



**National Pharmaceutical Control Bureau  
Ministry of Health Malaysia**

**USER MANUAL**  
QUEST 3+ System  
Module: **Variation**  
**(Front-End)**

**Document No.: Q3+/User Manual/M7/1**

**Version 2.1**

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SELANGOR

## Pengemaskinian Dokumen

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<b>1.0</b>	14/07/2016	MOHAMAD SYAFIQ AZWAN BIN MUSTAFA	-	Pasukan Projek, Jawatankuasa Teknikal Projek, Jawatankuasa Pemandu Projek
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## Pengesahan Dokumen

.....

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[Pengarah Regulatori Farmasi]

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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 for Variation Application
2. Variation payment
3. Variation Correspondence

### **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. Mozilla Firefox latest version (recommended) or other internet explorer
4. Valid Digital Certificate (USB Token) – To be purchased online during Membership Application
5. PDF Reader/Writer Software
6. Photo editor to edit (crop, resize or other editing functions) your attachments in jpg format
7. 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.

## Contact Person

If you have any enquiries, please contact the following person based on your nature of inquiry:

### Administrative Enquiries:

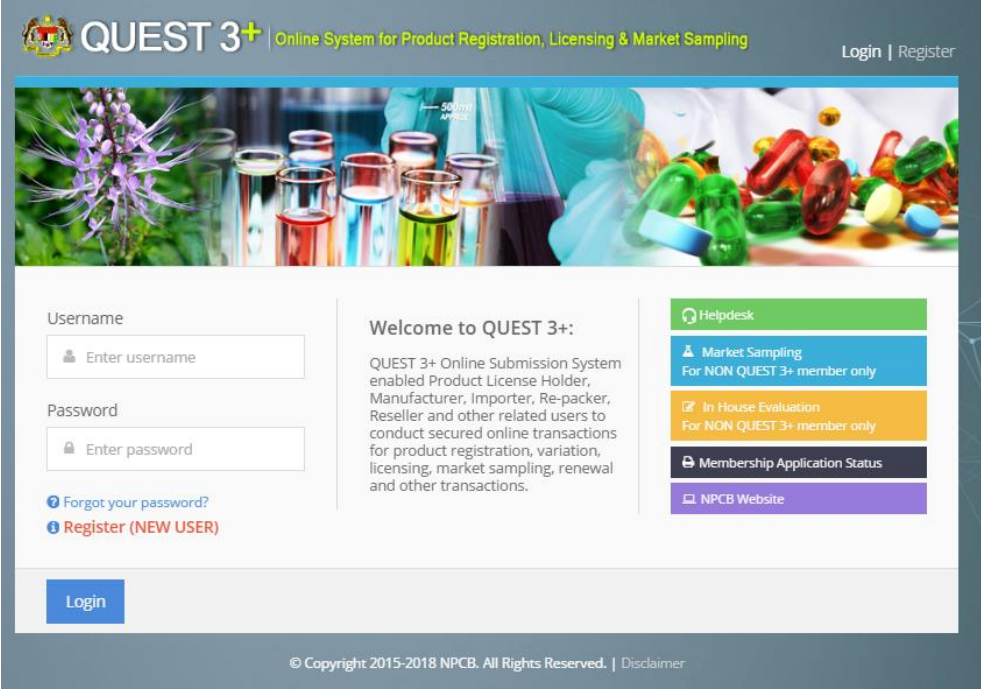
Name: Cik Nurulfajar Mohd Jamid  
Ketua Penolong Pengarah Kanan, BPFK  
Email: [nfajar@bpfk.gov.my](mailto:nfajar@bpfk.gov.my)  
Telephone: +60 3-7883 5400

### Technical Enquiries:

Name: Zuraini Ariffin (Pengurus Projek QUEST 3+ Persada Digital Sdn Bhd)  
Email: [Zuraini@mypersada.com](mailto:Zuraini@mypersada.com)  
Telephone: +60 3-6141 8151

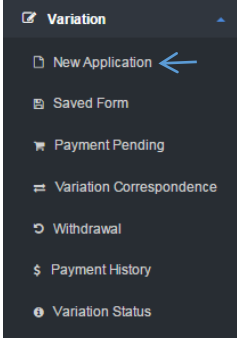
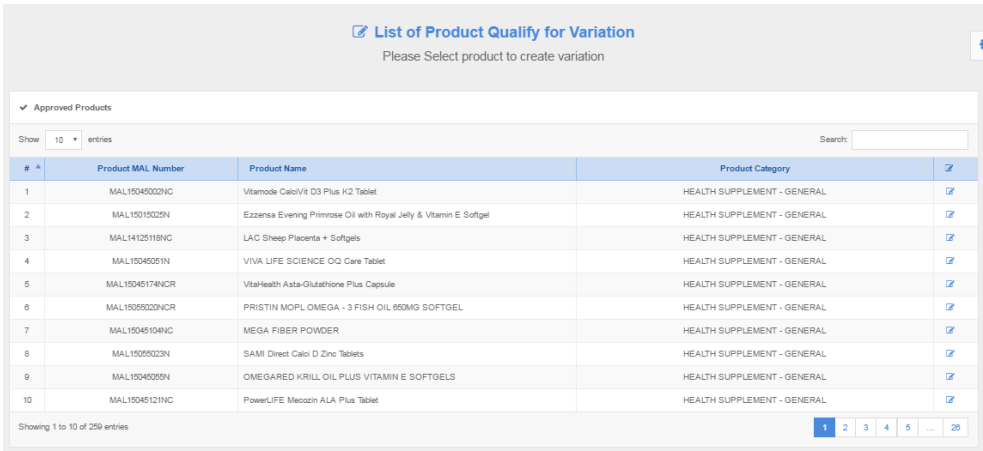
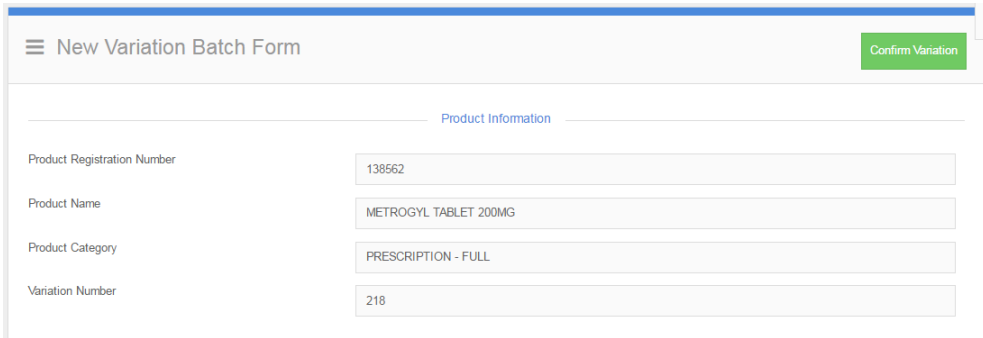
Name: Muhamad Hazree Haris (Technical Manager)  
Email: [hazree@mypersada.com](mailto:hazree@mypersada.com)  
Telephone: +60 3-6141 8151

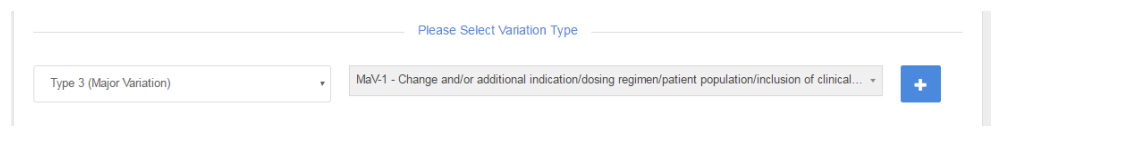
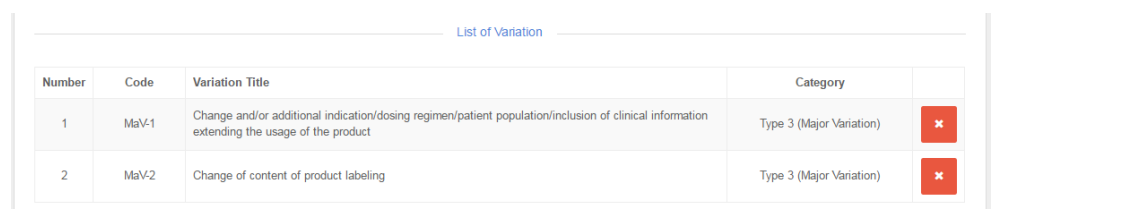
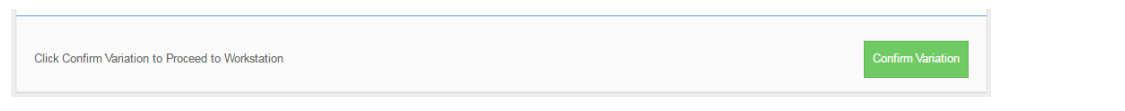
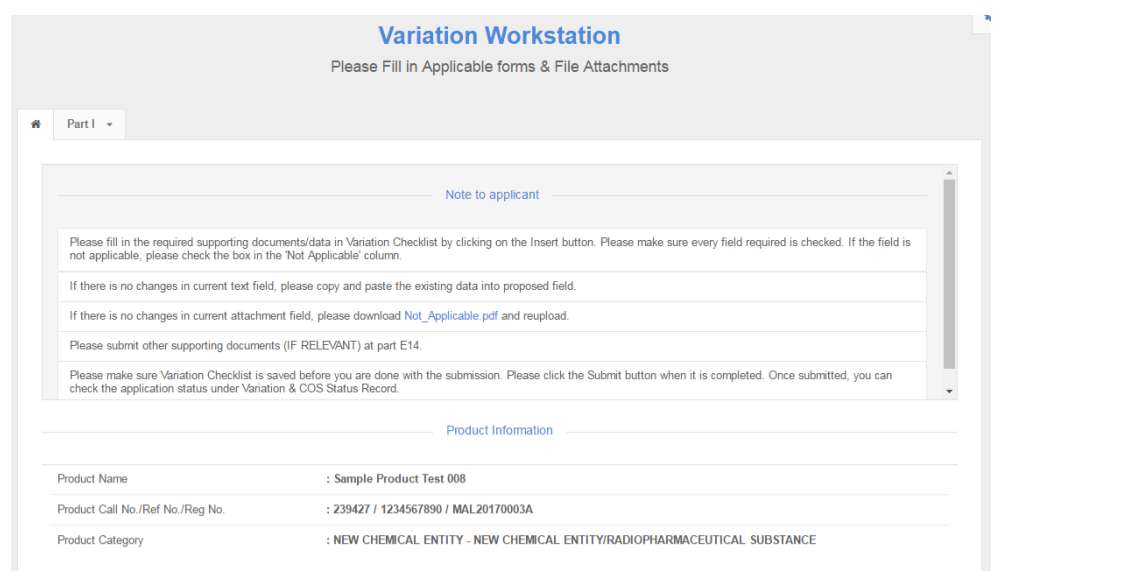
## 1.0 QUEST3+ Front-end login

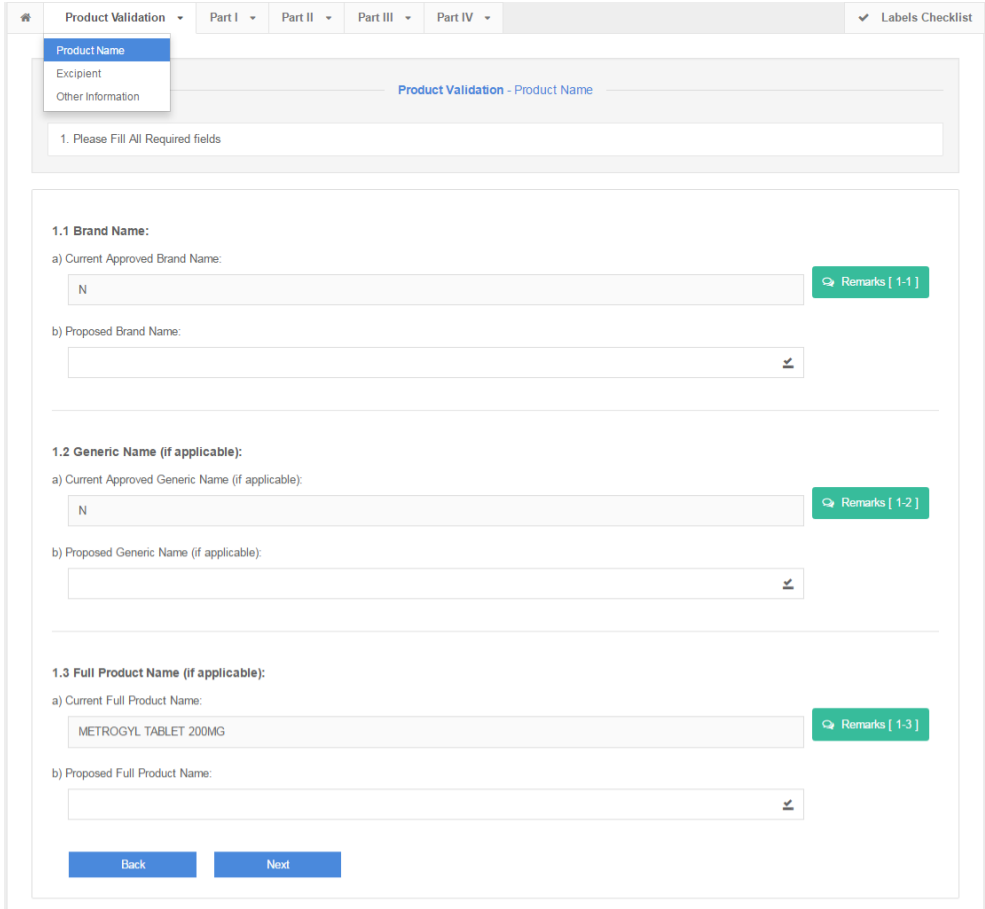
#	SCREENSHOTS / EXPLANATION
1	Login
FG1	
EX1	<p><b>Explanation:</b> To access the Quest 3+ system, user need to use the URL as below: <a href="https://quest3plus.bpfk.gov.my/front-end">https://quest3plus.bpfk.gov.my/front-end</a> Figure 1 as the above will appear and the user will need to enter the following information:</p> <ol style="list-style-type: none"> <li>1. User Name: User ID</li> <li>2. Password: Enter Password.</li> <li>3. Click Login</li> </ol>

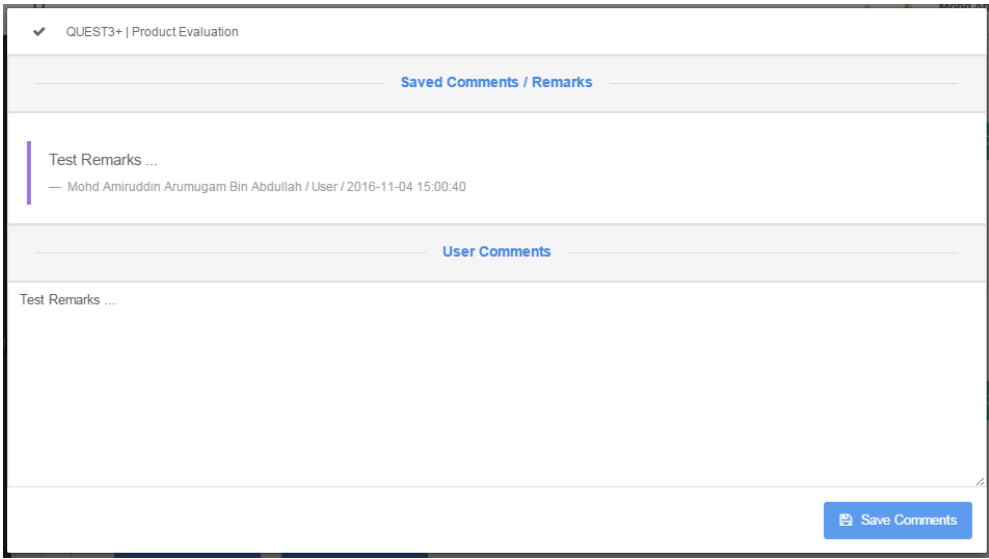
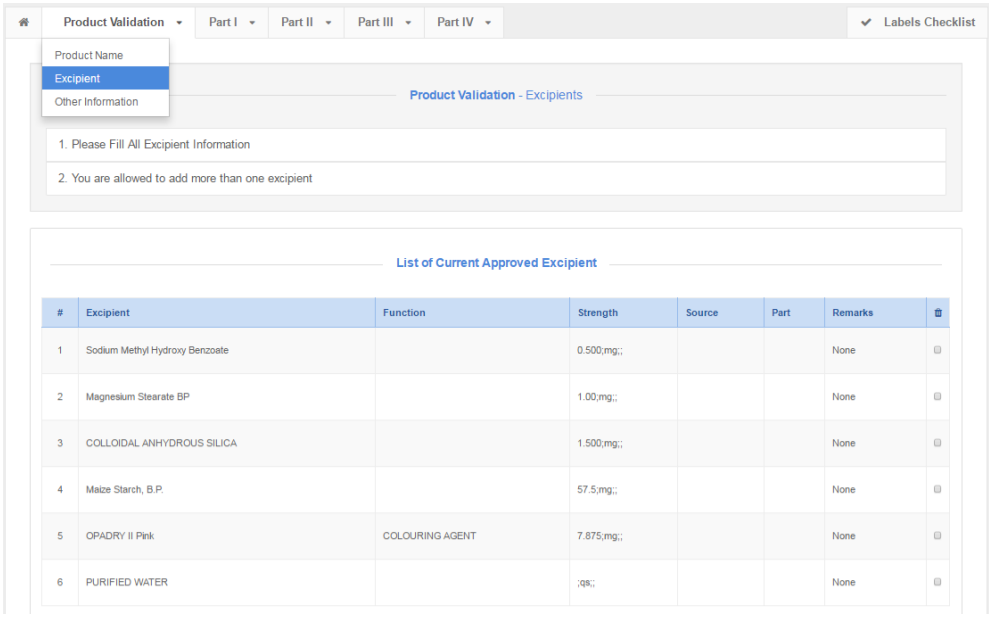


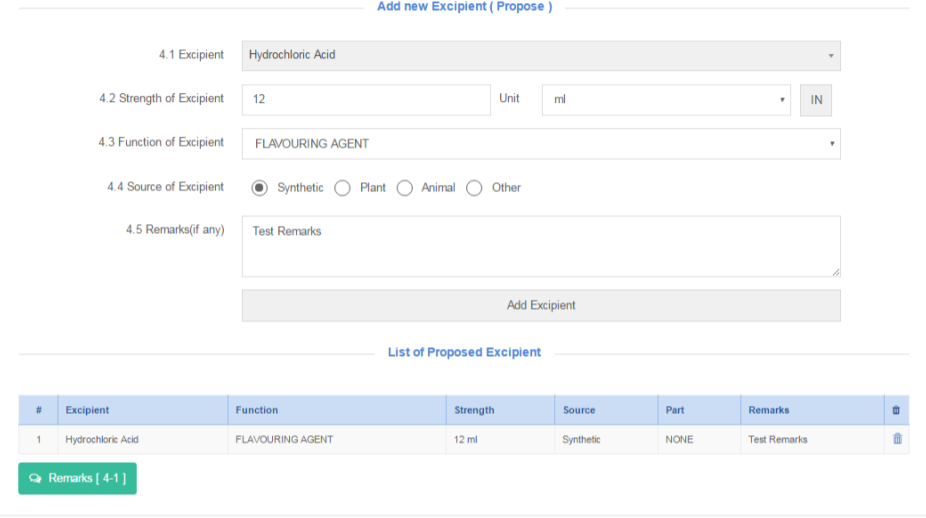
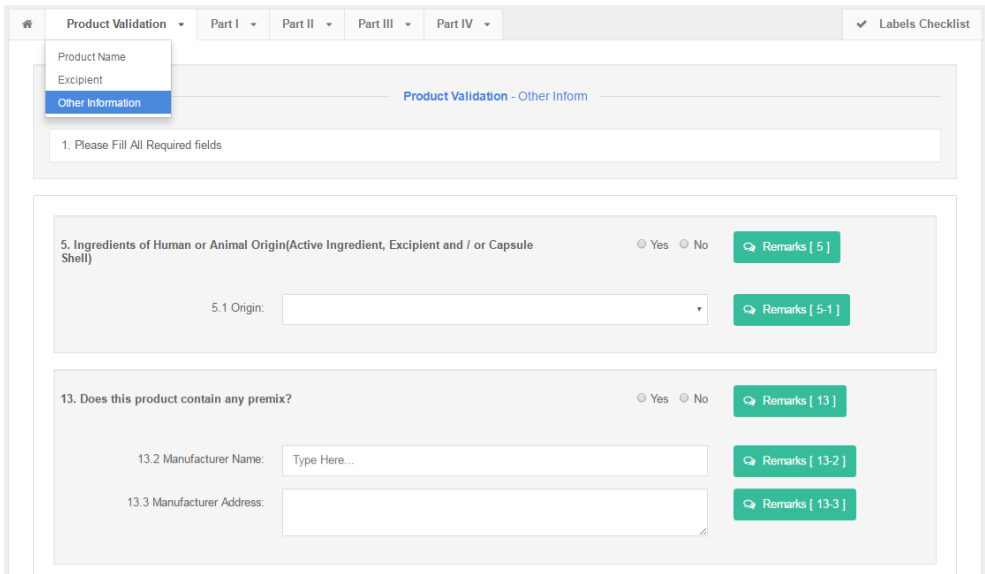
## 2.0 Variation

#	SCREENSHOTS / EXPLANATION																																																							
2.1	<b>Variation Application</b>																																																							
2.1.1	New Application																																																							
FG2																																																								
EX2	<b>Explanation:</b> Click on side menu 'Variation / New Application'																																																							
FG3	 <table border="1"> <caption>List of Product Quality for Variation</caption> <thead> <tr> <th>#</th> <th>Product MAL Number</th> <th>Product Name</th> <th>Product Category</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL15045002NC</td> <td>Vitamode Calc/Vt D3 Plus H2 Tablet</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>2</td> <td>MAL150150025N</td> <td>Ezzensa Evening Primrose Oil with Royal Jelly &amp; Vitamin E Softgel</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>3</td> <td>MAL14125118NC</td> <td>LAC Sheep Placenta + Softgels</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>4</td> <td>MAL150450051N</td> <td>VIVA LIFE SCIENCE OQ Care Tablet</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>5</td> <td>MAL15045174NCR</td> <td>VitaHealth Asta-Glutathione Plus Capsule</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>6</td> <td>MAL150650203NCR</td> <td>PRISTIN MOPL OMEGA - 3 FISH OIL 650MG SOFTGEL</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>7</td> <td>MAL15045104NC</td> <td>MEGA FIBER POWDER</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>8</td> <td>MAL150550023N</td> <td>SAMI Direct Calc/D Zinc Tablets</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>9</td> <td>MAL150450055N</td> <td>OMEGARED KRILL OIL PLUS VITAMIN E SOFTGELS</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> <tr> <td>10</td> <td>MAL15045121NC</td> <td>PowerLIFE Mecozin ALA Plus Tablet</td> <td>HEALTH SUPPLEMENT - GENERAL</td> <td>✍</td> </tr> </tbody> </table>	#	Product MAL Number	Product Name	Product Category		1	MAL15045002NC	Vitamode Calc/Vt D3 Plus H2 Tablet	HEALTH SUPPLEMENT - GENERAL	✍	2	MAL150150025N	Ezzensa Evening Primrose Oil with Royal Jelly & Vitamin E Softgel	HEALTH SUPPLEMENT - GENERAL	✍	3	MAL14125118NC	LAC Sheep Placenta + Softgels	HEALTH SUPPLEMENT - GENERAL	✍	4	MAL150450051N	VIVA LIFE SCIENCE OQ Care Tablet	HEALTH SUPPLEMENT - GENERAL	✍	5	MAL15045174NCR	VitaHealth Asta-Glutathione Plus Capsule	HEALTH SUPPLEMENT - GENERAL	✍	6	MAL150650203NCR	PRISTIN MOPL OMEGA - 3 FISH OIL 650MG SOFTGEL	HEALTH SUPPLEMENT - GENERAL	✍	7	MAL15045104NC	MEGA FIBER POWDER	HEALTH SUPPLEMENT - GENERAL	✍	8	MAL150550023N	SAMI Direct Calc/D Zinc Tablets	HEALTH SUPPLEMENT - GENERAL	✍	9	MAL150450055N	OMEGARED KRILL OIL PLUS VITAMIN E SOFTGELS	HEALTH SUPPLEMENT - GENERAL	✍	10	MAL15045121NC	PowerLIFE Mecozin ALA Plus Tablet	HEALTH SUPPLEMENT - GENERAL	✍
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EX3	<b>Explanation:</b> FG3 show a list of approved product in a company. Click on the edit icon to proceed to Variation Workstation.																																																							
FG4	 <p><b>New Variation Batch Form</b> <span style="float: right;">Confirm Variation</span></p> <p>Product Information</p> <p>Product Registration Number: 138562</p> <p>Product Name: METROGYL TABLET 200MG</p> <p>Product Category: PRESCRIPTION - FULL</p> <p>Variation Number: 218</p>																																																							
EX4	<b>Explanation:</b>																																																							

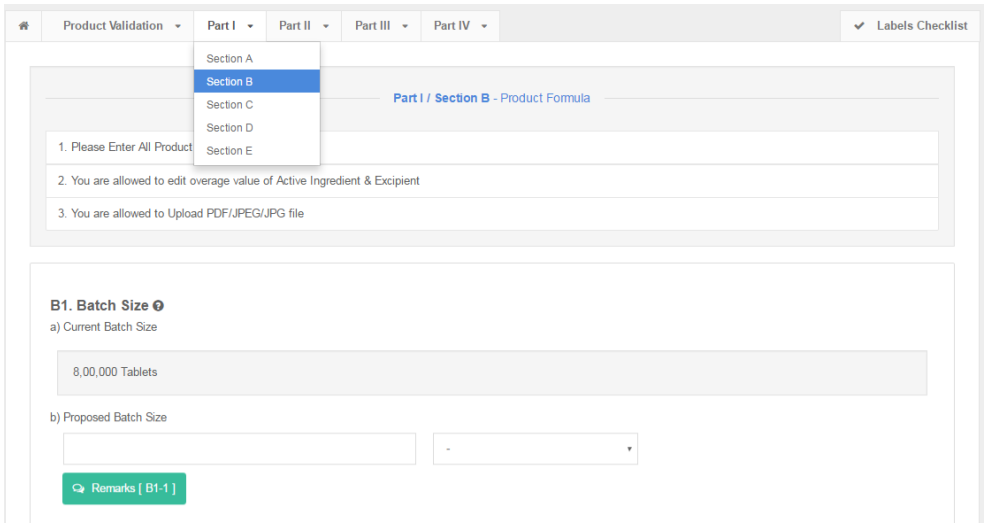
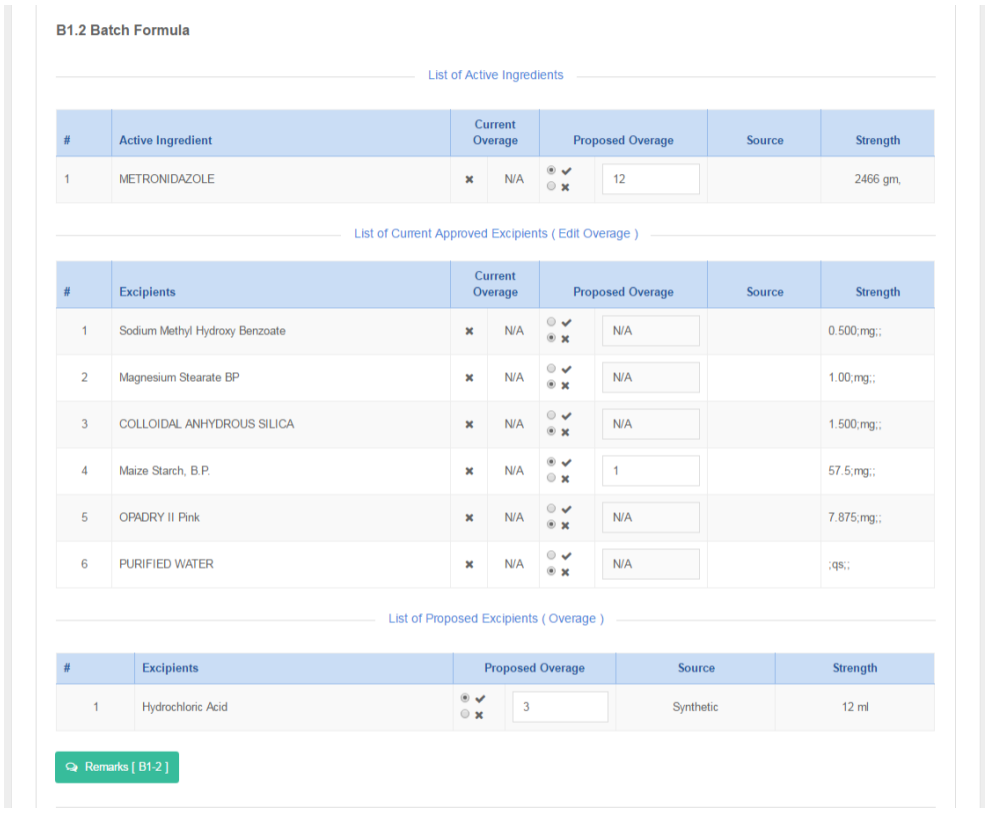
	<p>FG4 shows the information about the product selected by user for Variation Process.</p>															
<p><b>FG5</b></p>																
<p><b>EX5</b></p>	<p><b>Explanation:</b> User can select more than one (1) Variation title by clicking the + button after selecting an option from the dropdown list.</p>															
<p><b>FG6</b></p>	 <table border="1" data-bbox="288 636 1225 768"> <thead> <tr> <th>Number</th> <th>Code</th> <th>Variation Title</th> <th>Category</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MaV-1</td> <td>Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product</td> <td>Type 3 (Major Variation)</td> <td>X</td> </tr> <tr> <td>2</td> <td>MaV-2</td> <td>Change of content of product labeling</td> <td>Type 3 (Major Variation)</td> <td>X</td> </tr> </tbody> </table>	Number	Code	Variation Title	Category		1	MaV-1	Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	Type 3 (Major Variation)	X	2	MaV-2	Change of content of product labeling	Type 3 (Major Variation)	X
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<p><b>EX6</b></p>	<p><b>Explanation:</b> FG6 shows a list of Variation Title added by user for a Variation application. User can click on the X button to remove the added Variation Title.</p>															
<p><b>FG7</b></p>																
<p><b>EX7</b></p>	<p><b>Explanation:</b> Click on Confirm Variation Button to proceed the application to Variation Workstation.</p>															
<p><b>FG8</b></p>	 <p><b>Variation Workstation</b> Please Fill in Applicable forms &amp; File Attachments</p> <p>Part 1</p> <p>Note to applicant</p> <p>Please fill in the required supporting documents/data in Variation Checklist by clicking on the Insert button. Please make sure every field required is checked. If the field is not applicable, please check the box in the 'Not Applicable' column.</p> <p>If there is no changes in current text field, please copy and paste the existing data into proposed field.</p> <p>If there is no changes in current attachment field, please download <a href="#">Not_Applicable.pdf</a> and reupload.</p> <p>Please submit other supporting documents (IF RELEVANT) at part E14.</p> <p>Please make sure Variation Checklist is saved before you are done with the submission. Please click the Submit button when it is completed. Once submitted, you can check the application status under Variation &amp; COS Status Record.</p> <p>Product Information</p> <p>Product Name : Sample Product Test 008</p> <p>Product Call No./Ref No./Reg No. : 239427 / 1234567890 / MAL20170003A</p> <p>Product Category : NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE</p>															
<p><b>EX8</b></p>	<p><b>Explanation:</b> FG8 shows the Home Screen for Variation Workstation.</p>															

<p><b>FG9</b></p>	<p style="text-align: center;"><a href="#">Involve Labels</a></p> <table border="1"> <thead> <tr> <th>#</th> <th>Code</th> <th>Label Desc</th> <th>Label Overlap</th> <th>Correspond</th> <th>Status</th> <th>Go</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>1.1</td> <td>Brand Name</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>2</td> <td>1.2</td> <td>Generic Name</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>3</td> <td>1.3</td> <td>Full Product Name</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>4</td> <td>4.1</td> <td>Excipient</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>5</td> <td>5.1</td> <td>Origin</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>6</td> <td>5</td> <td>Ingredients of Human or Animal Origin (Active Ingredients, Excipients and/or Capsule Shell)</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>7</td> <td>13</td> <td>Does this Product Contains Any Premix ?</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>8</td> <td>13.3</td> <td>Manufacturer Address</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>9</td> <td>13.2</td> <td>Manufacturer Name</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>➤</td> </tr> <tr> <td>10</td> <td>A1</td> <td>Active Ingredient</td> <td>—</td> <td>N/A</td> <td>📄</td> <td>➤</td> </tr> </tbody> </table>	#	Code	Label Desc	Label Overlap	Correspond	Status	Go	1	1.1	Brand Name	—	N/A	▲	➤	2	1.2	Generic Name	—	N/A	▲	➤	3	1.3	Full Product Name	—	N/A	▲	➤	4	4.1	Excipient	—	N/A	▲	➤	5	5.1	Origin	—	N/A	▲	➤	6	5	Ingredients of Human or Animal Origin (Active Ingredients, Excipients and/or Capsule Shell)	—	N/A	▲	➤	7	13	Does this Product Contains Any Premix ?	—	N/A	▲	➤	8	13.3	Manufacturer Address	—	N/A	▲	➤	9	13.2	Manufacturer Name	—	N/A	▲	➤	10	A1	Active Ingredient	—	N/A	📄	➤
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10	A1	Active Ingredient	—	N/A	📄	➤																																																																								
<p><b>EX9</b></p>	<p><b>Explanation:</b> FG9 show a part of label involved in a Variation Application. <b>**Some Labels are not applicable/available in some Variation Titles.</b></p>																																																																													
<p><b>FG10</b></p>																																																																														
<p><b>EX10</b></p>	<p><b>Explanation:</b> Click on Product Validation / Product Name. Fill the required particular in the text box. User can leave remarks for the Evaluator by clicking the Remarks Button on the right side of each field.</p>																																																																													

<p><b>FG11</b></p>																																																									
<p><b>EX11</b></p>	<p><b>Explanation:</b> FG11 shows User Remarks Popup window. Fill remarks in the field provided and click on Save Comments button. Click anywhere outside the popup window to close the popup window.</p>																																																								
<p><b>FG12</b></p>	 <table border="1" data-bbox="300 1352 1217 1659"> <thead> <tr> <th>#</th> <th>Excipient</th> <th>Function</th> <th>Strength</th> <th>Source</th> <th>Part</th> <th>Remarks</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Sodium Methyl Hydroxy Benzoate</td> <td></td> <td>0.500,mg,;</td> <td></td> <td></td> <td>None</td> <td><input type="checkbox"/></td> </tr> <tr> <td>2</td> <td>Magnesium Stearate BP</td> <td></td> <td>1.00,mg,;</td> <td></td> <td></td> <td>None</td> <td><input type="checkbox"/></td> </tr> <tr> <td>3</td> <td>COLLOIDAL ANHYDROUS SILICA</td> <td></td> <td>1.500,mg,;</td> <td></td> <td></td> <td>None</td> <td><input type="checkbox"/></td> </tr> <tr> <td>4</td> <td>Maize Starch, B.P.</td> <td></td> <td>57.5,mg,;</td> <td></td> <td></td> <td>None</td> <td><input type="checkbox"/></td> </tr> <tr> <td>5</td> <td>OPADRY II Pink</td> <td>COLOURING AGENT</td> <td>7.875,mg,;</td> <td></td> <td></td> <td>None</td> <td><input type="checkbox"/></td> </tr> <tr> <td>6</td> <td>PURIFIED WATER</td> <td></td> <td>.08,;</td> <td></td> <td></td> <td>None</td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	#	Excipient	Function	Strength	Source	Part	Remarks		1	Sodium Methyl Hydroxy Benzoate		0.500,mg,;			None	<input type="checkbox"/>	2	Magnesium Stearate BP		1.00,mg,;			None	<input type="checkbox"/>	3	COLLOIDAL ANHYDROUS SILICA		1.500,mg,;			None	<input type="checkbox"/>	4	Maize Starch, B.P.		57.5,mg,;			None	<input type="checkbox"/>	5	OPADRY II Pink	COLOURING AGENT	7.875,mg,;			None	<input type="checkbox"/>	6	PURIFIED WATER		.08,;			None	<input type="checkbox"/>
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4	Maize Starch, B.P.		57.5,mg,;			None	<input type="checkbox"/>																																																		
5	OPADRY II Pink	COLOURING AGENT	7.875,mg,;			None	<input type="checkbox"/>																																																		
6	PURIFIED WATER		.08,;			None	<input type="checkbox"/>																																																		
<p><b>EX12</b></p>	<p><b>Explanation:</b> Click on Product Validation / Excipient. FG12 show a list of current approved excipient for the product. User can click on checkbox on the trash-icon column to propose delete current approved excipient.</p>																																																								

<p><b>FG13</b></p>	
<p><b>EX13</b></p>	<p><b>Explanation:</b> Fill the following field:</p> <ul style="list-style-type: none"> <li>4.1 Excipient</li> <li>4.2 Strength of Excipient</li> <li>4.3 Function of Excipient</li> <li>4.4 Source of Excipient</li> <li>4.5 Remarks(if any)</li> </ul> <p>Then click on the Add Excipient Button. Click on the trash-icon located on each row to delete added proposed excipient.</p>
<p><b>FG14</b></p>	
<p><b>EX14</b></p>	<p><b>Explanation:</b> Click on Product Validation / Other Information. Fill the required field.</p>

<p><b>FG15</b></p>	<p><b>A4. Product Description</b></p> <p>a) Current Product Description</p> <p>Pink round, biconvex film coated tablets.</p> <p>b) Proposed Product Description</p> <p>Remarks [ A4 ]</p>
<p><b>EX15</b></p>	<p><b>Explanation:</b></p> <p>FG15 shows one of the field available in the Variation Title.</p> <p>User can view the current data on part a)</p> <p>User can fill the new data on the text area on part b)</p> <p>Click on Remarks button to leave a remark to Evaluator.</p> <p>Fill the following field</p> <p>A4 – A20</p>
<p><b>FG16</b></p>	<p><b>A21. ATC Code</b></p> <p>a) Current ATC Code</p> <p>J01XD01</p> <p>b) Proposed ATC Code</p> <p>Level 1: CARDIOVASCULAR SYSTEM</p> <p>Level 2: BETA BLOCKING AGENTS</p> <p>Level 3: BETA BLOCKING AGENTS THIAZIDES AND OTHER DIURETIC</p> <p>Level 4: BETA BLOCKING AGENTS, NON-SELECTIVE, THIAZIDES AND OTHER DIURETICS</p> <p>Level 5: TIMOLOL, THIAZIDES AND OTHER DIURETICS</p> <p>Generated ATC Code: C07DA06</p> <p>Remarks [ A21 ]</p>
<p><b>EX16</b></p>	<p><b>Explanation:</b></p> <p>To fill label A21. ATC Code, user need to select the ATC code starting from Level. Click to select ATC Code.</p>

<p><b>FG17</b></p>	
<p><b>EX17</b></p>	<p><b>Explanation:</b> Click on Part 1 / Section B – Product Formula Fill the B1. Batch Size by entering the data in text box provided. Select the unit by clicking on the dropdown option.</p>
<p><b>FG18</b></p>	
<p><b>EX18</b></p>	<p><b>Explanation:</b> User is require to fill all the Proposed Overage column in the table shown in FG18</p>

**FG19**

**B2. Batch Manufacturing Formula**

a) Current Batch Manufacturing Formula

b) Proposed Batch Manufacturing Formula

Choose File Chrysanthemum.jpg

Remarks [ B2 ]

**EX19**

**Explanation:**

Click on the Choose File button to select a file to be uploaded in the system.

User can View the uploaded file by clicking on the blue eye-icon button.

Click on the red dustbin-icon button to remove the uploaded file.

**FG20**

Product Validation Part I Part II Part III Part IV Labels Checklist

Section A  
Section B  
**Section C**  
Section D  
Section E

Part I / Section C - Particulars of packing

1. Click "ADD" button after repeat these steps if there is more than one(1) pack size.  
2. To delete an entry from the list, click on the "DELETE" button. For editing, click on the "EDIT" button.  
3. Those field with symbol \* is a compulsory fields. If those fields are not filled, submission of application is not permitted.

a) Current Particular of Packing

#	C1. Pack Size	Field	Data	
1	1000Tablet GRAMS [WEIGHT]	C2. Immediate Container Type	PLASTIC	
		C3. Container Type Description	HDPE PLASTIC container	
		C4. Barcode / Serial No.	300200201507	
		C5. Recommended Distributor's Price	RM 30.00	
		C6. Recommended Retail Price	RM 40.00	

b) Proposed Particular of Packing

C1. Pack Size\* : 12 Unit KILOGRAMS

C2. Immediate Container Type\* : PAPER If Other, please specify

C3. Container Type Description\* : Desc

C4. Barcode / Serial No. (if applicable) : 123456789

C5. Recommended Distributor's Price\* : 80

C6. Recommended Retail Price\* : 90

List of Pack Size Add Pack Size

Success! Packing Particular has been Added

#	C1. Pack Size	Field	Data	Action
1	12 KILOGRAMS [Weight]	C2. Immediate Container Type	PAPER []	
		C3. Container Type Description	Desc	
		C4. Barcode / Serial No.	123456789	
		C5. Recommended Distributor's Price	RM 80.00	
		C6. Recommended Retail Price	RM 90.00	









**EX20**

**Explanation:**

Click on Part 1/ Section C

Fill all the required field marked with \* then click on the Add Pack Size button to add new proposed Pack Size.



	<p>User can click on checkbox on the trash-icon column to propose delete current approved pack size.</p> <p>Click on the trash-icon located on the action column on each row to delete added proposed pack size.</p>																				
<p><b>FG21</b></p>	<p><b>D1. Label (mock-up) for immediate Container:</b> </p> <p>a) Current Label (mock-up) for immediate Container:</p> <div data-bbox="284 443 1236 495" style="border: 1px solid #ccc; padding: 5px; background-color: #f9f9f9;"> <p>No Current Approved Data</p> </div> <div data-bbox="284 510 1236 618" style="border: 1px solid #ccc; padding: 5px; background-color: #f9f9f9;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e1e8f4;"> <th>#</th> <th>Attachment</th> <th>Date of Attachment</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Lignopad_Inner label new(1).pdf</td> <td>16-04-2016</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> </div> <p>b) Proposed Label (mock-up) for immediate Container:</p> <div data-bbox="284 656 906 696" style="border: 1px solid #ccc; padding: 5px; background-color: #f9f9f9;"> <p>Choose File <span style="float: right;">Desert.jpg</span></p> </div> <div data-bbox="284 707 1236 748" style="background-color: #e8f5e9; padding: 5px; margin: 5px 0;"> <p>Success! The file V_252_20161121_031426_D1.jpg has been uploaded</p> </div> <div data-bbox="284 768 1236 904" style="border: 1px solid #ccc; padding: 5px; background-color: #f9f9f9;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e1e8f4;"> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Chrysanthemum.jpg</td> <td>21 Nov 2016 - 11:17 AM</td> <td style="text-align: center;"></td> </tr> <tr> <td>2</td> <td>Desert.jpg</td> <td>21 Nov 2016 - 11:17 AM</td> <td style="text-align: center;"></td> </tr> </tbody> </table> </div> <div data-bbox="284 920 416 954" style="background-color: #e8f5e9; padding: 5px; margin-top: 5px;"> <p> Remarks [ D1 ]</p> </div>	#	Attachment	Date of Attachment		1	Lignopad_Inner label new(1).pdf	16-04-2016	<input type="checkbox"/>	#	Attachment	Date of Attach		1	Chrysanthemum.jpg	21 Nov 2016 - 11:17 AM		2	Desert.jpg	21 Nov 2016 - 11:17 AM	
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2	Desert.jpg	21 Nov 2016 - 11:17 AM																			
<p><b>EX21</b></p>	<p><b>Explanation:</b></p> <p>Click on Part 1 / Section D</p> <p>FG21 show a part of Section D. User can view current attachment files by clicking on the filename in the Current label table.</p> <p>Click on the Choose file Button to upload new files for Variation.</p> <p>User can click on checkbox on the trash-icon column to propose delete current approved attachments.</p> <p>Click on the red trash-icon button to remove uploaded attachments.</p> <p>Multiple file attachment are available in some Field/Label.</p> <p>Fill the required field D1-D5</p>																				

FG22

<span style="border: 1px solid #ccc; padding: 2px;">E1-E2</span> <span style="margin-left: 5px;">E3</span> <span style="margin-left: 5px;">E4</span> <span style="margin-left: 5px;">E5</span> <span style="margin-left: 5px;">E6-E12</span> <span style="margin-left: 5px;">E13</span> <span style="margin-left: 5px;">E14-E17</span>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

**E1. Product Owner** Help

**E1.1. Product Owner & Role**

a) Current Product Owner & Role:

b) Proposed Product Owner & Role:

ASHLEY DERMACARE LABORATORY LTD. : A11-01, DAMANSARA INTAN, SS20/27, ▼

B-PRODUCT HOLDER ▼

Remarks [ E1-1 ]

---

**E1.2. Letter of Authorization from Product Owner:**

a) Current Letter of Authorization from Product Owner:

b) Proposed Letter of Authorization from Product Owner:

Choose File

Chrysanthemum.jpg

Remarks [ E1-2 ]

---

**E2. Contract Manufacturer and Repacker**

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

a) Current Letter of Appointment of the Contract Manufacturer from the Product Owner:

b) Proposed Letter of Appointment of the Contract Manufacturer from the Product Owner:

Choose File

Desert.jpg

Remarks [ E2-1 ]

---

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

a) Current Letter of Acceptance from the Contract Manufacturer:

b) Proposed Letter of Acceptance from the Contract Manufacturer:

Choose File

Hydrangeas.jpg

Remarks [ E2-2 ]

---

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

a) Current Letter of Appointment of the Repacker from the Product Owner:

b) Proposed Letter of Appointment of the Repacker from the Product Owner:

Choose File

Jellyfish.jpg

Remarks [ E2-3 ]

---

**E2.4. Letter of Acceptance from the Repacker:**

a) Current Letter of Acceptance from the Repacker:

b) Proposed Letter of Acceptance from the Repacker:

Choose File

Koala.jpg

Remarks [ E2-4 ]

<b>EX22</b>	<b>Explanation:</b> Click on Part 1 / Section E / E1 – E2. Key-in the followings:-  E1 upload attachment file  E2 upload attachment file
-------------	------------------------------------------------------------------------------------------------------------------------------------------------------------

FG23

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

**E3. Certificate of Pharmaceutical Product (CPP)** Help

**E3.1. Certificate of Pharmaceutical: 0**

a) Current Certificate of Pharmaceutical:

b) Proposed Certificate of Pharmaceutical:

Certificate No.  Choose File Please Select A File

Remarks [ E3-1 ]

---

**E3.2. CPP Issuing Body 0**

a) Current CPP Issuing Body:

1182

b) Proposed CPP Issuing Body:

Remarks [ E3-2 ]

---

**E3.3. Is this product licensed to be placed on the market for use in the exporting country? 0**

a) Current Answer and Remark:

Y Yes

b) Proposed Answer and Remark:

Yes  NO

Remarks [ E3-3 ]

---

**E3.4. Is this product on the market in the exporting country? 0**

a) Current Answer and Remark:

Yes

b) Proposed Answer and Remark:

Yes  NO

Remarks [ E3-4 ]

---

**E3.5. Date of issue of CPP 0**

a) Current Date of issue of CPP:

2003-05-23 00:00:00

b) Proposed Date of issue of CPP:

Remarks [ E3-5 ]

---

**E3.6. Date of expiry of CPP 0**

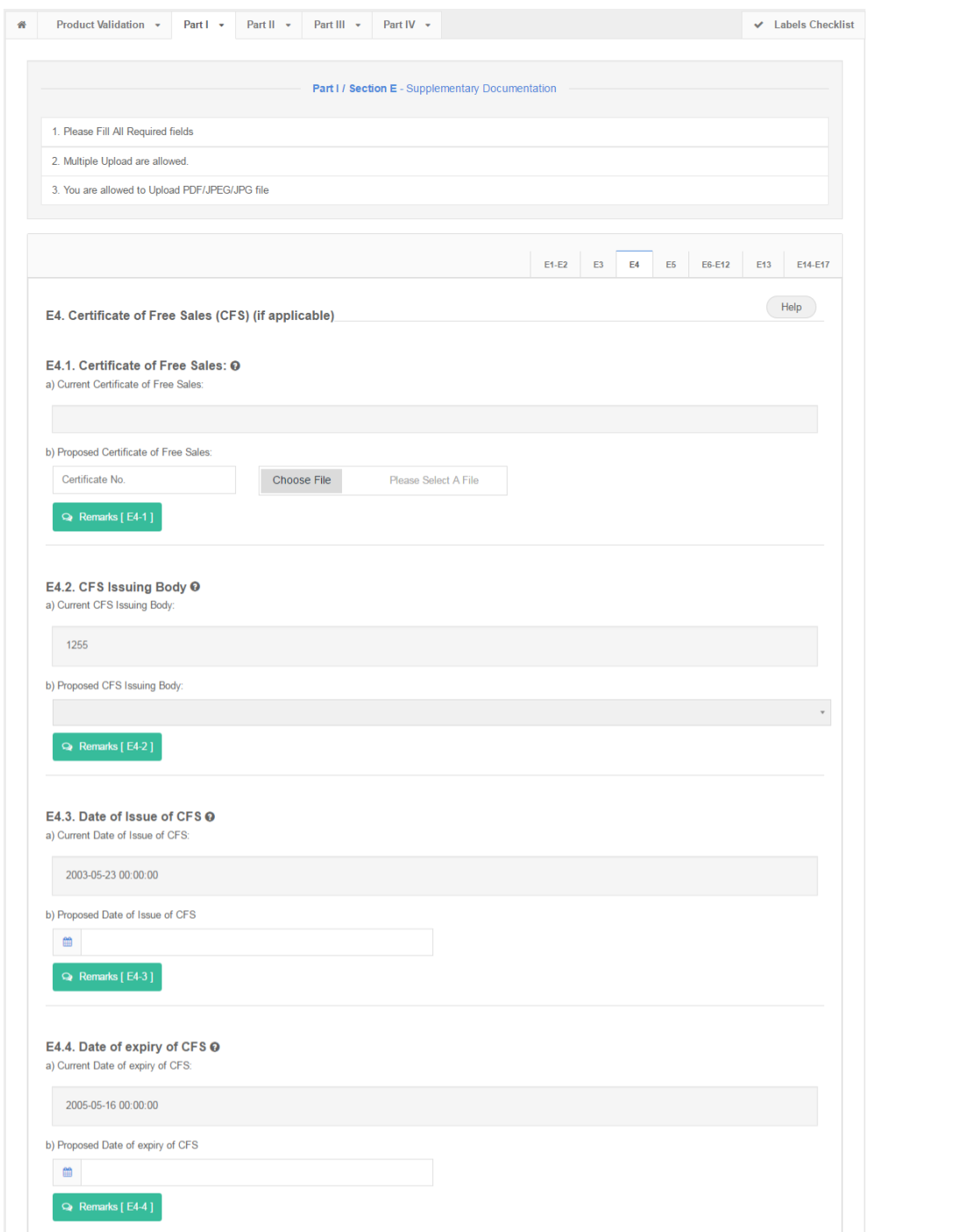
a) Current Date of expiry of CPP:

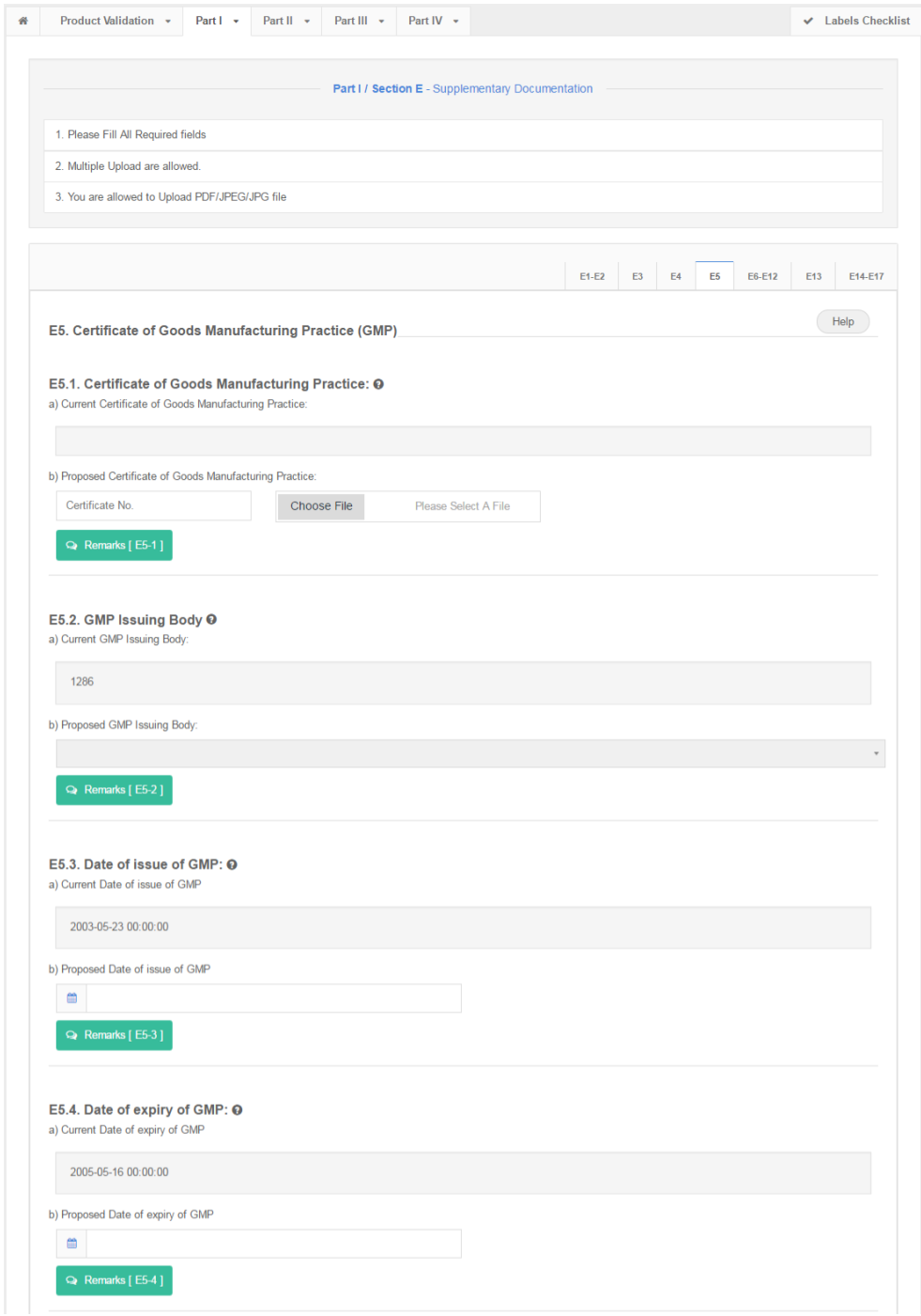
2005-05-16 00:00:00

b) Proposed Date of expiry of CPP:

Remarks [ E3-6 ]

<b>EX23</b>	<b>Explanation:</b> Click on Part 1 / Section E / E3. Key-in the followings:- E3.1 upload attachment file E3.2 fill in issuing body - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list E3.3 fill in reason E3.4 fill in reason E3.5 fill in date E3.6 fill in date
-------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

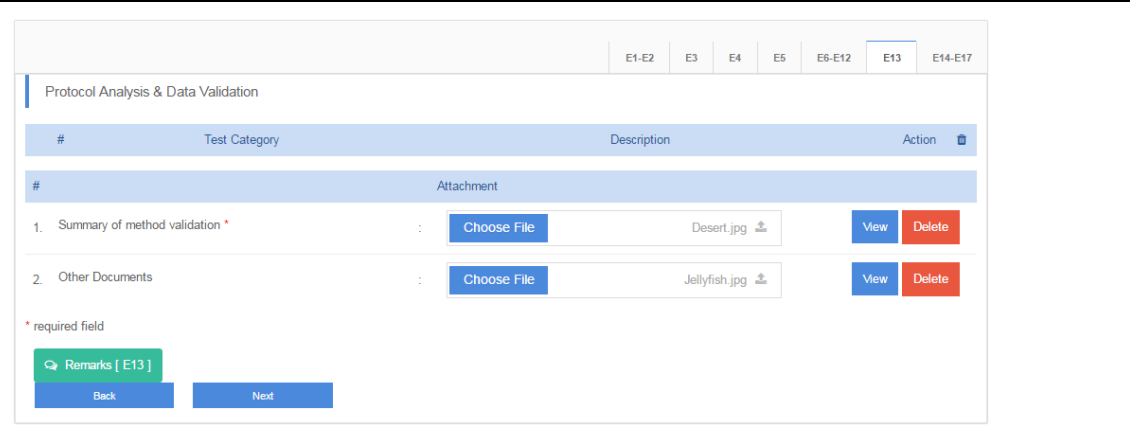
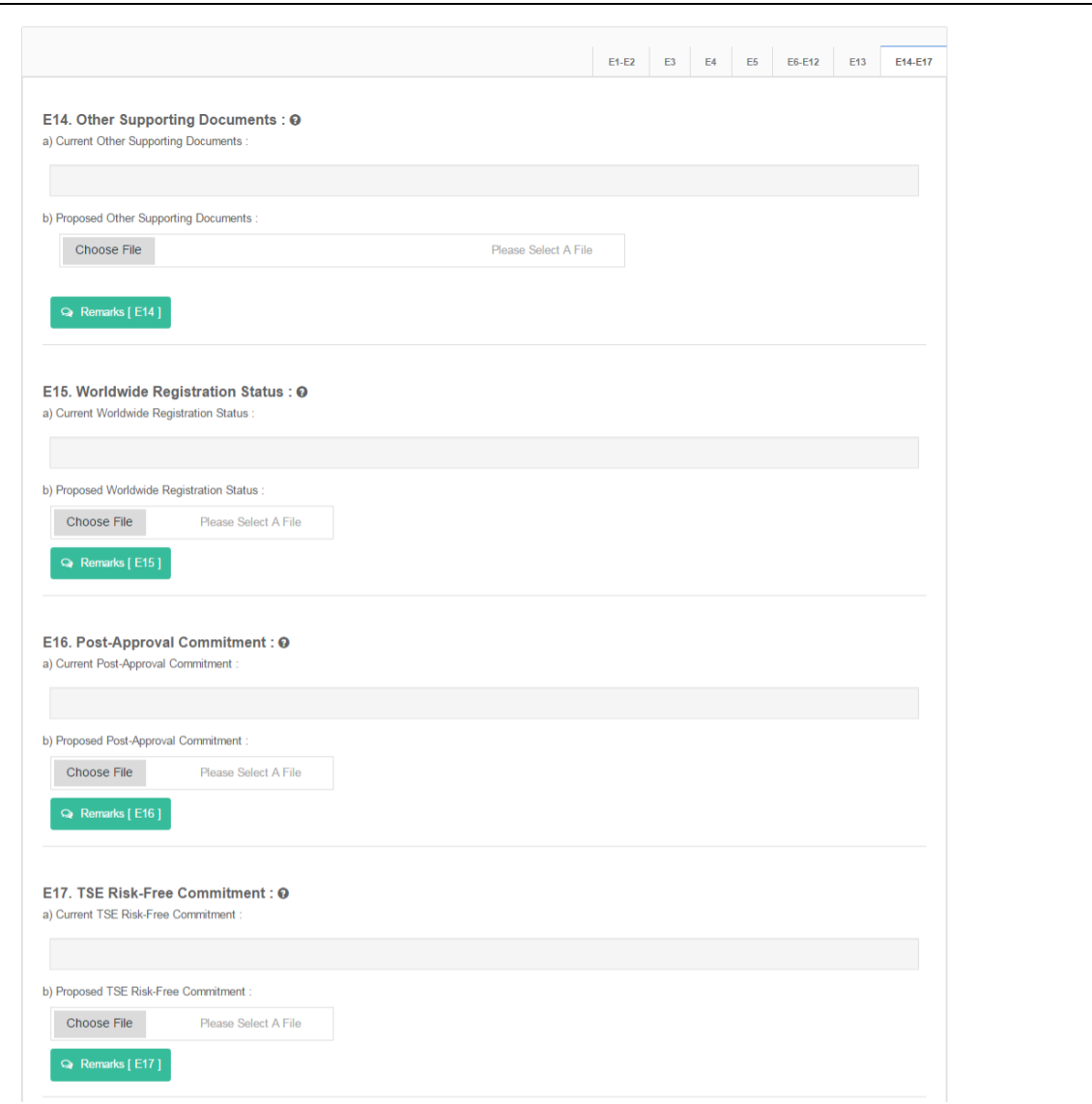
<p><b>FG24</b></p>	
<p><b>EX24</b></p>	<p><b>Explanation:</b> Click on Part 1 / Section E / E4. Key-in the followings:- E4.1 upload attachment file E4.2 fill in issuing body - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list E4.3 fill in date E4.4 fill in date</p>

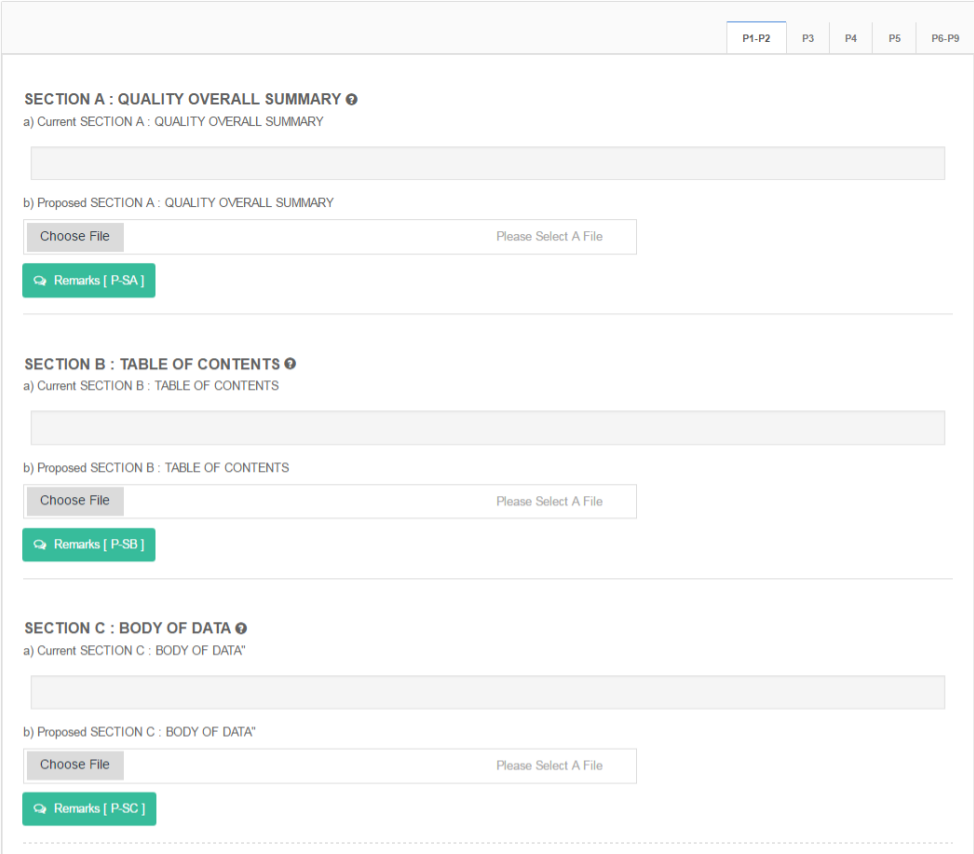
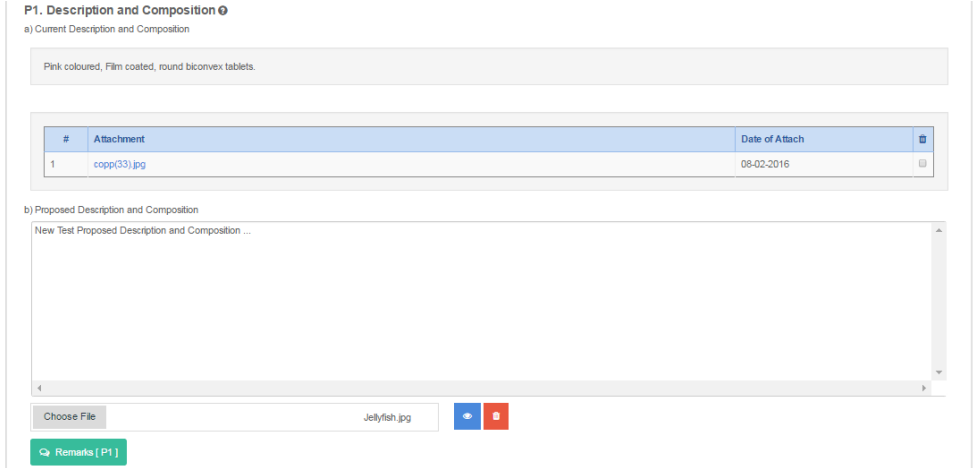
<p><b>FG25</b></p>	
<p><b>EX25</b></p>	<p><b>Explanation:</b></p> <p>Click on Part 1 / Section E / E5. Key-in the followings:-</p> <p>E5.1 upload attachment file</p> <p>E5.2 fill in issuing body</p> <ul style="list-style-type: none"> <li>- Fill in issuing body by entering a minimum 3 character and choose from the dropdown list</li> </ul> <p>E5.3 fill in date</p> <p>E5.4 fill in date</p>



<p><b>FG26</b></p>	<p><b>E7. Other Manufacturer(s) Involved :</b> ⓘ</p> <p>a) Current Other Manufacturer(s) Involved:</p> <table border="1" data-bbox="300 353 1212 436"> <thead> <tr> <th>No</th> <th>Manufacturer Name</th> <th>Manufacturer Address</th> <th>Processing Step</th> <th>GMP Certificate</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>b) Proposed Other Manufacturer(s) Involved:</p> <p>Manufacturer(s) Involved : ⓘ FERTIN PHARMA A/S : DANDYVEJ VEJILE VEJILE</p> <p>Address : DANDYVEJ VEJILE VEJILE</p> <p>Processing Step : PACKING</p> <p>GMP Certificate : Choose File Koala.jpg Cancel</p> <p>ADD</p> <table border="1" data-bbox="300 705 1133 772"> <thead> <tr> <th>No.</th> <th>Manufacturer Name</th> <th>Manufacturer Address</th> <th>Processing Step</th> <th>GMP</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>FERTIN PHARMA A/S</td> <td>DANDYVEJ VEJILE VEJILE</td> <td>PACKING</td> <td>View Remove</td> </tr> </tbody> </table> <p>Remarks [ E7 ]</p>	No	Manufacturer Name	Manufacturer Address	Processing Step	GMP Certificate						No.	Manufacturer Name	Manufacturer Address	Processing Step	GMP	1	FERTIN PHARMA A/S	DANDYVEJ VEJILE VEJILE	PACKING	View Remove
No	Manufacturer Name	Manufacturer Address	Processing Step	GMP Certificate																	
No.	Manufacturer Name	Manufacturer Address	Processing Step	GMP																	
1	FERTIN PHARMA A/S	DANDYVEJ VEJILE VEJILE	PACKING	View Remove																	
<p><b>EX26</b></p>	<p><b>Explanation:</b></p> <p>Click on Manufacturer(s) Involved field to search for a manufacturer.</p> <p>Select Address and Processing Step.</p> <p>Upload GMP by clicking on the Choose File button</p> <p>Click on ADD button to add the selected manufacturer.</p>																				
<p><b>FG27</b></p>	<p><b>E8. Importer :</b> ⓘ</p> <p>a) Current Importer Involved:</p> <table border="1" data-bbox="300 1164 1220 1265"> <thead> <tr> <th>No</th> <th>Importer Name</th> <th>Importer Address</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>UNIMED SDN BHD</td> <td>53, JALAN TEMBAGA SD5/2B,BANDAR BARU SRI DAMANSARA</td> </tr> </tbody> </table> <p>b) Proposed Importer Involved:</p> <p>Importer: GERMAX SDN. BHD. : NO:10, JALAN PJU 3/48, SUNWAY DAMANSARA TECHNOLOGY P...</p> <p>Importer Address: NO:10, JALAN PJU 3/48, SUNWAY DAMANSARA TECHNOLOGY PARK</p> <p>ADD</p> <table border="1" data-bbox="300 1422 1220 1489"> <thead> <tr> <th>No.</th> <th>Manufacturer Name</th> <th>Manufacturer Address</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>GERMAX SDN. BHD.</td> <td>NO:10, JALAN PJU 3/48, SUNWAY DAMANSARA TECHNOLOGY PARK</td> </tr> </tbody> </table> <p>Remove</p> <p>Remarks [ E8 ]</p>	No	Importer Name	Importer Address	1	UNIMED SDN BHD	53, JALAN TEMBAGA SD5/2B,BANDAR BARU SRI DAMANSARA	No.	Manufacturer Name	Manufacturer Address	1	GERMAX SDN. BHD.	NO:10, JALAN PJU 3/48, SUNWAY DAMANSARA TECHNOLOGY PARK								
No	Importer Name	Importer Address																			
1	UNIMED SDN BHD	53, JALAN TEMBAGA SD5/2B,BANDAR BARU SRI DAMANSARA																			
No.	Manufacturer Name	Manufacturer Address																			
1	GERMAX SDN. BHD.	NO:10, JALAN PJU 3/48, SUNWAY DAMANSARA TECHNOLOGY PARK																			
<p><b>EX27</b></p>	<p><b>Explanation:</b></p> <p>Click on Importer field to search.</p> <p>Select Importer Address.</p> <p>Click on ADD button to add the selected Importer.</p>																				



<p><b>FG28</b></p>	<p><b>E9. Store Address :</b></p> <p>a) Current Store Involved:</p> <table border="1"> <thead> <tr> <th>No</th> <th>Store Name</th> <th>Store Address</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>b) Proposed Store Involved:</p> <p>Store: NUFERA BIO TECH SDN BHD : SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 ...</p> <p>Store Address: SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA.</p> <p><b>ADD</b></p> <table border="1"> <thead> <tr> <th>No.</th> <th>Store Name</th> <th>Store Address</th> <th> </th> </tr> </thead> <tbody> <tr> <td>1</td> <td>NUFERA BIO TECH SDN BHD</td> <td>SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA,</td> <td><b>Remove</b></td> </tr> </tbody> </table> <p><b>Remarks [ E9 ]</b></p>	No	Store Name	Store Address				No.	Store Name	Store Address		1	NUFERA BIO TECH SDN BHD	SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA,	<b>Remove</b>
No	Store Name	Store Address													
No.	Store Name	Store Address													
1	NUFERA BIO TECH SDN BHD	SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA,	<b>Remove</b>												
<p><b>EX28</b></p>	<p><b>Explanation:</b></p> <p>Click on Store field to search.</p> <p>Select Store Address.</p> <p>Click on ADD button to add the selected Store.</p>														
<p><b>FG29</b></p>	<p><b>E10. Summary of Product Characteristic / Product Data Sheet (if applicable) :</b></p> <p>a) Current Summary of Product Characteristic / Product Data Sheet (if applicable) :</p> <p> </p> <p>b) Proposed Summary of Product Characteristic / Product Data Sheet (if applicable) :</p> <p>Choose File Penguins.jpg <b>View</b> <b>Delete</b></p> <p><b>Remarks [ E10 ]</b></p> <hr/> <p><b>E11. Company Core Data Sheet (CCDS) (if applicable) :</b></p> <p>a) Current Company Core Data Sheet (CCDS) (if applicable) :</p> <p> </p> <p>b) Proposed Company Core Data Sheet (CCDS) (if applicable) :</p> <p>Choose File Koala.jpg <b>View</b> <b>Delete</b></p> <p><b>Remarks [ E11 ]</b></p> <hr/> <p><b>E12. Analysis Protocol :</b></p> <p>a) Current Analysis Protocol :</p> <p> </p> <p>b) Proposed Company Analysis Protocol :</p> <p>Choose File Penguins.jpg <b>View</b> <b>Delete</b></p> <p><b>Remarks [ E12 ]</b></p>														
<p><b>EX29</b></p>	<p><b>Explanation:</b></p> <p>Click on Choose File button to select and upload attachment file for E10, E11, and E12.</p>														

<p><b>FG30</b></p>	
<p><b>EX30</b></p>	<p><b>Explanation:</b> Click on Part 1/ Section E / E13. Click Choose File button to select and upload attachment.</p>
<p><b>FG31</b></p>	

<p><b>EX31</b></p>	<p><b>Explanation:</b> Click on Part 1 / Section E / E14 – E17. Click Choose File button to select and upload attachment.</p>								
<p><b>FG32</b></p>	 <p>The screenshot shows a navigation bar with tabs P1-P2, P3, P4, P5, and P6-P9. Below are three sections:</p> <ul style="list-style-type: none"> <li><b>SECTION A : QUALITY OVERALL SUMMARY</b> <ul style="list-style-type: none"> <li>a) Current SECTION A : QUALITY OVERALL SUMMARY (text area)</li> <li>b) Proposed SECTION A : QUALITY OVERALL SUMMARY           <ul style="list-style-type: none"> <li>Choose File (Please Select A File)</li> <li>Remarks [ P-SA ]</li> </ul> </li> </ul> </li> <li><b>SECTION B : TABLE OF CONTENTS</b> <ul style="list-style-type: none"> <li>a) Current SECTION B : TABLE OF CONTENTS (text area)</li> <li>b) Proposed SECTION B : TABLE OF CONTENTS           <ul style="list-style-type: none"> <li>Choose File (Please Select A File)</li> <li>Remarks [ P-SB ]</li> </ul> </li> </ul> </li> <li><b>SECTION C : BODY OF DATA</b> <ul style="list-style-type: none"> <li>a) Current SECTION C : BODY OF DATA* (text area)</li> <li>b) Proposed SECTION C : BODY OF DATA*           <ul style="list-style-type: none"> <li>Choose File (Please Select A File)</li> <li>Remarks [ P-SC ]</li> </ul> </li> </ul> </li> </ul>								
<p><b>EX32</b></p>	<p><b>Explanation:</b> Click Choose File button to select and upload attachment.</p>								
<p><b>FG33</b></p>	 <p>The screenshot shows 'P1. Description and Composition' with the following elements:</p> <ul style="list-style-type: none"> <li>a) Current Description and Composition: Pink coloured, Film coated, round biconvex tablets.</li> <li>Attachment Table:       <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>copp(33).jpg</td> <td>08-02-2016</td> <td></td> </tr> </tbody> </table> </li> <li>b) Proposed Description and Composition: New Test Proposed Description and Composition ...</li> <li>Choose File (Jellyfish.jpg)</li> <li>Remarks [ P1 ]</li> </ul>	#	Attachment	Date of Attach		1	copp(33).jpg	08-02-2016	
#	Attachment	Date of Attach							
1	copp(33).jpg	08-02-2016							
<p><b>EX33</b></p>	<p><b>Explanation:</b> Type or paste text on the text area and click on Choose File Button to upload attachment.</p>								

<p><b>FG34</b></p>	<p>P2. Pharmaceutical Development</p> <hr/> <p><b>P2.1 Information on Development Studies</b> </p> <p>a) Current Information on Development Studies</p> <p>Not Applicable</p> <p>b) Proposed Information on Development Studies</p> <div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div> <p>Choose File <span style="margin-left: 100px;">Please Select A File</span></p> <p> Remarks [ P2.1 ]</p>
<p><b>EX34</b></p>	<p><b>Explanation:</b></p> <p>Type or paste text on the text area and click on Choose File Button to upload attachment.</p> <p>Key-in for the following P2.2 – P2.7.</p>

FG35

P1-P2 P3 P4 P5 P6-P9

P3. Manufacturer

**P3.1 Batch Formula**

a) Current Batch Formula

---

**P3.2 Manufacturing Process and Process Control**

a) Current Manufacturing Process and Process Control

Please Refer Section B1.2

b) Proposed Manufacturing Process and Process Control

Please Select A File

Remarks [ P3-2 ]

---

**P3.2.1 Manufacturing Process Flowchart**

a) Current Manufacturing Process Flowchart

b) Proposed Manufacturing Process Flowchart

Please Select A File

Remarks [ P3-2-1 ]

---

**P3.3 Control of Critical Steps and Intermediate**

a) Current Control of Critical Steps and Intermediate

IN PROCESS QUALITY CONTROL:

SL.NO.	TESTS	Stage at which Test is done	Frequency of Sampling	Quantity of Sample taken each time.
1.	Description	After drying of granules	Once	5 g granules
2.	Moisture content	After drying of granules	Once	5 g granules
3.	Assay	Before compression	Once	20 g granules ready for

b) Proposed Control of Critical Steps and Intermediate

Please Select A File

Remarks [ P3-3 ]

---

**P3.4 Process Validation and/or Evaluation**

a) Current Control of Critical Steps and Intermediate

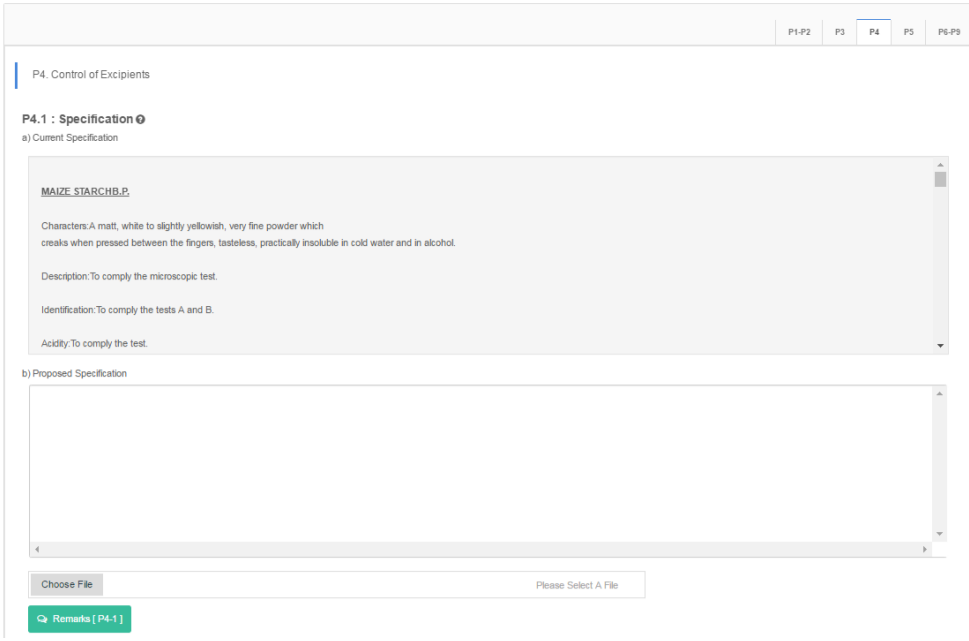
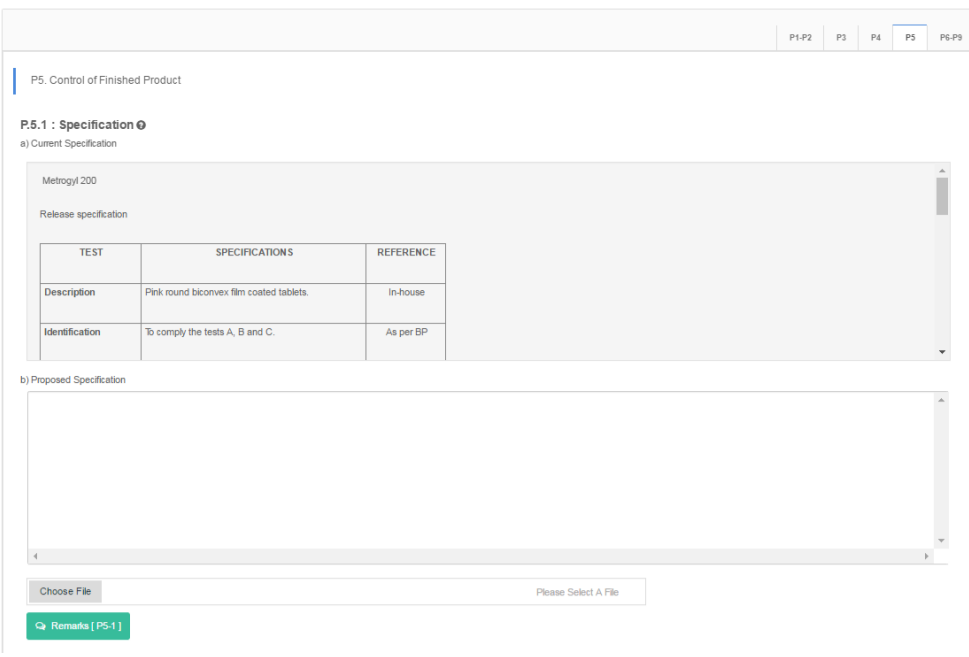
b) Proposed Control of Critical Steps and Intermediate

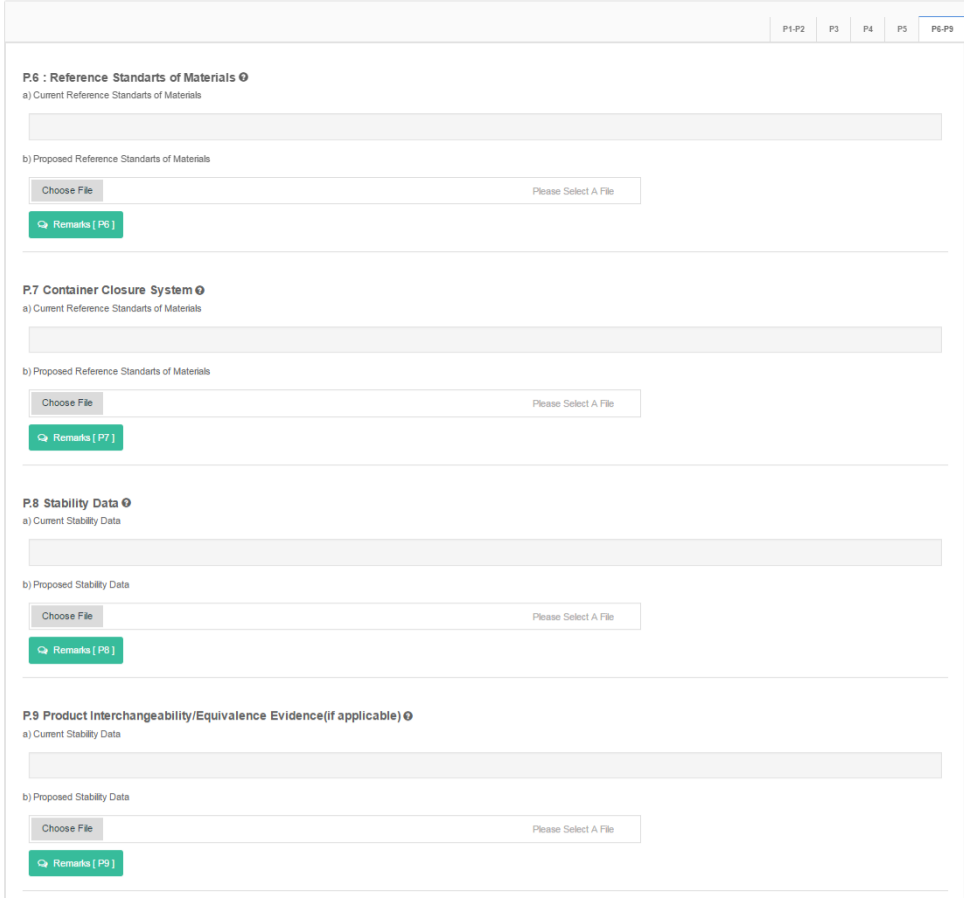
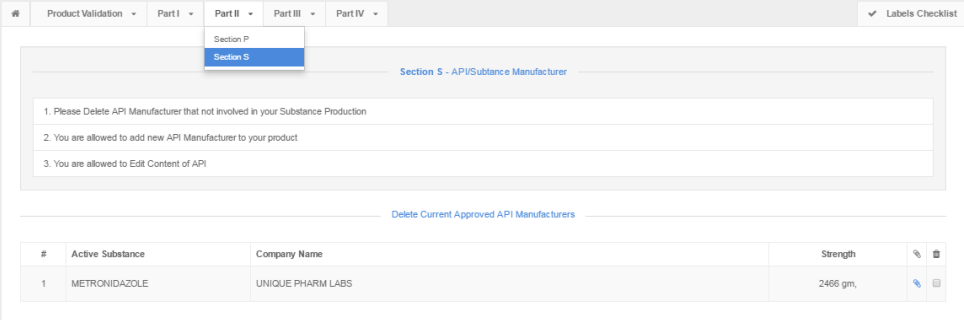
Please Select A File

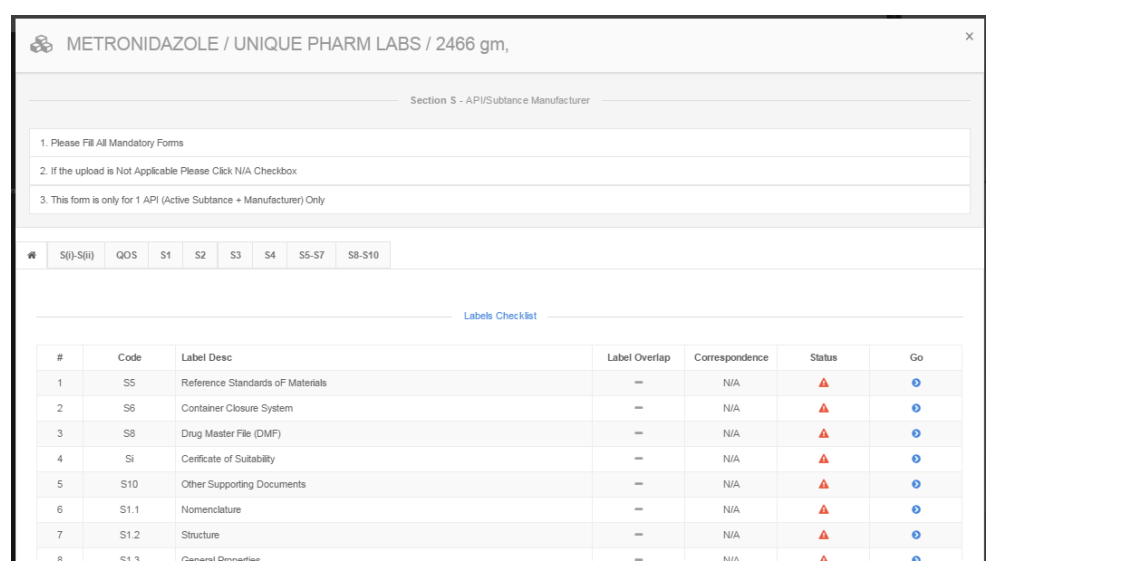
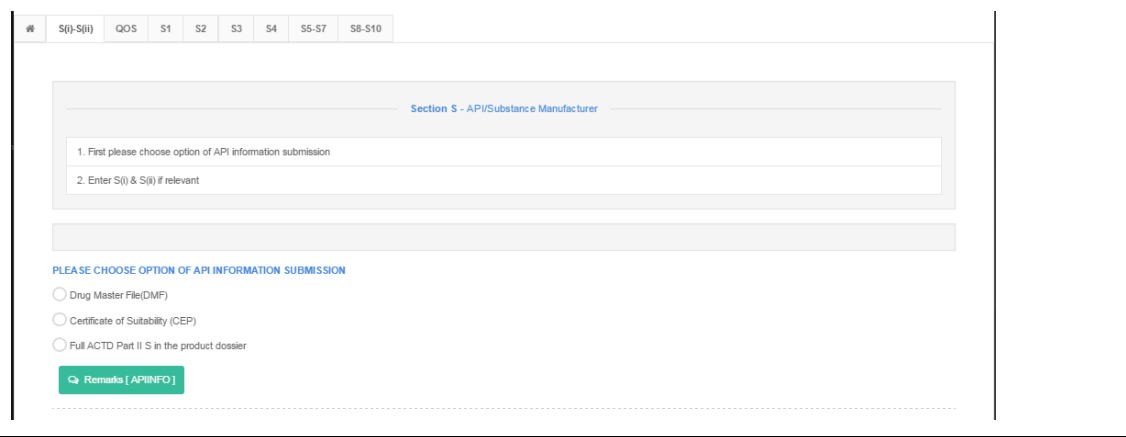
Remarks [ P3-4 ]

EX35

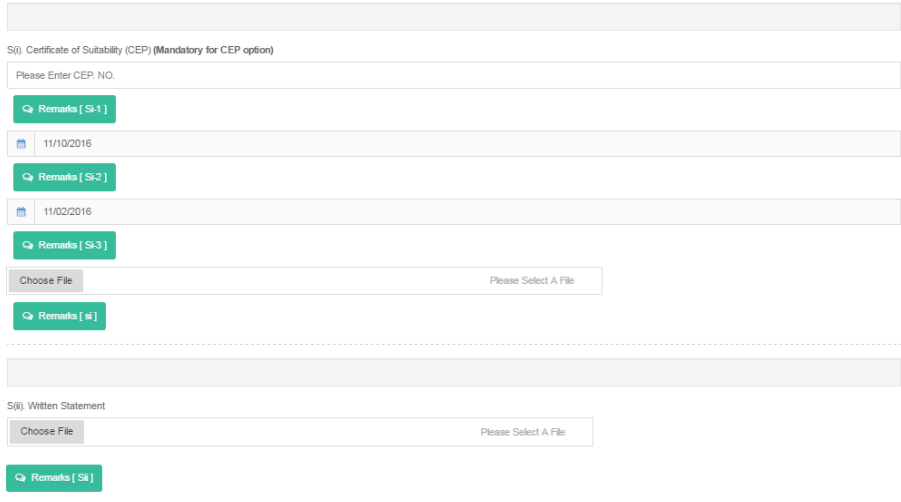
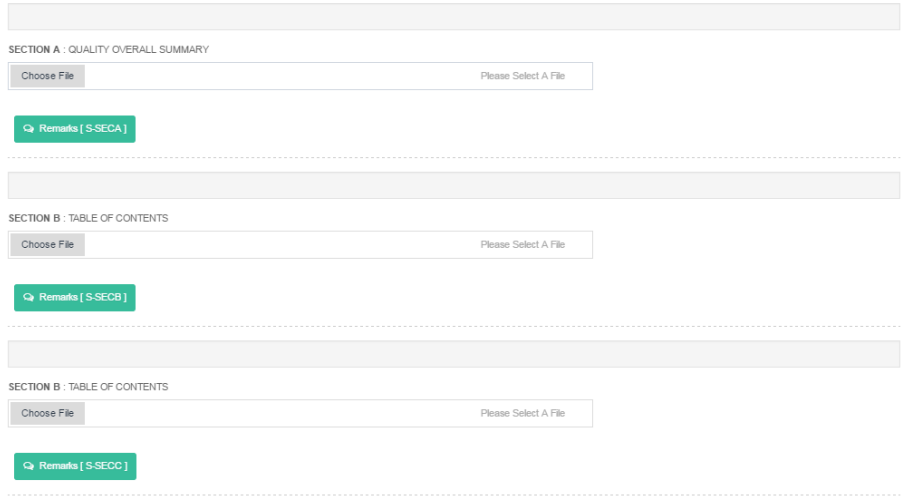
**Explanation:**  
Type or paste text on the text area and click on Choose File Button to upload attachment.  
Key-in for the following P3.2 – P3.4.

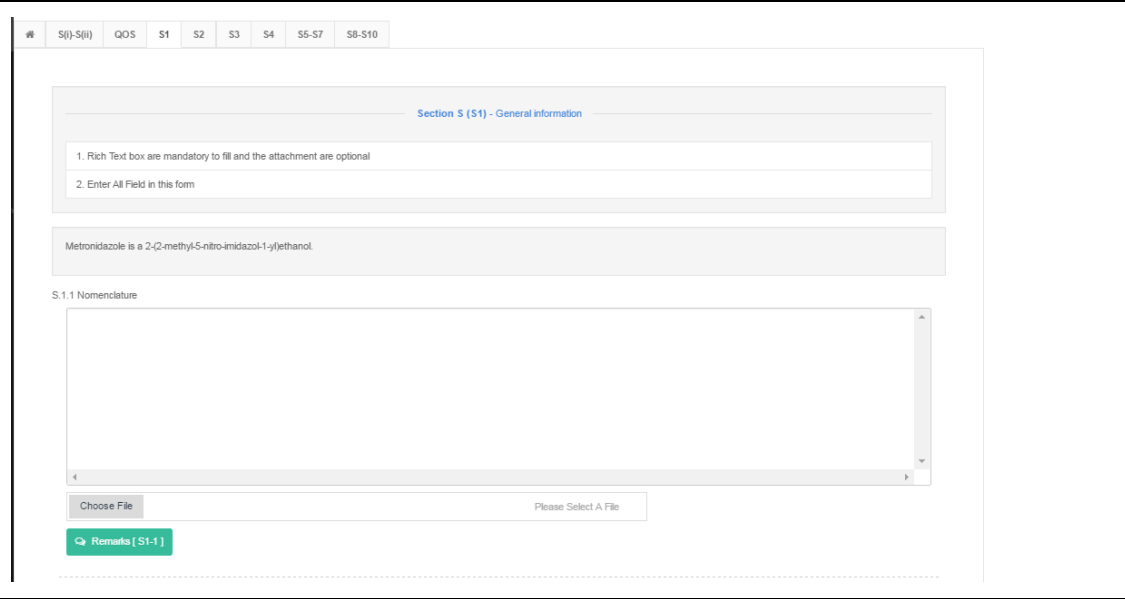
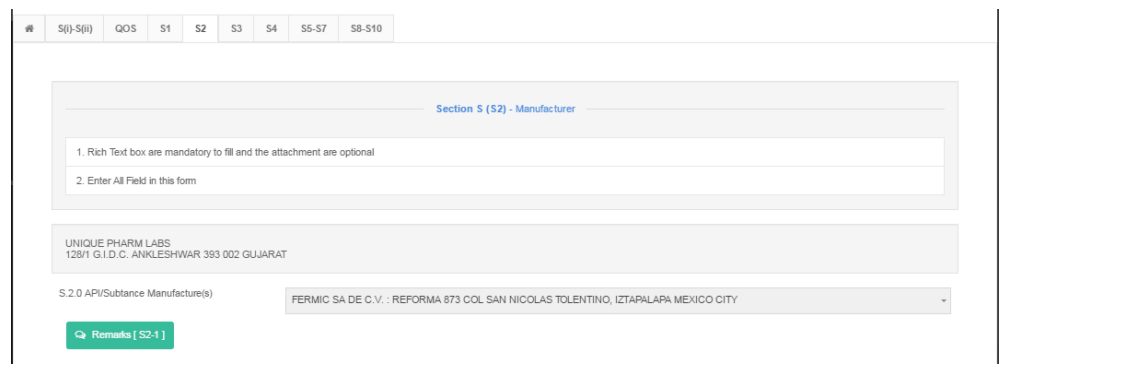
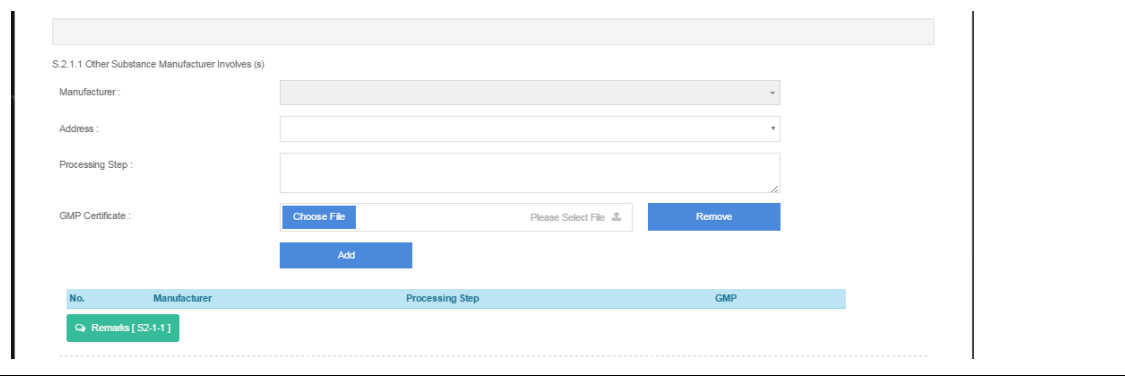
<p><b>FG36</b></p>										
<p><b>EX36</b></p>	<p><b>Explanation:</b> Type or paste text on the text area and click on Choose File Button to upload attachment. Key-in for the following P4.1 – P4.6.</p>									
<p><b>FG37</b></p>	 <table border="1" data-bbox="300 1346 715 1464"> <thead> <tr> <th>TEST</th> <th>SPECIFICATIONS</th> <th>REFERENCE</th> </tr> </thead> <tbody> <tr> <td>Description</td> <td>Pink round biconvex film coated tablets.</td> <td>In-house</td> </tr> <tr> <td>Identification</td> <td>To comply the tests A, B and C.</td> <td>As per BP</td> </tr> </tbody> </table>	TEST	SPECIFICATIONS	REFERENCE	Description	Pink round biconvex film coated tablets.	In-house	Identification	To comply the tests A, B and C.	As per BP
TEST	SPECIFICATIONS	REFERENCE								
Description	Pink round biconvex film coated tablets.	In-house								
Identification	To comply the tests A, B and C.	As per BP								
<p><b>EX37</b></p>	<p><b>Explanation:</b> Type or paste text on the text area and click on Choose File Button to upload attachment. Key-in for the following P5.1 – P5.11.</p>									

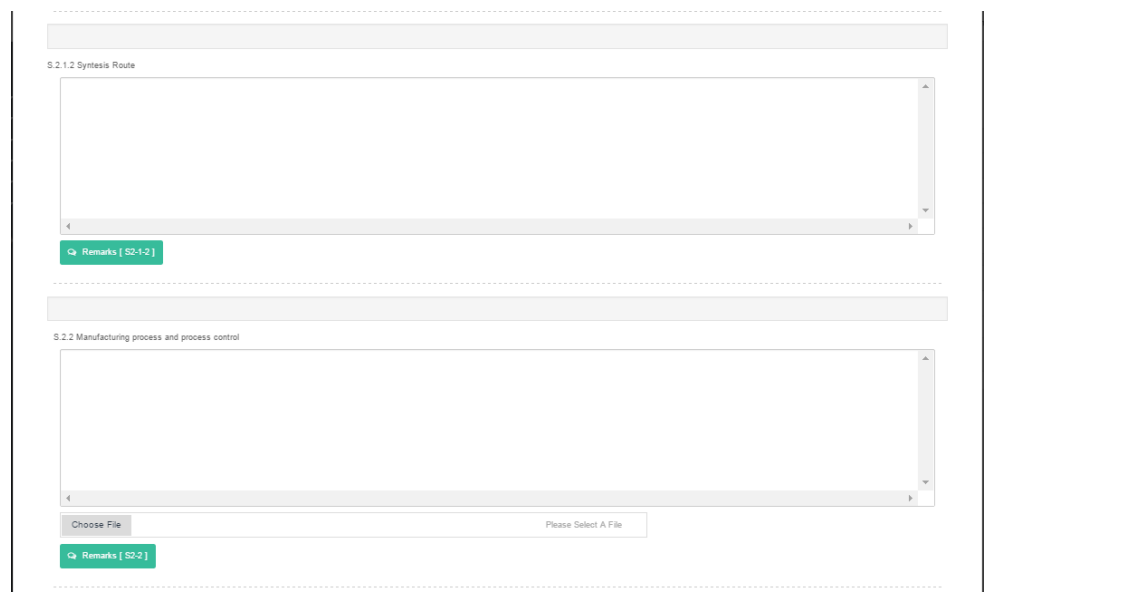
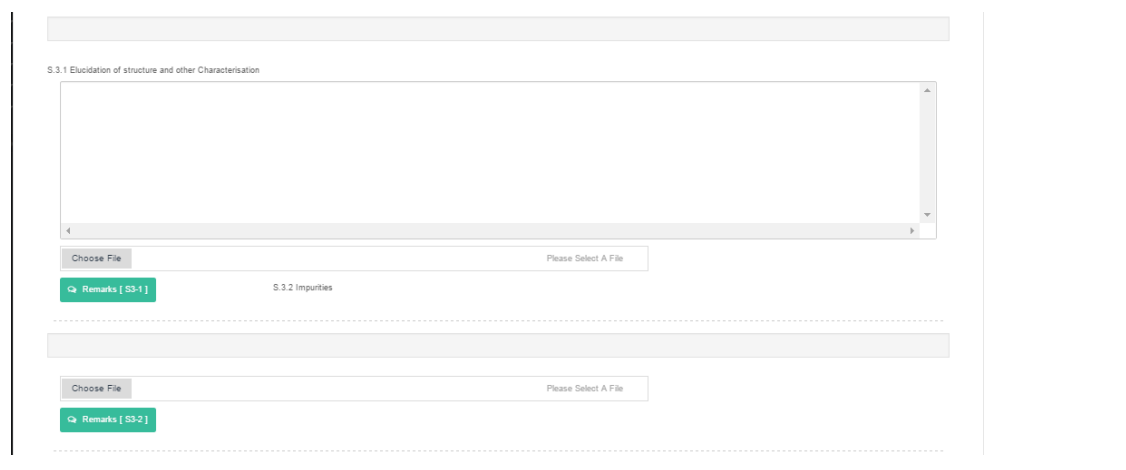
<p><b>FG38</b></p>	
<p><b>EX38</b></p>	<p><b>Explanation:</b> Click on Choose File button to upload attachment for P6 – P9.</p>
<p><b>FG39</b></p>	
<p><b>EX39</b></p>	<p><b>Explanation:</b> Click on Part 2 / Section S Click on the clip-icon to open the popup form.</p>

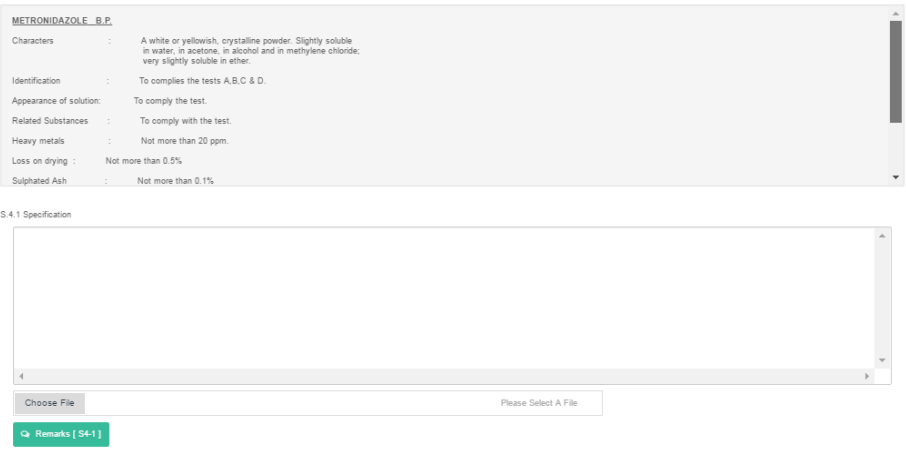
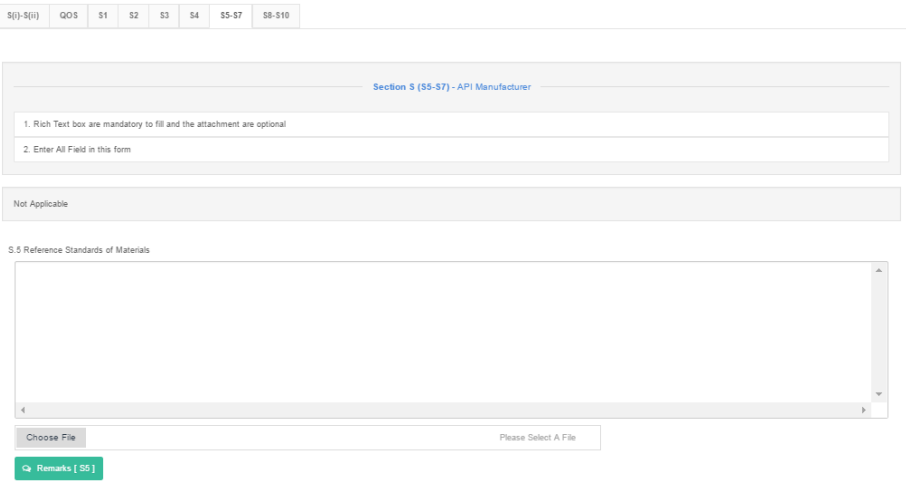
<p><b>FG40</b></p>	 <table border="1"> <thead> <tr> <th>#</th> <th>S(i)-S(ii)</th> <th>QOS</th> <th>S1</th> <th>S2</th> <th>S3</th> <th>S4</th> <th>S5-S7</th> <th>S8-S10</th> </tr> </thead> <tbody> <tr> <td colspan="9" style="text-align: center;"><a href="#">Labels Checklist</a></td> </tr> <tr> <th>#</th> <th>Code</th> <th>Label Desc</th> <th>Label Overlap</th> <th>Correspondence</th> <th>Status</th> <th>Go</th> <td colspan="2"></td> </tr> <tr> <td>1</td> <td>S5</td> <td>Reference Standards of Materials</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>2</td> <td>S6</td> <td>Container Closure System</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>3</td> <td>S8</td> <td>Drug Master File (DMF)</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>4</td> <td>Si</td> <td>Certificate of Suitability</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>5</td> <td>S10</td> <td>Other Supporting Documents</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>6</td> <td>S1.1</td> <td>Nomenclature</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>7</td> <td>S1.2</td> <td>Structure</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> <tr> <td>8</td> <td>S1.3</td> <td>General Description</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>ⓘ</td> <td colspan="2"></td> </tr> </tbody> </table>	#	S(i)-S(ii)	QOS	S1	S2	S3	S4	S5-S7	S8-S10	<a href="#">Labels Checklist</a>									#	Code	Label Desc	Label Overlap	Correspondence	Status	Go			1	S5	Reference Standards of Materials	—	N/A	▲	ⓘ			2	S6	Container Closure System	—	N/A	▲	ⓘ			3	S8	Drug Master File (DMF)	—	N/A	▲	ⓘ			4	Si	Certificate of Suitability	—	N/A	▲	ⓘ			5	S10	Other Supporting Documents	—	N/A	▲	ⓘ			6	S1.1	Nomenclature	—	N/A	▲	ⓘ			7	S1.2	Structure	—	N/A	▲	ⓘ			8	S1.3	General Description	—	N/A	▲	ⓘ		
#	S(i)-S(ii)	QOS	S1	S2	S3	S4	S5-S7	S8-S10																																																																																												
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1	S5	Reference Standards of Materials	—	N/A	▲	ⓘ																																																																																														
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3	S8	Drug Master File (DMF)	—	N/A	▲	ⓘ																																																																																														
4	Si	Certificate of Suitability	—	N/A	▲	ⓘ																																																																																														
5	S10	Other Supporting Documents	—	N/A	▲	ⓘ																																																																																														
6	S1.1	Nomenclature	—	N/A	▲	ⓘ																																																																																														
7	S1.2	Structure	—	N/A	▲	ⓘ																																																																																														
8	S1.3	General Description	—	N/A	▲	ⓘ																																																																																														
<p><b>EX40</b></p>	<p><b>Explanation:</b> FG40 shows a popup form for Section S.</p>																																																																																																			
<p><b>FG41</b></p>																																																																																																				
<p><b>EX41</b></p>	<p><b>Explanation:</b> Click on S(i)-S(ii) Select API Information</p>																																																																																																			

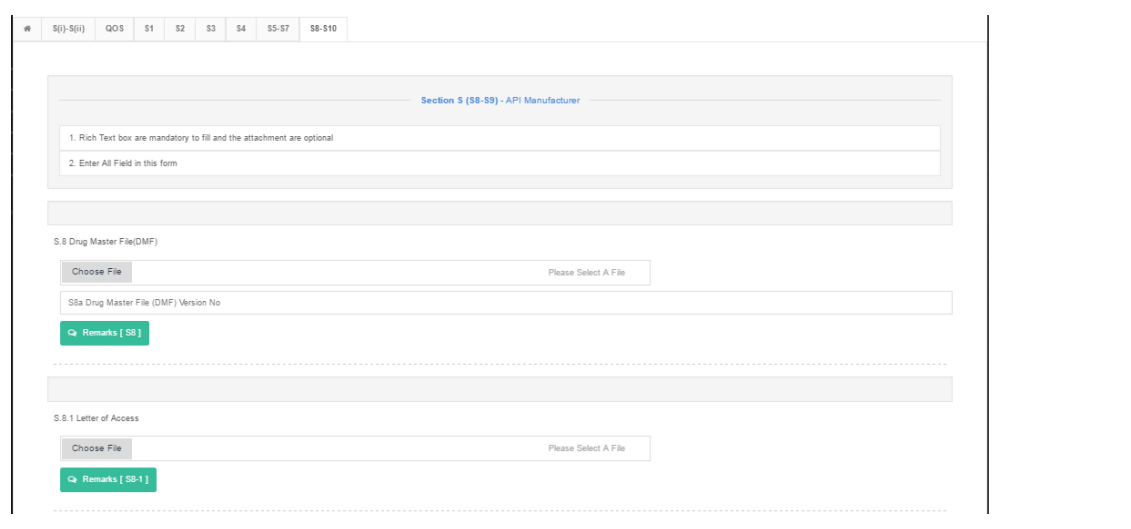
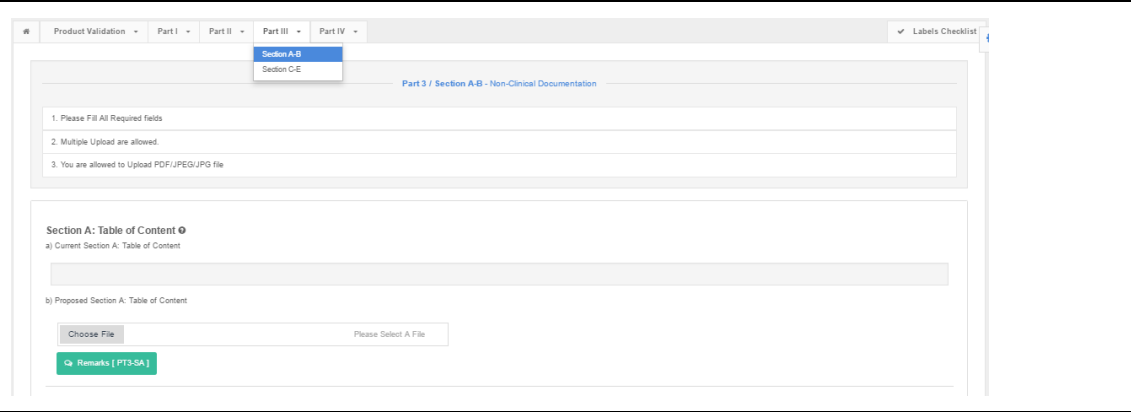


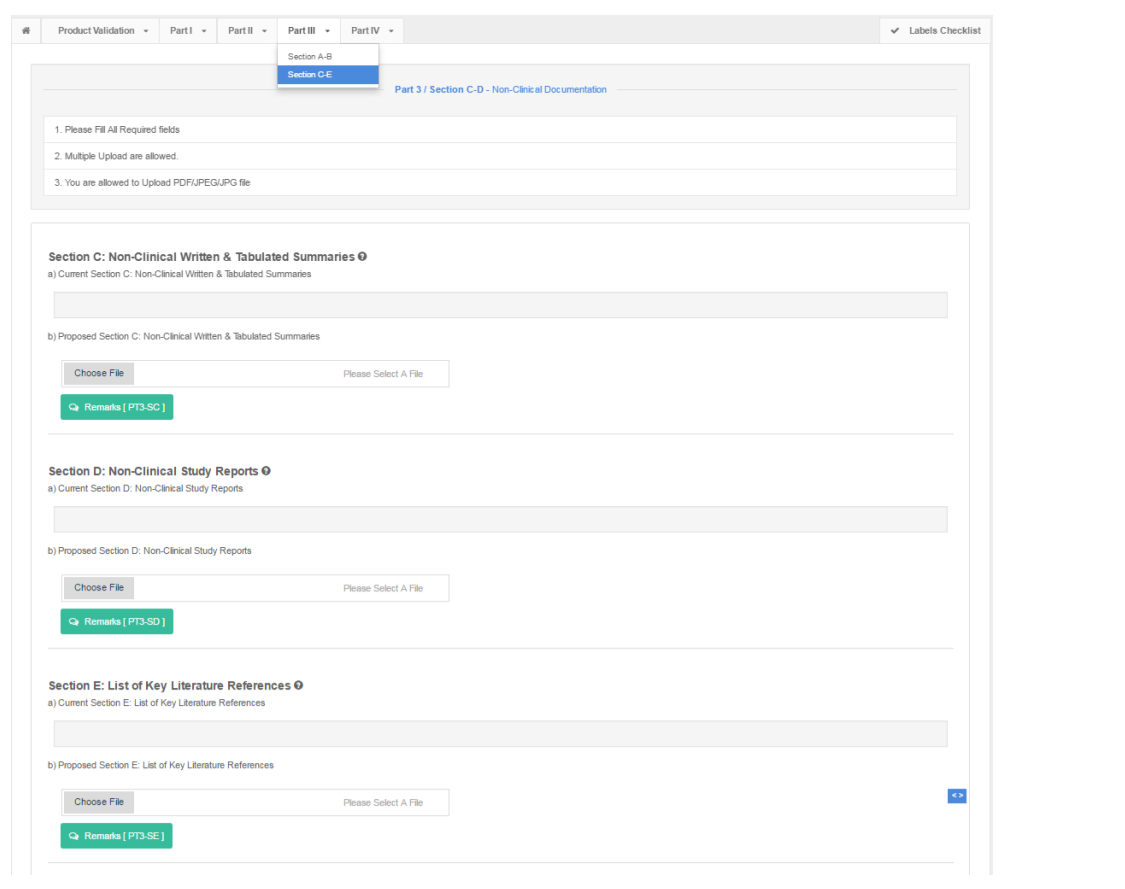
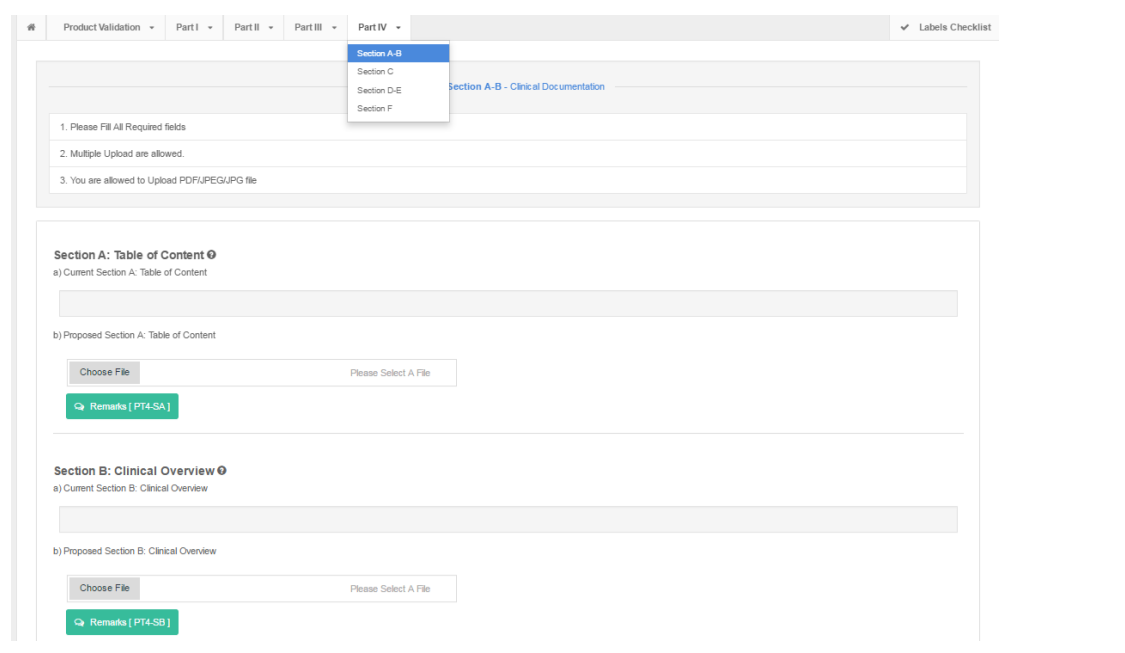
<p><b>FG42</b></p>	
<p><b>EX42</b></p>	<p><b>Explanation:</b> Select Date by clicking on the calendar-icon. Click on Choose File button to upload attachment</p>
<p><b>FG43</b></p>	
<p><b>EX43</b></p>	<p><b>Explanation:</b> Click on QOS Click on Choose File button to upload attachment</p>

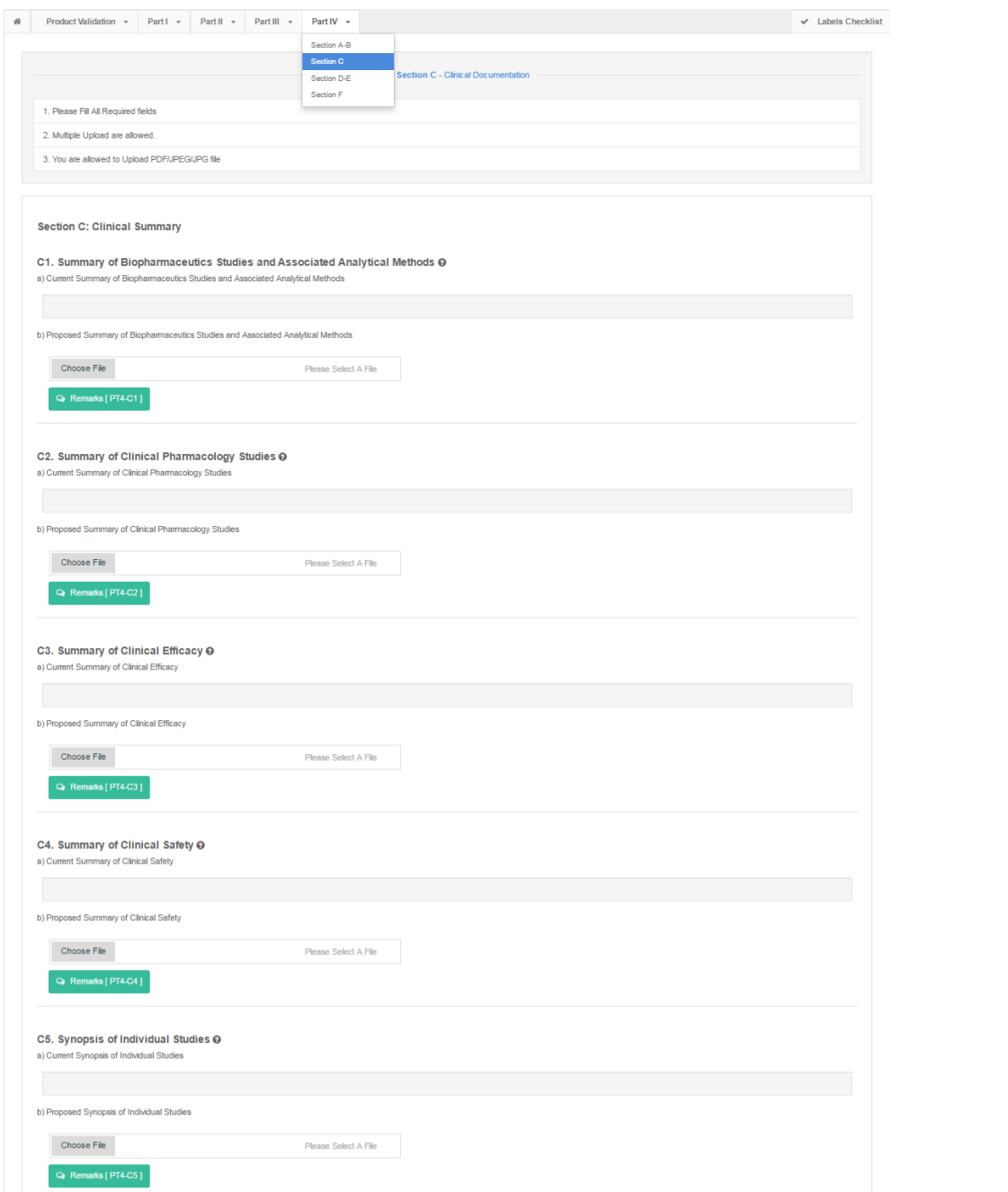
<p><b>FG44</b></p>	
<p><b>EX44</b></p>	<p><b>Explanation:</b> Click on S1 Type or paste text into the text area. Click on Choose File button to upload attachment. Key-in the following S.1.1 – S.1.3</p>
<p><b>FG45</b></p>	
<p><b>EX45</b></p>	<p><b>Explanation:</b> Click on the dropdown option to search for API Substance Manufacturer.</p>
<p><b>FG46</b></p>	
<p><b>EX46</b></p>	<p><b>Explanation:</b> Click on Manufacturer field to search for a manufacturer.</p>

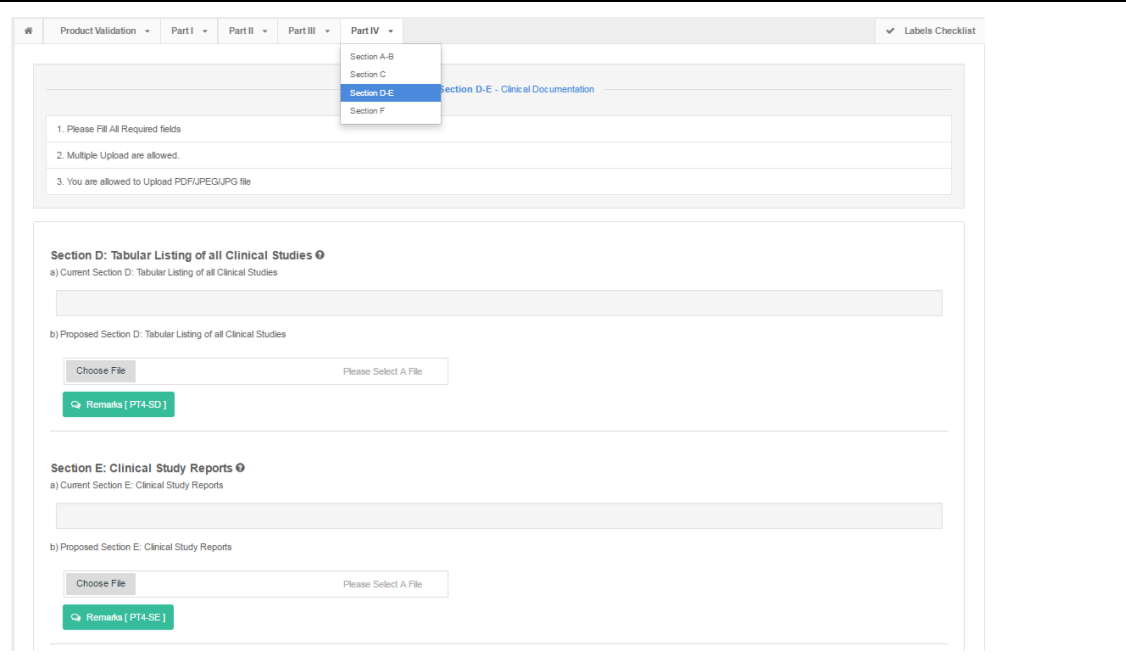
	<p>Select Address and key-in Processing Step. Upload GMP by clicking on the Choose File button Click on ADD button to add the selected manufacturer.</p>
<p><b>FG47</b></p>	
<p><b>EX47</b></p>	<p><b>Explanation:</b> Type or paste text into the text area. Click on Choose File button to upload attachment.</p>
<p><b>FG48</b></p>	
<p><b>EX48</b></p>	<p><b>Explanation:</b> Click on S3 Type or paste text into the text area. Click on Choose File button to upload attachment.</p>

<p><b>FG49</b></p>	
<p><b>EX49</b></p>	<p><b>Explanation:</b> Click on S4 Type or paste text into the text area. Click on Choose File button to upload attachment. Key-in the following S.4.1 – S.4.5</p>
<p><b>FG50</b></p>	
<p><b>EX50</b></p>	<p><b>Explanation:</b> Click on S5-S7 Type or paste text into the text area. Click on Choose File button to upload attachment. Key-in the following S.5 – S.7</p>

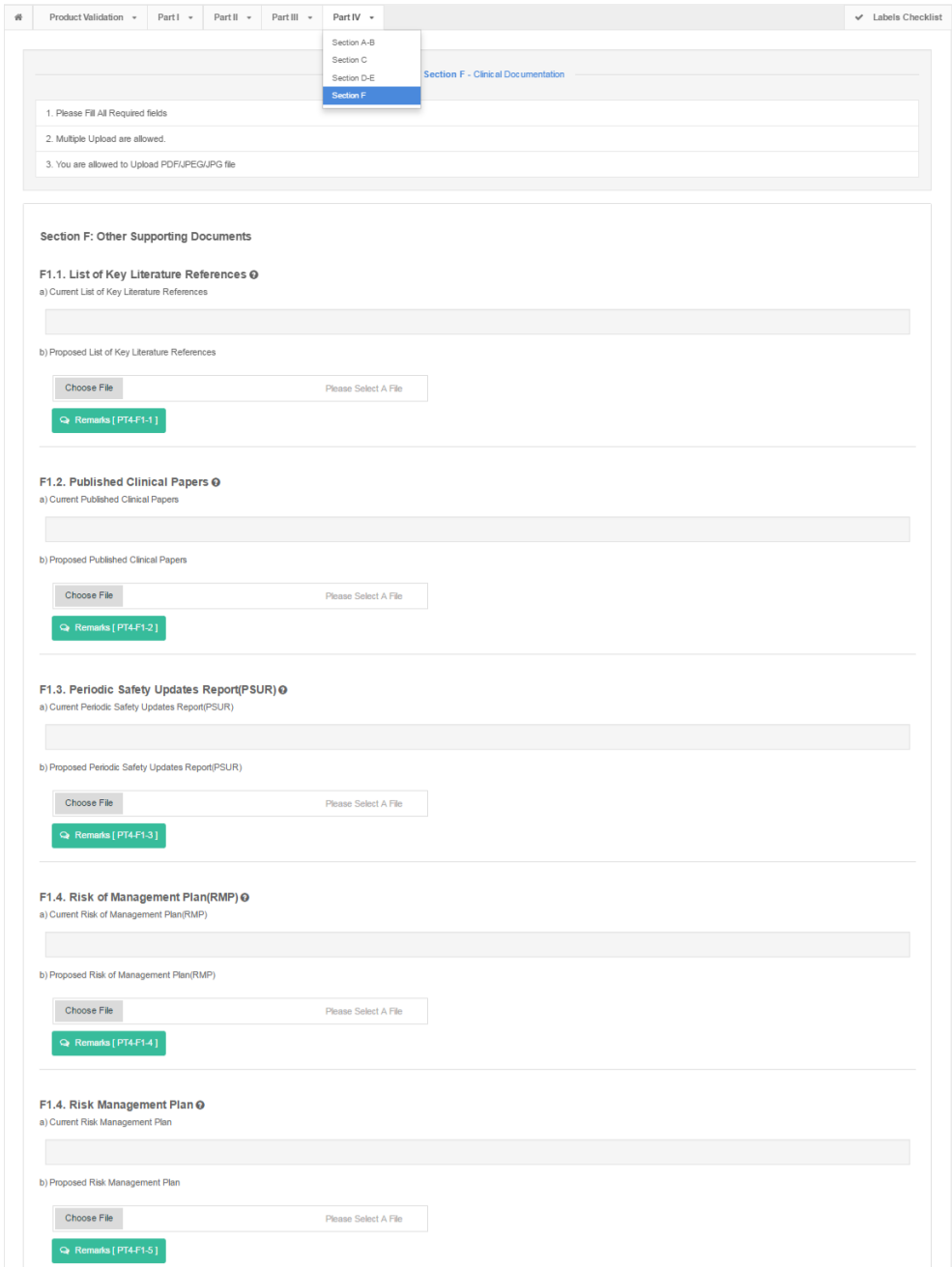

<p><b>FG51</b></p>	
<p><b>EX51</b></p>	<p><b>Explanation:</b> Click on S8-10 Type or paste text into the text area. Click on Choose File button to upload attachment. Click on calendar-icon to select date Key-in the following S8 – S10 Click anywhere outside the popup form to close.</p>
<p><b>FG52</b></p>	
<p><b>EX52</b></p>	<p><b>Explanation:</b> Click on Part 3 / Section A-B Click on Choose File button to upload attachment. Key-in the following Section A – Section B</p>

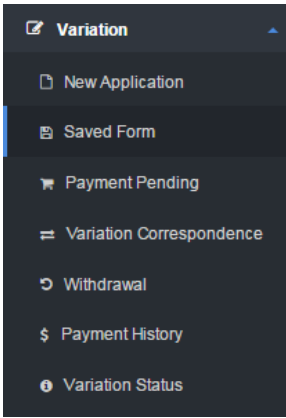
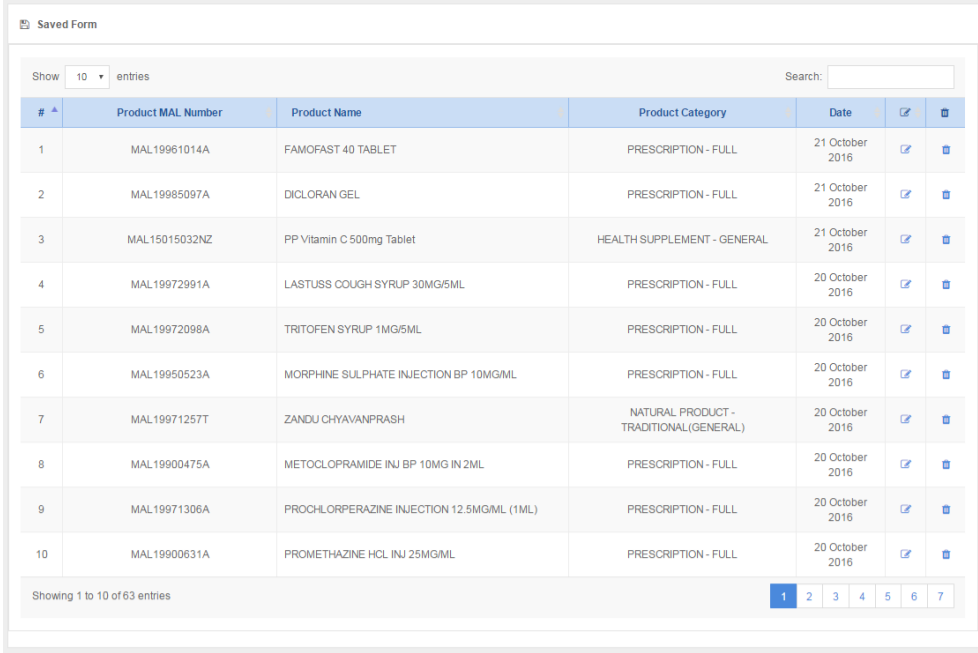
<p><b>FG53</b></p>	
<p><b>EX53</b></p>	<p><b>Explanation:</b> Click on Choose File button to select and upload attachment.</p>
<p><b>FG54</b></p>	
<p><b>EX54</b></p>	<p><b>Explanation:</b> Click on Choose File button to select and upload attachment.</p>

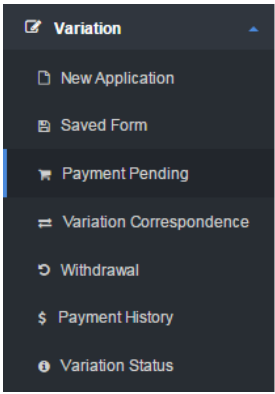
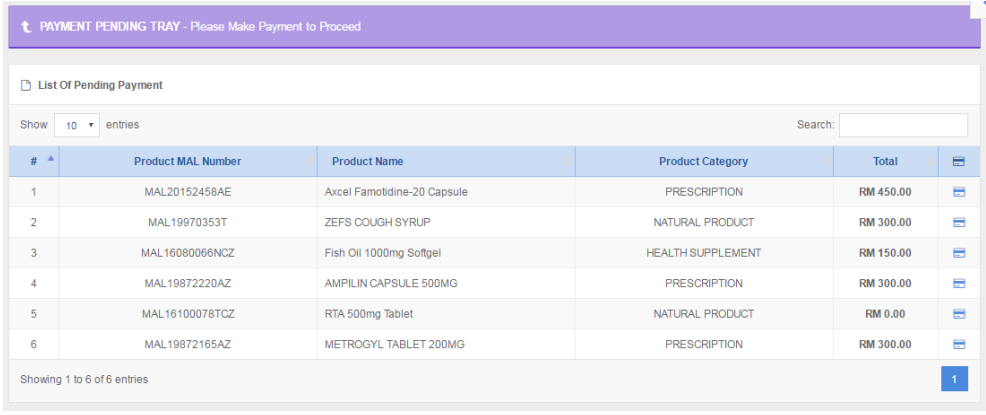
<b>FG55</b>	 <p>The screenshot displays the 'Section C - Clinical Documentation' interface. At the top, a navigation menu shows 'Part IV' selected, with a dropdown menu open containing 'Section A-B', 'Section C', 'Section D-E', and 'Section F'. Below the menu, there are instructions: '1. Please Fill All Required fields', '2. Multiple Upload are allowed.', and '3. You are allowed to Upload PDF/JPEG/JPG file'. The main content area is titled 'Section C: Clinical Summary' and contains five sub-sections: C1. Summary of Biopharmaceutics Studies and Associated Analytical Methods, C2. Summary of Clinical Pharmacology Studies, C3. Summary of Clinical Efficacy, C4. Summary of Clinical Safety, and C5. Synopsis of Individual Studies. Each sub-section has a 'Current Summary' and a 'Proposed Summary' field, a 'Choose File' button, and a 'Remarks' button (e.g., 'Remarks [PT4-C1]').</p>
<b>EX55</b>	<p><b>Explanation:</b> Click on Part 4 / Section C Click on Choose File button to select and upload attachment.</p>

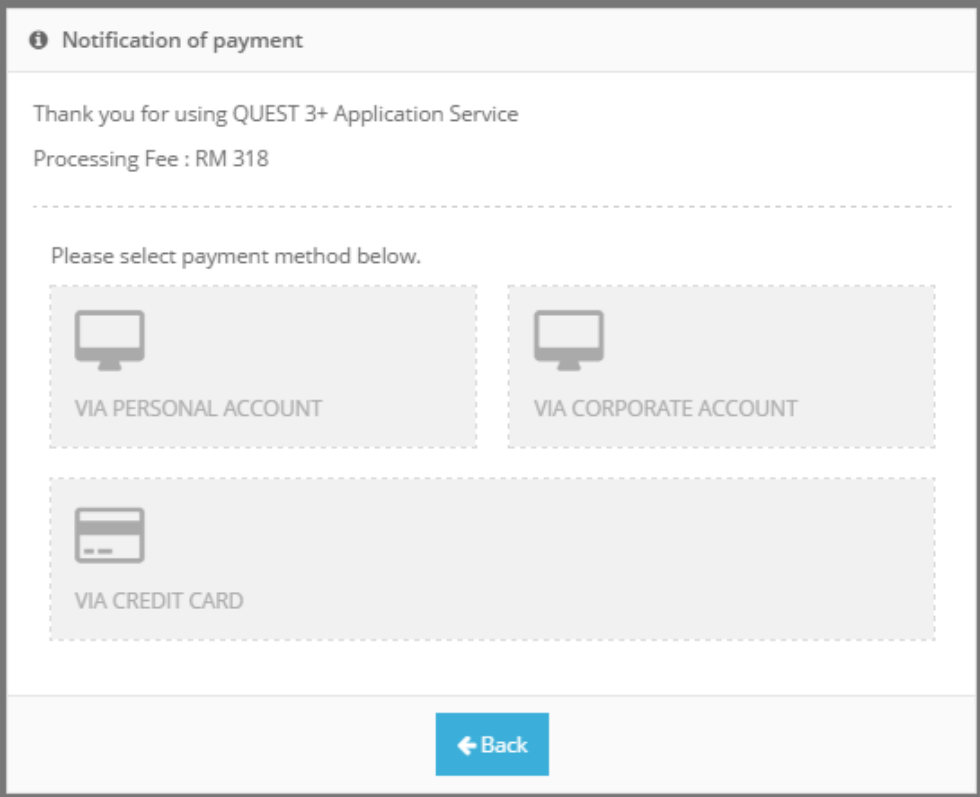
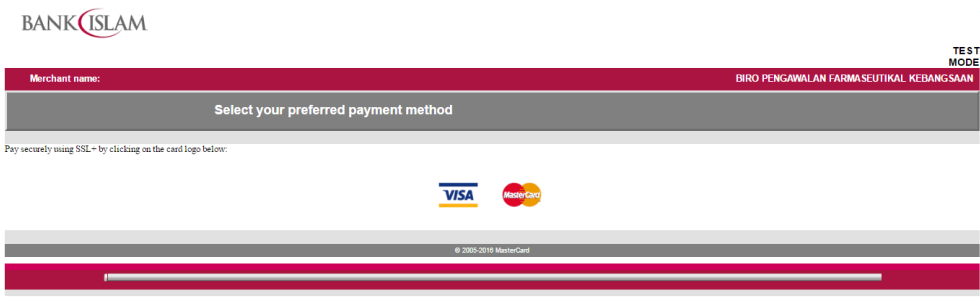
<p><b>FG56</b></p>	
<p><b>EX56</b></p>	<p><b>Explanation:</b> Click on Part 4 / Section D-E Click on Choose File button to select and upload attachment.</p>

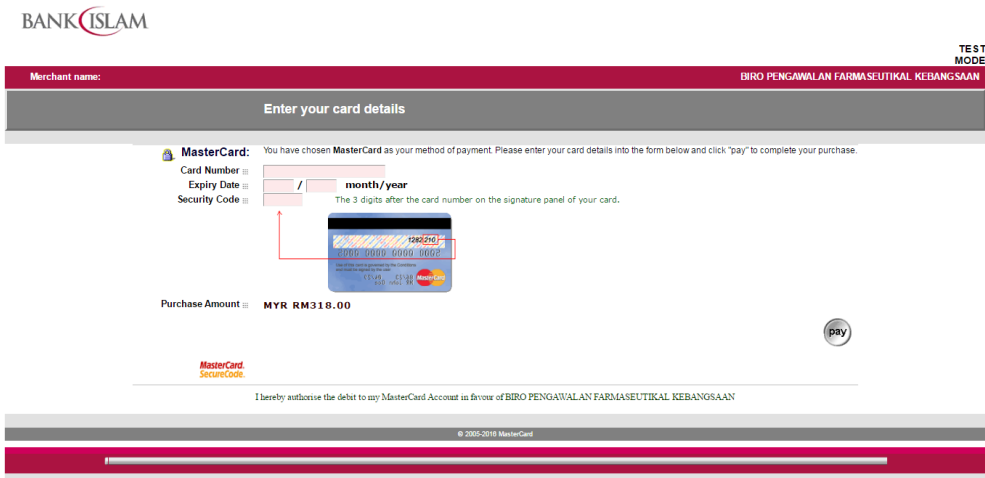
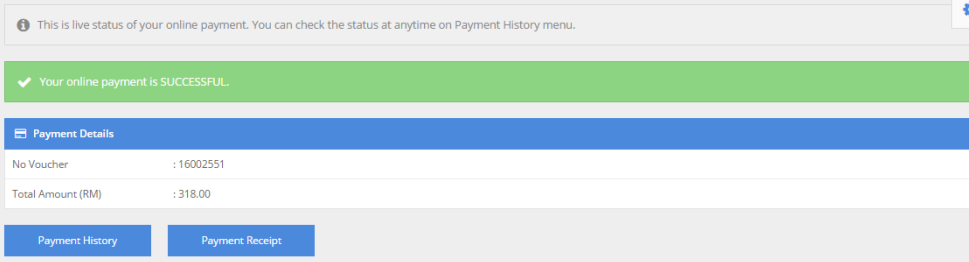
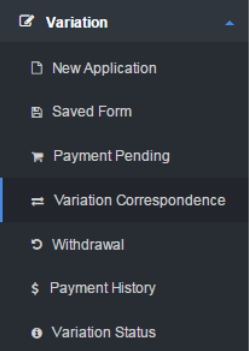


<p><b>FG57</b></p>	
<p><b>EX57</b></p>	<p><b>Explanation:</b> Click on Part 4 / Section F Click on Choose File button to select and upload attachment.</p>
<p><b>FG58</b></p>	
<p><b>EX58</b></p>	<p><b>Explanation:</b> After finish filling all the required fields. Click on home-icon and scroll down to bottom of page. Click on Submit Variation button as shown in FG58</p>

2.2	<b>Saved Form</b>																																																																													
FG59																																																																														
EX59	<p><b>Explanation:</b> Click on Variation / Saved Form</p>																																																																													
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EX60	<p><b>Explanation:</b> FG60 show a list of saved form. Click on the edit-icon to open the saved form Click on the trash-icon to delete the saved form</p>																																																																													
2.3	<b>Payment Pending</b>																																																																													

<p><b>FG61</b></p>	 <p>The screenshot shows a dark-themed menu titled "Variation" with the following options: New Application, Saved Form, Payment Pending, Variation Correspondence, Withdrawal, Payment History, and Variation Status.</p>																																										
<p><b>EX61</b></p>	<p><b>Explanation:</b> Click on Variation / Payment Pending</p>																																										
<p><b>FG62</b></p>	 <p>The screenshot shows a "PAYMENT PENDING TRAY" with a list of pending payments. The list includes columns for #, Product MAL Number, Product Name, Product Category, Total, and a credit card icon. The data is as follows:</p> <table border="1"> <thead> <tr> <th>#</th> <th>Product MAL Number</th> <th>Product Name</th> <th>Product Category</th> <th>Total</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL20152458AE</td> <td>Axcel Famotidine-20 Capsule</td> <td>PRESCRIPTION</td> <td>RM 450.00</td> <td></td> </tr> <tr> <td>2</td> <td>MAL19970353T</td> <td>ZEFS COUGH SYRUP</td> <td>NATURAL PRODUCT</td> <td>RM 300.00</td> <td></td> </tr> <tr> <td>3</td> <td>MAL16080066NCZ</td> <td>Fish Oil 1000mg Softgel</td> <td>HEALTH SUPPLEMENT</td> <td>RM 150.00</td> <td></td> </tr> <tr> <td>4</td> <td>MAL19872220AZ</td> <td>AMPILIN CAPSULE 500MG</td> <td>PRESCRIPTION</td> <td>RM 300.00</td> <td></td> </tr> <tr> <td>5</td> <td>MAL16100078TCZ</td> <td>RTA 500mg Tablet</td> <td>NATURAL PRODUCT</td> <td>RM 0.00</td> <td></td> </tr> <tr> <td>6</td> <td>MAL19872165AZ</td> <td>METROGYL TABLET 200MG</td> <td>PRESCRIPTION</td> <td>RM 300.00</td> <td></td> </tr> </tbody> </table> <p>Showing 1 to 6 of 6 entries</p>	#	Product MAL Number	Product Name	Product Category	Total		1	MAL20152458AE	Axcel Famotidine-20 Capsule	PRESCRIPTION	RM 450.00		2	MAL19970353T	ZEFS COUGH SYRUP	NATURAL PRODUCT	RM 300.00		3	MAL16080066NCZ	Fish Oil 1000mg Softgel	HEALTH SUPPLEMENT	RM 150.00		4	MAL19872220AZ	AMPILIN CAPSULE 500MG	PRESCRIPTION	RM 300.00		5	MAL16100078TCZ	RTA 500mg Tablet	NATURAL PRODUCT	RM 0.00		6	MAL19872165AZ	METROGYL TABLET 200MG	PRESCRIPTION	RM 300.00	
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<p><b>EX62</b></p>	<p><b>Explanation:</b> FG62 shows a list Variation Application with Pending payment status. Click on the credit card-icon to proceed with payment.</p>																																										

<p><b>FG63</b></p>	
<p><b>EX63</b></p>	<p><b>Explanation:</b> FG63 shows list of available payment method. Click on Payment Method icon to continue.</p>
<p><b>FG64</b></p>	
<p><b>EX64</b></p>	<p><b>Explanation:</b> Select preferred payment method by clicking on the icon.</p>

<p><b>FG65</b></p>	
<p><b>EX65</b></p>	<p><b>Explanation:</b> Enter card details and click pay button.</p>
<p><b>FG66</b></p>	
<p><b>EX66</b></p>	<p><b>Explanation:</b> FG66 show the result of previous payment. Click on Payment History to go to Payment History page. Click on Payment Receipt button to view receipt.</p>
<p><b>2.4</b></p>	<p><b>Variation Correspondence</b></p>
<p><b>FG67</b></p>	
<p><b>EX67</b></p>	<p><b>Explanation:</b> Click on Variation / Variation Correspondence</p>

### ⇌ Variation Correspondence

Click to open saved & editable Variation

↶ IN TRAY - List of Product Replied Correspondence

☐ List Of Correspondence Application

Show  entries Search:

#	Product MAL Number	Product Name	Product Category	Date	Correspond x Times	⇌ Correspond	↶ Withdraw
1	MAL16100054HCZ	NP290916	VETERINARY	20 October 2016	1st	⇌ Correspond	↶ Withdraw
2	MAL19872165AZ	METROGYL TABLET 200MG	PRESCRIPTION	04 November 2016	1st	⇌ Correspond	↶ Withdraw

Showing 1 to 2 of 2 entries 1

↷ OUT TRAY - List of Product Corresponded

☐ List Of Awaiting Reply Correspondence

Show  entries Search:

#	Product MAL Number	Product Name	Correspond x Times	⇌ Stat	PPP	API	LAB
1	MAL20081744A	Optivate POWDER FOR INJECTION BIOLOGICS - BLOOD PRODUCTS	2nd	Evaluation	☐	–	–
2	MAL19871727A	ZEET EXPECTORANT PRESCRIPTION - FULL	3rd	Evaluation	☐	–	–
3	MAL20081735A	THYROGEN (THYROTROPIN ALFA) BIOLOGICS - BLOOD PRODUCTS	2nd	Evaluation	☐	–	–
4	MAL19870754AZ	SALBUTAMOL SULFATE TABLET 4MG PRESCRIPTION - FULL	2nd	Evaluation	✔	☐	–
5	MAL19900474A	BUPIVACAINE INJ BP 0.5% WV (10ML) PRESCRIPTION - FULL	2nd	Evaluation	✔	☐	–
6	MAL20041000AZ	IGANTET ANTI-TETANUS IMMUNOGLOBULIN GRIFOLS INJECTION 250 IU/ml BIOLOGICS - BLOOD PRODUCTS	2nd	Evaluation	☐	–	–

Showing 1 to 6 of 6 entries 1

**EX68 Explanation:**

The IN TRAY table shows a list of Variation Application that needs to be correspond/replied by the user/applicant

The OUT TRAY table shows a list of Variation Application that has been replied by user/applicants

Click on the Correspond button to reply correspondence.

Click on the Withdraw button to withdraw/cancel the application. Refer (FG74 – FG75, EX74 – EX75)

### Variation Workstation

Please Fill in Applicable forms & File Attachments

Product Validation - Part I - Part II - Part III - Part IV
Labels Checklist

Note to applicant

Please fill in the required supporting documents/data in Variation Checklist by clicking on the Insert button. Please make sure every field required is checked. If the field is not applicable, please check the box in the 'Not Applicable' column.

You can click on the section tabs above to refer to the current approved data.

Please submit other supporting documents (IF RELEVANT) at part E14.

Please make sure Variation Checklist is saved before you are done with the submission. Please click the Submit button when it is completed. Once submitted, you can check the application status under Variation & COS Status Record.

Product Information

Product Name : METROGYL TABLET 200MG

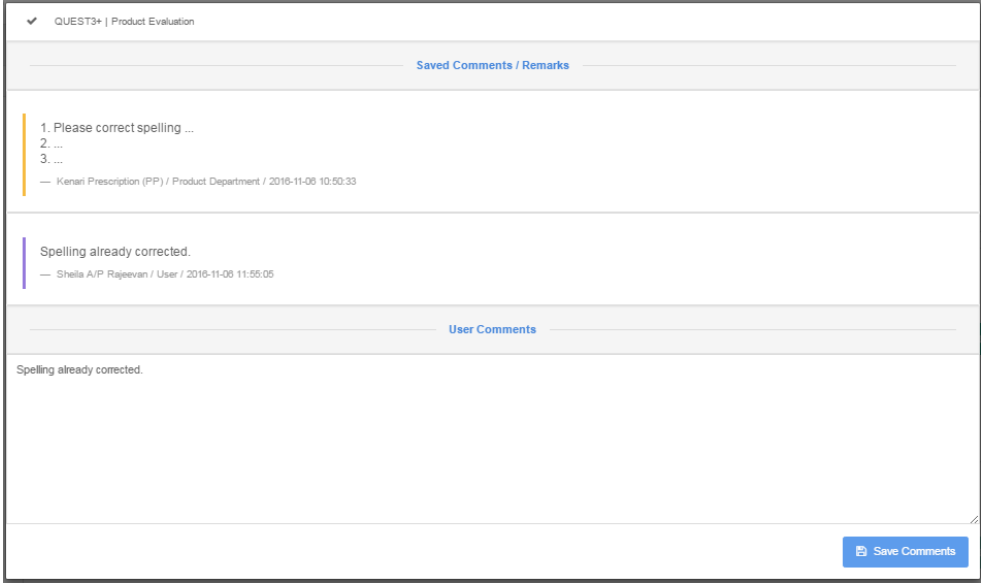
Product Call No./Ref No./Reg No. : 138562 / 1987070087A / MAL19872165AZ


















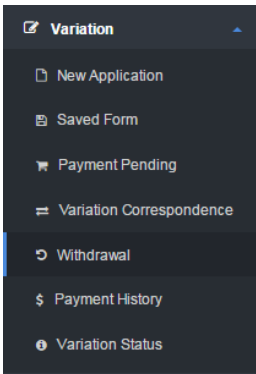
Product Category : PRESCRIPTION - FULL

Involve Variation Types

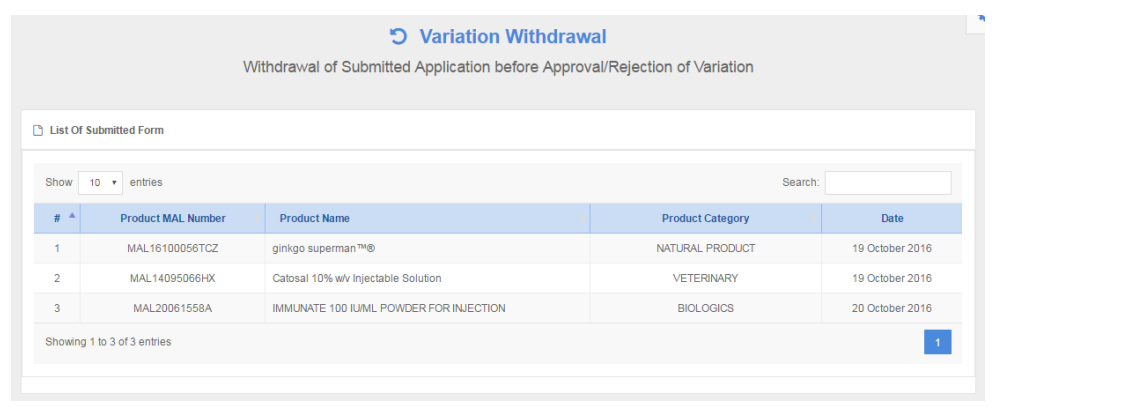
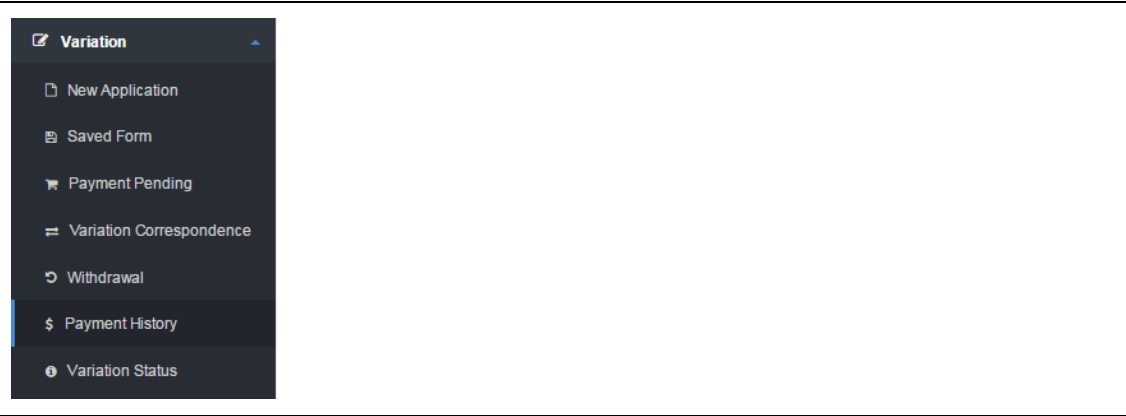
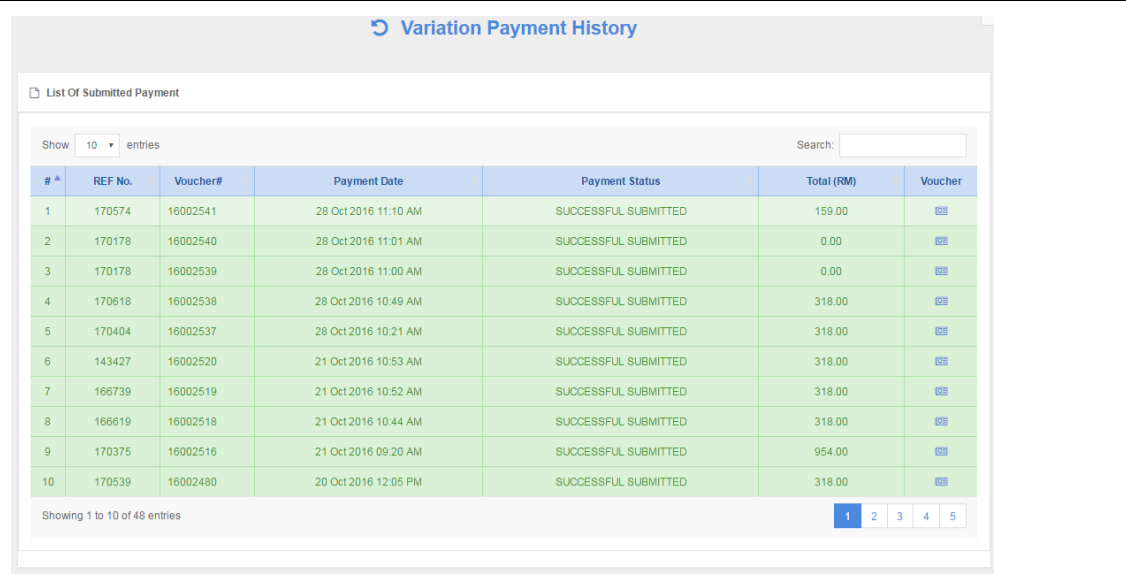
No.	Code	Variation Title	Category
1	MaV98	All Field Open	Type 3 (Major Variation)

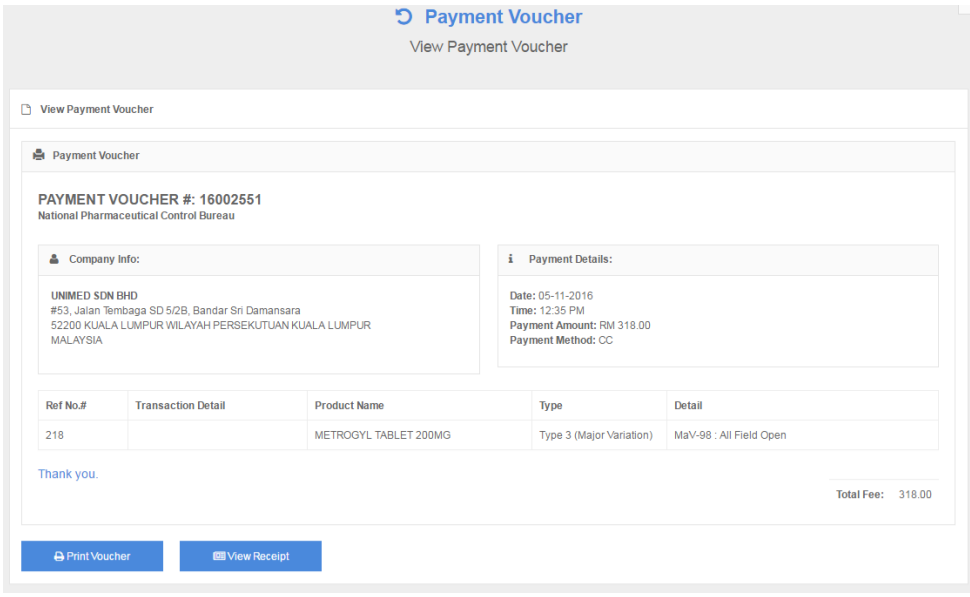
Involve Labels

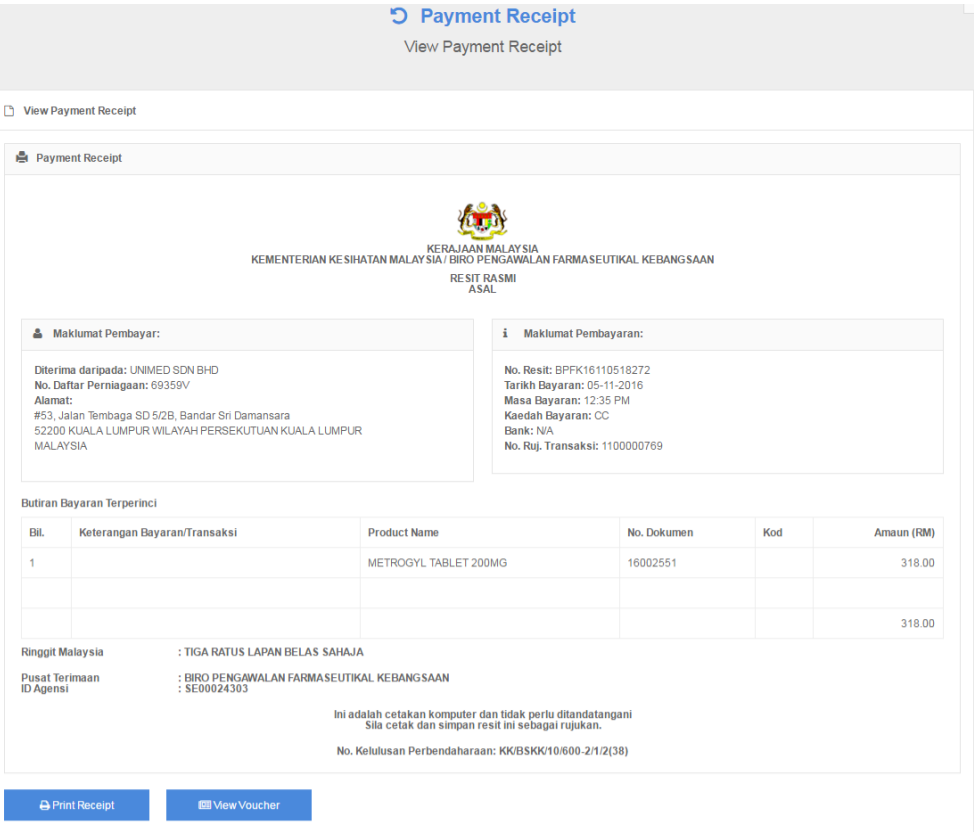
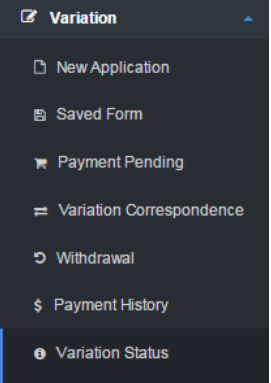
<p><b>EX69</b></p>	<p><b>Explanation:</b> FG69 shows a Variation Workstation Opened when user click on Correspond button in FG68.</p>
<p><b>FG70</b></p>	<p>1.1 Brand Name: a) Current Approved Brand Name:  <input type="text" value="N"/> <span style="float: right; background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">Remarks [ 1-1 ]</span>            b) Proposed Brand Name:  <input type="text" value="New Meister Brand"/></p>
<p><b>EX70</b></p>	<p><b>Explanation:</b> User/applicants can only edit/ammends or make changes on label marked as reject by Evaluator. Click on the remarks button to view comments/remarks from the Evaluator.</p>
<p><b>FG71</b></p>	
<p><b>EX71</b></p>	<p><b>Explanation:</b> FG71 shows a popup form appear when user click on Remarks button. User can see the remarks/comments from the evaluator User can reply to the comments by typing appropriate comments on the textarea provided and click on Save Comments button. Click anywhere outside the popup box to close.</p>

<p><b>FG72</b></p>	<p><b>D1. Label (mock-up) for immediate Container:</b> </p> <p>a) Current Label (mock-up) for immediate Container:</p> <div data-bbox="288 356 1238 533"> <p>No Current Approved Data</p> <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>foil.pdf</td> <td>08-02-2016</td> <td></td> </tr> </tbody> </table> </div> <p>b) Proposed Label (mock-up) for immediate Container:</p> <div data-bbox="288 568 1238 808"> <p><input type="button" value="Choose File"/> Please Select A File</p> <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Penguins.jpg</td> <td>2016-11-05 09:50:17</td> <td></td> </tr> <tr> <td>2</td> <td>Koala.jpg</td> <td>2016-11-06 11:10:25</td> <td></td> </tr> </tbody> </table> <p><input type="button" value="Remarks [ D1 ]"/></p> </div>	#	Attachment	Date of Attach		1	foil.pdf	08-02-2016		#	Attachment	Date of Attach		1	Penguins.jpg	2016-11-05 09:50:17		2	Koala.jpg	2016-11-06 11:10:25	
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<p><b>EX72</b></p>	<p><b>Explanation:</b></p> <p>FG72 show a sample label with multiple attachments (D1) that requires the users to correspond.</p> <p>Click on Choose File button to select and upload new attachments.</p> <p>Click on the file name to view the uploaded files.</p> <p>Click on red trash-icon button to delete the uploaded files</p> <p>Click on Remarks button to open popup Remarks/Comments form.</p>																				
<p><b>FG73</b></p>																					
<p><b>EX73</b></p>	<p><b>Explanation:</b></p> <p>Click on the Correspond button located at the bottom of home page in the Variation Workstation after finish completing the corresponded label.</p>																				
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<p><b>FG74</b></p>																					
<p><b>EX74</b></p>	<p><b>Explanation:</b></p> <p>Click on Variation / Withdrawal</p>																				



<p><b>FG75</b></p>	 <p style="text-align: center;"><b>Variation Withdrawal</b></p> <p style="text-align: center;">Withdrawal of Submitted Application before Approval/Rejection of Variation</p> <p>List Of Submitted Form</p> <p>Show 10 entries Search: <input type="text"/></p> <table border="1"> <thead> <tr> <th>#</th> <th>Product MAL Number</th> <th>Product Name</th> <th>Product Category</th> <th>Date</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL16100056TCZ</td> <td>ginkgo superman™</td> <td>NATURAL PRODUCT</td> <td>19 October 2016</td> </tr> <tr> <td>2</td> <td>MAL14095066HX</td> <td>Catosal 10% w/v Injectable Solution</td> <td>VETERINARY</td> <td>19 October 2016</td> </tr> <tr> <td>3</td> <td>MAL20061558A</td> <td>IMMUNATE 100 IU/ML POWDER FOR INJECTION</td> <td>BIOLOGICS</td> <td>20 October 2016</td> </tr> </tbody> </table> <p>Showing 1 to 3 of 3 entries</p>	#	Product MAL Number	Product Name	Product Category	Date	1	MAL16100056TCZ	ginkgo superman™	NATURAL PRODUCT	19 October 2016	2	MAL14095066HX	Catosal 10% w/v Injectable Solution	VETERINARY	19 October 2016	3	MAL20061558A	IMMUNATE 100 IU/ML POWDER FOR INJECTION	BIOLOGICS	20 October 2016																																																									
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<p><b>FG76</b></p>	 <p><b>Variation</b></p> <ul style="list-style-type: none"> <li>New Application</li> <li>Saved Form</li> <li>Payment Pending</li> <li>Variation Correspondence</li> <li>Withdrawal</li> <li><b>Payment History</b></li> <li>Variation Status</li> </ul>																																																																													
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4	170618	16002538	28 Oct 2016 10:49 AM	SUCCESSFUL SUBMITTED	318.00																																																																									
5	170404	16002537	28 Oct 2016 10:21 AM	SUCCESSFUL SUBMITTED	318.00																																																																									
6	143427	16002520	21 Oct 2016 10:53 AM	SUCCESSFUL SUBMITTED	318.00																																																																									
7	166739	16002519	21 Oct 2016 10:52 AM	SUCCESSFUL SUBMITTED	318.00																																																																									
8	166619	16002518	21 Oct 2016 10:44 AM	SUCCESSFUL SUBMITTED	318.00																																																																									
9	170375	16002516	21 Oct 2016 09:20 AM	SUCCESSFUL SUBMITTED	954.00																																																																									
10	170539	16002480	20 Oct 2016 12:05 PM	SUCCESSFUL SUBMITTED	318.00																																																																									

<p><b>EX77</b></p>	<p><b>Explanation:</b> FG77 show a list of payment made by user. Click on the card-icon to view payment Voucher.</p>
<p><b>FG78</b></p>	
<p><b>EX78</b></p>	<p><b>Explanation:</b> FG78 shows a sample voucher generated by the system. Click on Print Voucher button to print the voucher Click on View Receipt button to view the receipt (Receipt can only be view with a successful payment)</p>

<p><b>FG79</b></p>	
<p><b>EX79</b></p>	<p><b>Explanation:</b> FG79 show a sample Receipt. Click on Print Receipt button to print the receipt. Click on View Voucher button to view voucher.</p>
<p><b>FG80</b></p>	
<p><b>EX80</b></p>	<p><b>Explanation:</b> Click on Variation / Variation Status</p>

<p><b>FG81</b></p>	<div style="text-align: center;"> <h3>Variation Status</h3> <p>List of Variation Submitted</p> </div> <div style="background-color: #28a745; color: white; padding: 5px; margin-top: 10px;"> <p>STATUS TRAY - Application Status</p> </div> <div style="margin-top: 10px;"> <p style="text-align: right;"> <span>☰ Pending</span>   <span>✓ Approved/Rejected/Withdrawn</span> </p> <p><small>ⓘ Please Choose either Pending Tab or Approved/Rejected Status of COS/Variation</small></p> <p>☐ List Of Pending Approval Variation/COS</p> <p>Show <span style="border: 1px solid #ccc; padding: 2px;">10</span> entries <span style="float: right;">Search: <input type="text"/></span></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #d9e1f2;"> <th>#</th> <th>Variation Code</th> <th>Product Name</th> <th>Status</th> <th>PPP</th> <th>API</th> <th>LAB</th> </tr> </thead> <tbody> <tr> <td>21</td> <td>212</td> <td>MAL16100061TCZ SUPERMAN® TONGKAT ALI 500MG NATURAL PRODUCT - HERBAL (MEDIUM)</td> <td>SUBMITTED (PAID)</td> <td>≡</td> <td>-</td> <td>🗨️</td> </tr> <tr> <td>22</td> <td>5</td> <td>MAL19900633A NEOSTIGMINE INJ BP 2.5MG IN 1ML PRESCRIPTION - FULL</td> <td>EVALUATION APPROVED</td> <td>✓</td> <td>-</td> <td>✓</td> </tr> <tr> <td>23</td> <td>136</td> <td>MAL19870754AZ SALBUTAMOL SULFATE TABLET 4MG PRESCRIPTION - FULL</td> <td>EVALUATION APPROVED</td> <td>✓</td> <td>✓</td> <td>-</td> </tr> <tr> <td>24</td> <td>191</td> <td>MAL20051437A HAEMATE P INJECTION 250IU &amp; 500IU BIOLOGICS - BLOOD PRODUCTS</td> <td>EVALUATION APPROVED</td> <td>✓</td> <td>-</td> <td>-</td> </tr> <tr> <td>25</td> <td>205</td> <td>MAL19973583A FRUSEMIDE INJECTION BP 10MG/ML 2ML PRESCRIPTION - FULL</td> <td>EVALUATION APPROVED</td> <td>✓</td> <td>-</td> <td>-</td> </tr> <tr> <td>26</td> <td>213</td> <td>MAL16100079TC TINGGI™ HERBAL MEDIUM cap NATURAL PRODUCT - HERBAL (MEDIUM)</td> <td>EVALUATION APPROVED</td> <td>✓</td> <td>-</td> <td>-</td> </tr> <tr> <td>27</td> <td>218</td> <td>MAL19872165AZ METROGYL TABLET 200MG PRESCRIPTION - FULL</td> <td>CORRESPOND EVALUATOR TO USER</td> <td>≡</td> <td>🗨️</td> <td>✓</td> </tr> <tr> <td>28</td> <td>18</td> <td>MAL20081744A Optivate POWDER FOR INJECTION BIOLOGICS - BLOOD PRODUCTS</td> <td>CORRESPOND USER TO EVALUATOR</td> <td>🗨️</td> <td>-</td> <td>-</td> </tr> <tr> <td>29</td> <td>27</td> <td>MAL19871727A ZEET EXPECTORANT PRESCRIPTION - FULL</td> <td>CORRESPOND USER TO EVALUATOR</td> <td>🗨️</td> <td>-</td> <td>-</td> </tr> <tr> <td>30</td> <td>91</td> <td>MAL20081735A THYROGEN (THYROTROPIN ALFA) BIOLOGICS - BLOOD PRODUCTS</td> <td>CORRESPOND USER TO EVALUATOR</td> <td>🗨️</td> <td>-</td> <td>-</td> </tr> </tbody> </table> <p style="font-size: small; margin-top: 5px;">Showing 21 to 30 of 33 entries <span style="float: right;">1 2 3 4</span></p> </div>	#	Variation Code	Product Name	Status	PPP	API	LAB	21	212	MAL16100061TCZ SUPERMAN® TONGKAT ALI 500MG NATURAL PRODUCT - HERBAL (MEDIUM)	SUBMITTED (PAID)	≡	-	🗨️	22	5	MAL19900633A NEOSTIGMINE INJ BP 2.5MG IN 1ML PRESCRIPTION - FULL	EVALUATION APPROVED	✓	-	✓	23	136	MAL19870754AZ SALBUTAMOL SULFATE TABLET 4MG PRESCRIPTION - FULL	EVALUATION APPROVED	✓	✓	-	24	191	MAL20051437A HAEMATE P INJECTION 250IU & 500IU BIOLOGICS - BLOOD PRODUCTS	EVALUATION APPROVED	✓	-	-	25	205	MAL19973583A FRUSEMIDE INJECTION BP 10MG/ML 2ML PRESCRIPTION - FULL	EVALUATION APPROVED	✓	-	-	26	213	MAL16100079TC TINGGI™ HERBAL MEDIUM cap NATURAL PRODUCT - HERBAL (MEDIUM)	EVALUATION APPROVED	✓	-	-	27	218	MAL19872165AZ METROGYL TABLET 200MG PRESCRIPTION - FULL	CORRESPOND EVALUATOR TO USER	≡	🗨️	✓	28	18	MAL20081744A Optivate POWDER FOR INJECTION BIOLOGICS - BLOOD PRODUCTS	CORRESPOND USER TO EVALUATOR	🗨️	-	-	29	27	MAL19871727A ZEET EXPECTORANT PRESCRIPTION - FULL	CORRESPOND USER TO EVALUATOR	🗨️	-	-	30	91	MAL20081735A THYROGEN (THYROTROPIN ALFA) BIOLOGICS - BLOOD PRODUCTS	CORRESPOND USER TO EVALUATOR	🗨️	-	-
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<p><b>EX81</b></p>	<p><b>Explanation:</b></p> <p>FG81 shows a list of variation application with their status.</p> <p>Click on Approved/Withdrawn/Rejected tab button to view Approved, Withdrawn, or Rejected variation application.</p>																																																																													
<p><b>FG82</b></p>	<div style="border: 1px solid #ccc; padding: 10px;"> <p>🔍 QUEST3+ Variation/COS Chronology</p> <p><b>Product Info</b></p> <p>Product Name: SALBUTAMOL SULFATE TABLET 4MG</p> <p>Registration Number: MAL19870754AZ</p> <p>Reference Number: 1986042471A</p> <p>Product Category: PRESCRIPTION</p> <p>Category Class: FULL</p> <p><b>Variation/COS Info</b></p> <p>Application Number: 000000042</p> <p>Date Created: 17 October 16</p> </div>																																																																													
<p><b>EX82</b></p>	<p><b>Explanation:</b></p>																																																																													

	FG82 show the detail of a Variation application.
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