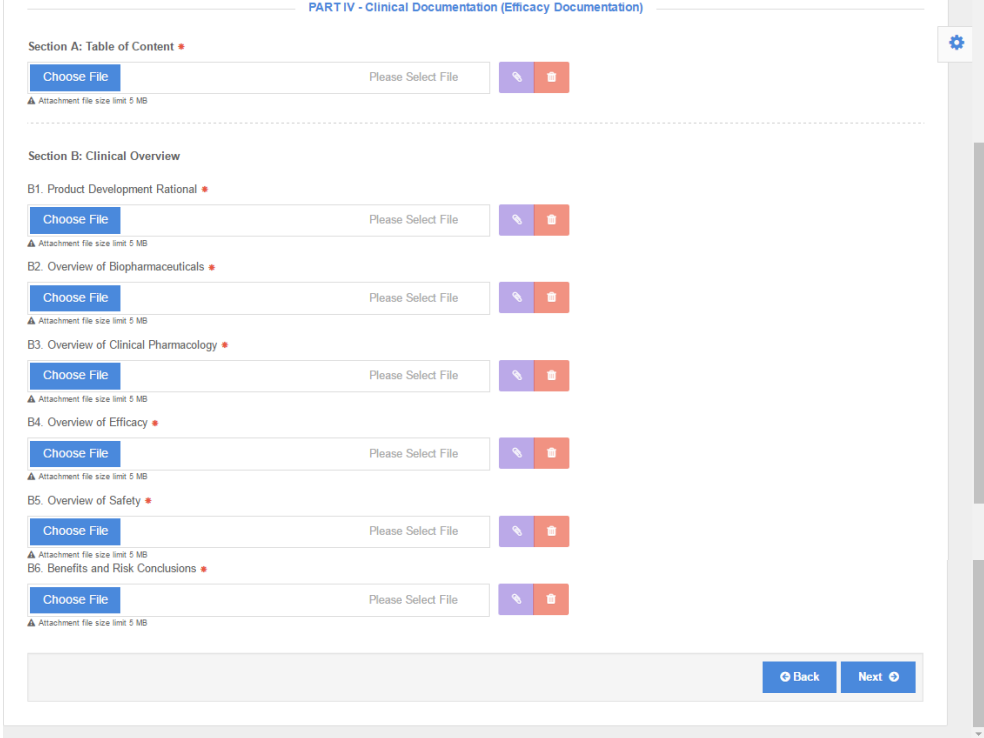
No.	API Name	Fields	Details	API Manufacturer Name	API Status	API Approved No.		
1	clpyon	Salt Form Strength Strength(Salt Free Equivalent) Source Form of Substance	undefined	Neuland Laboratories Limited,	UNAPPROVED API	-	Details	DELETE

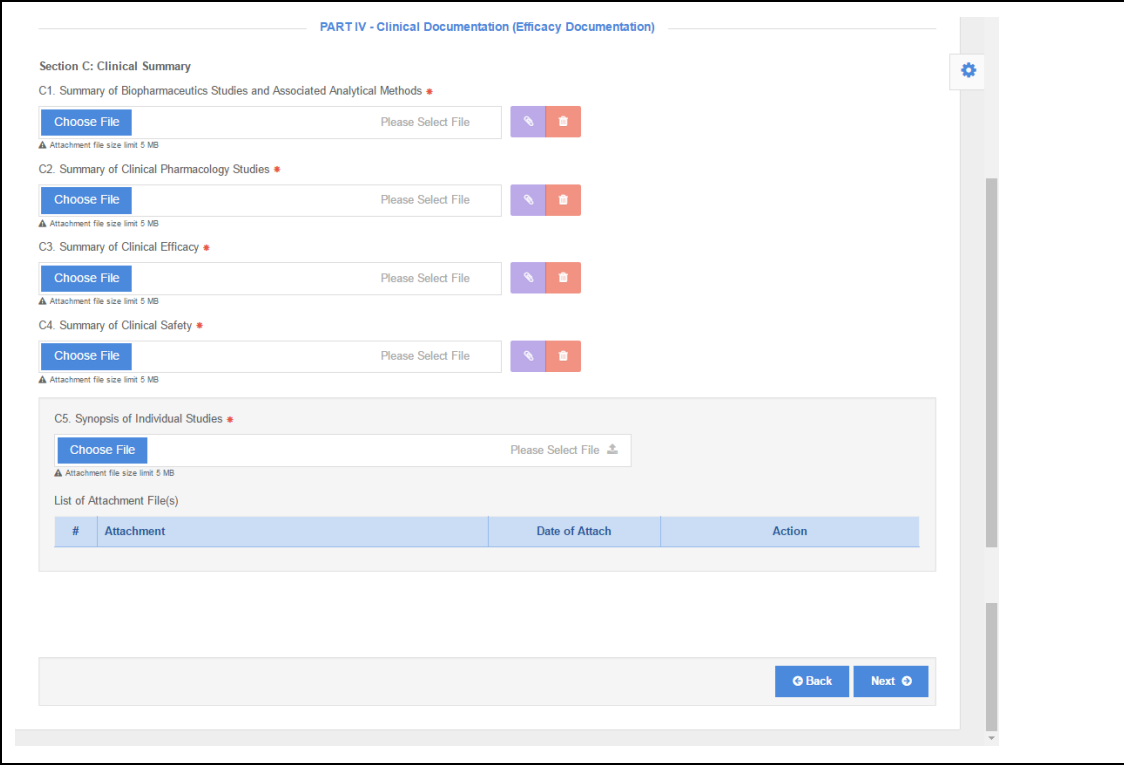
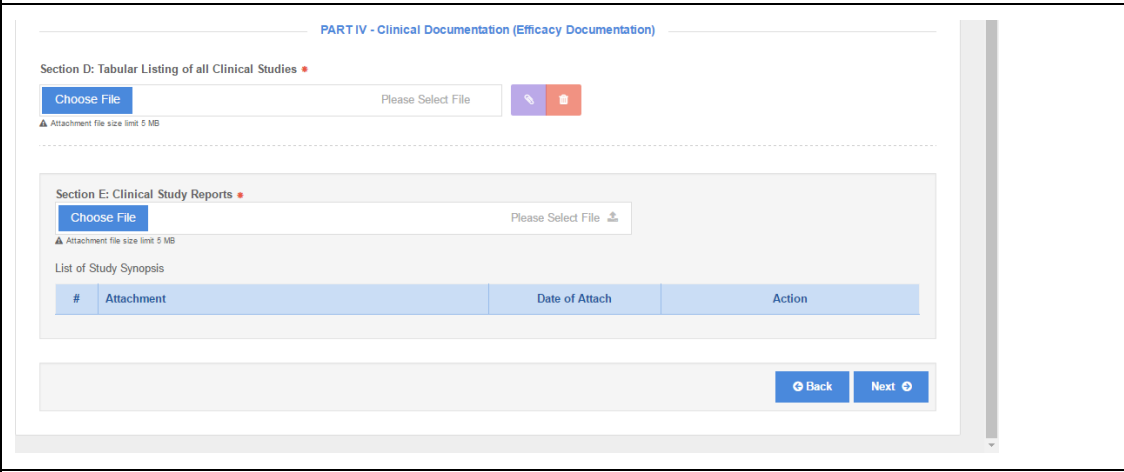
EX90.1
Explanation:
 Answer all question by choose yes or no then choose manufacturer.
 Click on “add” button to add manufacturer
 Click “details” button to open section S.
 Click “delete” button to delete manufacturer.

11.5 **TAB-4 Part III**

11.5.1 Section A - B

<p>FG91</p>	
<p>EX91</p>	<p>Explanation: Key-in the followings:-</p> <ul style="list-style-type: none"> A upload attachment file B1 upload attachment file B2 upload attachment file B3 upload attachment file B4 upload attachment file B5 upload attachment file B6 upload attachment file
<p>11.5.2</p>	<p>Section C - E</p>
<p>FG92</p>	
<p>EX92</p>	<p>Explanation: Key-in the followings:-</p> <ul style="list-style-type: none"> C upload attachment file D upload attachment file E upload attachment file

11.6	TAB-5 Part IV
11.6.1	Section A - B
FG93	
EX93	<p>Explanation: Key-in the followings:-</p> <ul style="list-style-type: none"> A upload attachment file B1 upload attachment file B2 upload attachment file B3 upload attachment file B4 upload attachment file B5 upload attachment file B6 upload attachment file
11.6.2	Section C

<p>FG94</p>	
<p>EX94</p>	<p>Explanation: Key-in the followings:-</p> <p>C1 upload attachment file C2 upload attachment file C3 upload attachment file C4 upload attachment file C5 upload attachment file</p>
<p>11.6.3</p>	<p>Section D - E</p>
<p>FG95</p>	
<p>EX95</p>	<p>Explanation: Key-in the followings:-</p> <p>D upload attachment file E upload attachment file</p>
<p>11.6.4</p>	<p>Section F</p>

FG96

PART IV - Clinical Documentation (Efficacy Documentation)

Section F

F1. List of Key Literature References *

Choose File

Please Select File



▲ Attachment file size limit 5 MB

F2. Published Clinical Papers *

Choose File

Please Select File

▲ Attachment file size limit 5 MB

List of Study Synopsis

#	Attachment	Date of Attach	Action
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F3. Periodic Safety Updates Report(PSUR) *

Choose File

Please Select File



▲ Attachment file size limit 5 MB

F4. Risk of Management Plan(RMP)

Choose File

Please Select File



▲ Attachment file size limit 5 MB

Back

Next

EX96

Explanation:

Key-in the followings:-

F1 upload attachment file

F2 upload attachment file

F3 upload attachment file

F4 upload attachment file

11.7

TAB-6 Submission & Declaration

FG97

Mandatory Labels

#	Field Name	Status
1	1.1 Brand Name	—
2	1.2 Generic Name	—
3	1.3 Full Product Name	✓
4	2.1 Dosage Form	⚠
5	2.2 Dosage Form Description	⚠
6	2.3 Source of Capsule Shell	—
7	2.4 Certificate to verify the Source of Capsule Shell	—
8	2.5 Colouring Agent used in capsule shell	—
9	2.6 Certificate Of Analysis of Capsule Shell	—
10	3.1 Active Ingredient	⚠
11	4.1 Excipient	—
12	5. Ingredients of Human or Animal Origin (Active Ingredient, Excipient and / or Capsule Shell)	⚠
13	5.1 Origin:	—
14	6. Manufacturer	
15	7. Is there any Contract Manufacturer Involved?	⚠
16	8. Is this Product a Second Source Product?	⚠
17	8.1 Declaration Letter	—
18	8.2 Product(s) from First Source	
19	9. Is there any Repacker Involved?	⚠
20	11. Is the Product Under Patent Protection?	—
21	11.1 Patent Protection	—
22	11.2 Filing Date	—
23	11.3 Grant Date	—
24	11.4 Patent Statement	—
25	12. Is this an Imported Product?	⚠
26	12.1 Section E Type	—
27	13. Does this product contain any premix?	⚠
28	13.1 Premix Form	—
29	13.2 Manufacturer Name	—
30	13.3 Manufacturer Address	—

147	B6. List of Literature Citations	▲				
148	Section C: Non-Clinical Written & Tabulated Summaries	▲				
149	Section D: Non-Clinical Study Reports	▲				
150	Section E: List of Key Literature References	▲				
151	Section A: Table of Content	▲				
152	B1. Product Development Rational	▲				
153	B2. Overview of Biopharmaceuticals	▲				
154	B3. Overview of Clinical Pharmacology	▲				
155	B4. Overview of Efficacy	▲				
156	B5. Overview of Safety	▲				
157	B6. Benefits and Risk Conclusions	▲				
158	C1. Summary of Biopharmaceutics Studies and Associated Analytical Methods	▲				
159	C2. Summary of Clinical Pharmacology Studies	▲				
160	C3. Summary of Clinical Efficacy	▲				
161	C4. Summary of Clinical Safety	▲				
162	C5. Synopsis of Individual Studies	▲				
163	Section D: Tabular Listing of all Clinical Studies	▲				
164	Section E: Clinical Study Reports	▲				
165	F1. List of Key Literature References	▲				
166	F2. Published Clinical Papers	▲				
167	F3. Periodic Safety Updates Report(PSUR)	▲				
168	F4. Risk of Management Plan(RMP)	—				
Section S Form Validation Status						
#	Active Ingredients	Manufacturer	Strength	Strength Salt Free	Type	Done
Submit Registration						
EX97	<p>Explanation: User can check by summary via status symbol, either each form is complete or not. Click on the field/section name to redirect to the field. Red icon refers to mandatory field. Purple icon refers to optional field. Green icon refers to field that already fill.</p>					