



**National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia**

USER MANUAL

QUEST 3+ System

**Module: CHANGE OF SITE
(Front-End)**

Document No.: Q3+/User Manual/M18/1

Version 2.0

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47810 PETALING JAYA,
SELANGOR**

Pengemaskinian Dokumen

Versi	Tarikh	Dikemaskini oleh	Ringkasan Perubahan	Senarai Edaran
1.0	14/07/2016	MOHAMAD SYAFIQ AZWAN BIN MUSTAFA		Pasukan Projek, Jawatankuasa Teknikal Projek, Jawatankuasa Pemandu Projek
2.0	21/11/2016	MOHAMAD SYAFIQ AZWAN BIN MUSTAFA	-Kemaskini berdasarkan semakan pengguna NPRA.	Pasukan Projek, Jawatankuasa Teknikal Projek, Jawatankuasa Pemandu Projek

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INTRODUCTION

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

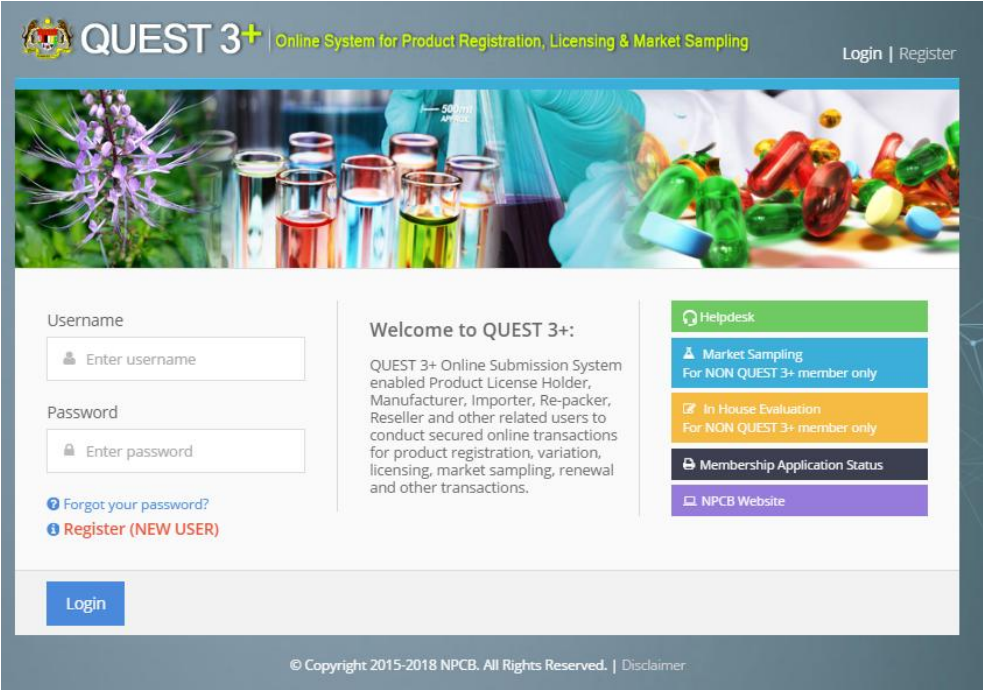
1. Application for Pre-Screening Change of Site (COS)
2. Application for Change of Site (COS)
3. COS payment
4. COS Correspondence

Pre-requisite:

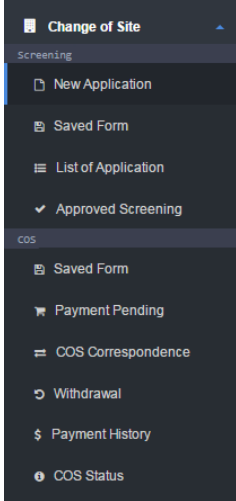
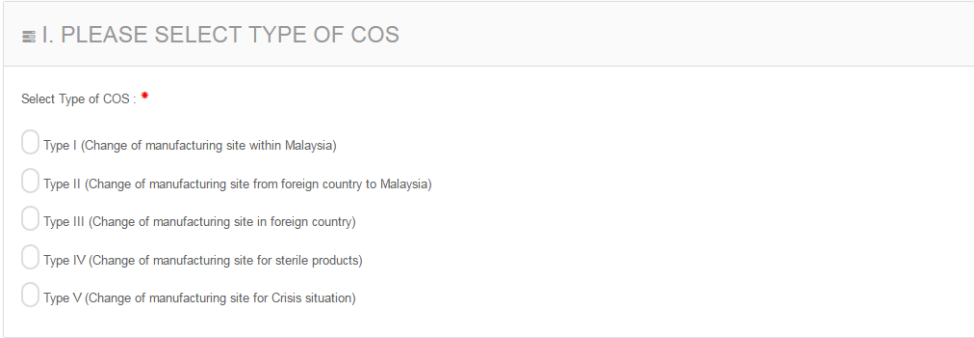
The application / registration process by the applicants will be conducted completely online including payments. The following are the pre-requisites before conducting the transactions in QUEST 3+:

1. Internet Ready PC
2. Broadband Internet connection
3. Google Chrome 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.

1.0 QUEST3+ Front-end login

#	SCREENSHOTS / EXPLANATION
1	<p data-bbox="252 353 304 376">Login</p> <div data-bbox="177 427 1380 1144"> <p data-bbox="188 434 229 456">FG1</p>  </div>
EX1	<p data-bbox="252 1182 368 1205">Explanation:</p> <p data-bbox="252 1211 836 1234">To access the Quest 3+ system, user need to use the URL as below:</p> <p data-bbox="252 1240 624 1263">https://quest3plus.bpfk.gov.my/front-end</p> <p data-bbox="252 1270 1050 1292">Figure 1 as the above will appear and the user will need to enter the following information:</p> <ol data-bbox="252 1323 539 1397" style="list-style-type: none"> 1. User Name: User ID 2. Password: Enter Password. 3. Click Login

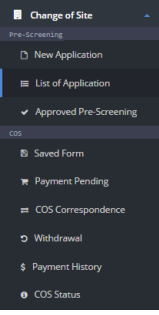
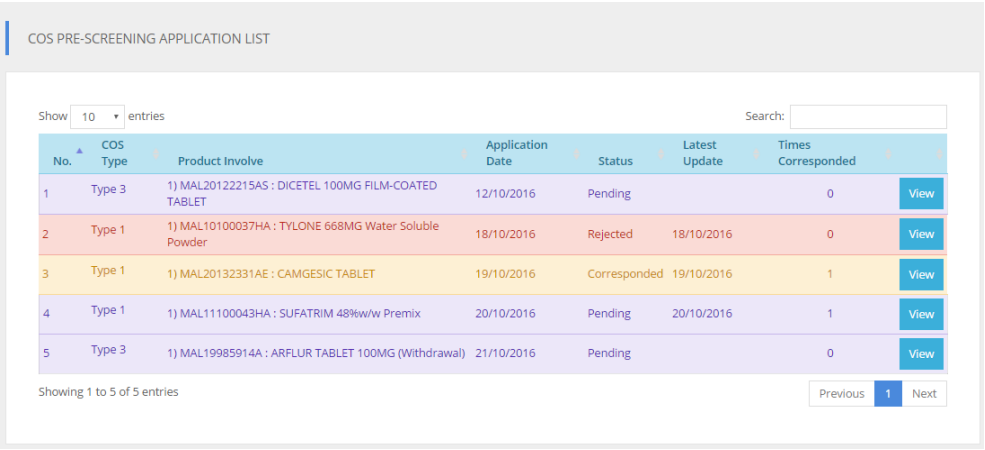
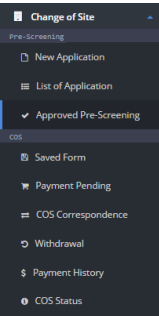
2.0 CHANGE OF SITE

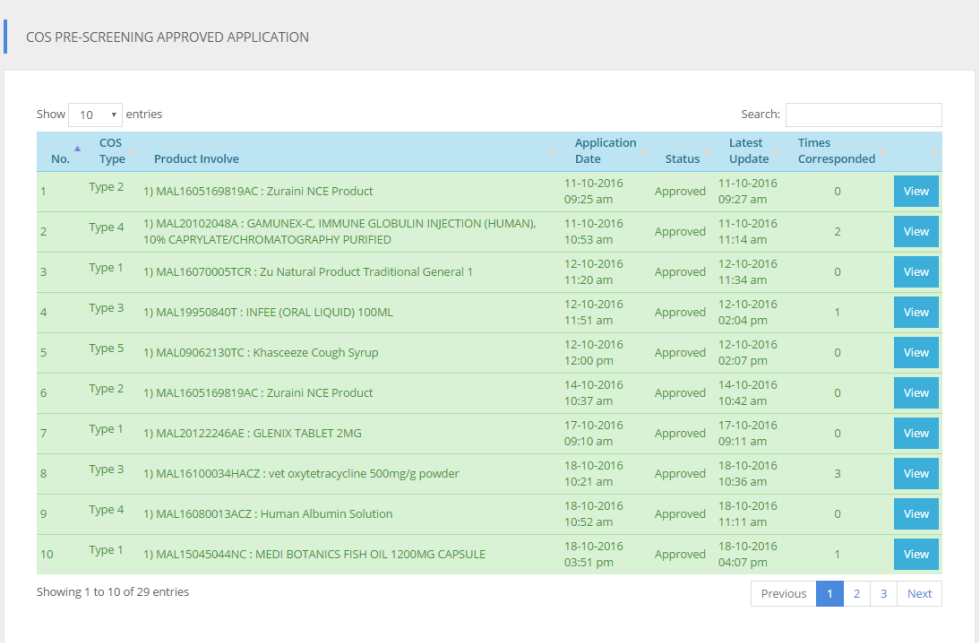

#	SCREENSHOTS / EXPLANATION
2.1	Screening
2.1.1	New Application
FG2	
EX2	<p>Explanation: Click on side menu 'Change of Site / New Application'</p>
FG3	
EX3	<p>Explanation: Click on appropriate Type of COS By Clicking on the label text or on the option circle.</p>
FG4	

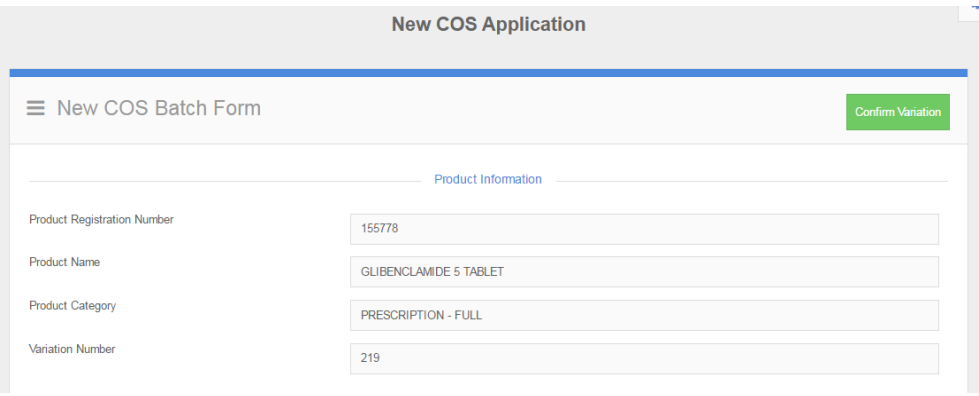
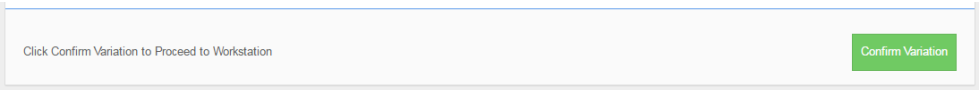
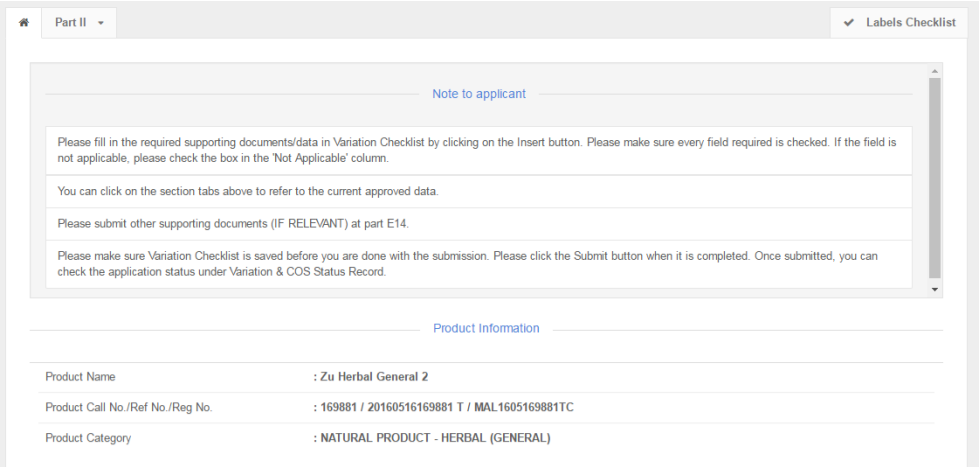
	<p>II. DETAILS OF PRODUCTS INVOLVED</p> <p>Select Product Category: *</p> <p>Select Factory/Manufacturer: *</p> <p>1) List of Product involved : *</p> <p>Search (Search by Product Registration No / Product Name) :</p> <p>ADD</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Registration No.</th> <th>Product Name</th> <th>Product Category</th> <th>Current Manufacturer's details</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td colspan="6"> </td> </tr> </tbody> </table>	No.	Registration No.	Product Name	Product Category	Current Manufacturer's details	Action						
No.	Registration No.	Product Name	Product Category	Current Manufacturer's details	Action								
<p>EX4</p>	<p>Explanation:</p> <p>User must select:</p> <ol style="list-style-type: none"> 1. Select Product Category *: Click to select the Product category 2. Select Factory/Manufacturer*: Click to select Factory/Manufacturer. Factory/Manufacturer option(s) listed based on selected COS Type and Product Category. 3. List of Product Involved*: Click to search product then press ADD Button. Product involved search result option listed based on selected COS Type, Product Category and Factory/Manufacturer. 												
<p>FG5</p>	<p>A. APPLICANT'S PARTICULAR</p> <p>1) Company Name : UNIMED SDN BHD</p> <p>2) Company Address : #53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara</p> <p>3) Telephone Number : 03-62721828</p> <p>4) Fax Number : 03-62721898</p>												
<p>EX5</p>	<p>Explanation:</p> <p>Applicant's Particular is automatically fetch and displayed by the system.</p>												
<p>FG6</p>													

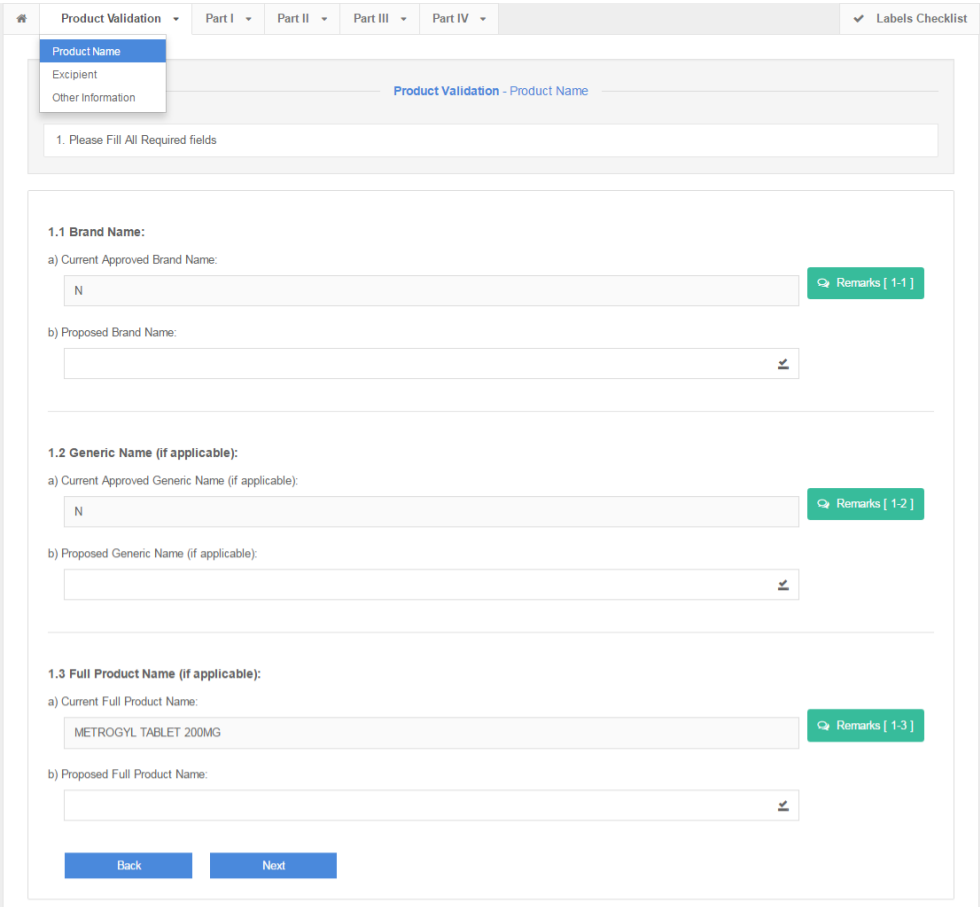
	<p>B. PARTICULAR OF MANUFACTURER</p> <p>1) Proposed Manufacturer's details : * <input type="text"/> <input type="button" value="NOT LISTED"/></p> <p>2) Is the proposed manufacturer the product owner : * <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>3) Product Owner details : <input type="text"/></p> <p>4) Relationship of the proposed manufacturing site with product owner : * <input type="text"/></p> <p>5) Good Manufacturing Practice/Manufacturer's License/Letter of confirmation : <input type="button" value="Choose File"/> <input type="text"/> Please Select A File <input type="button" value="Clear"/> <small>▲ Attachment file size limit 5 MB. Please Select .pdf, .jpg, .jpeg, .doc, .docx, .xls, and .xlsx files only</small></p> <p>6) Certificate of pharmaceutical product (CPP) : <input type="button" value="Choose File"/> <input type="text"/> Please Select A File <input type="button" value="Clear"/> <small>▲ Attachment file size limit 5 MB. Please Select .pdf, .jpg, .jpeg, .doc, .docx, .xls, and .xlsx files only</small></p> <p>7) Certificate of free scale (CFS) : <input type="button" value="Choose File"/> <input type="text"/> Please Select A File <input type="button" value="Clear"/> <small>▲ Attachment file size limit 5 MB. Please Select .pdf, .jpg, .jpeg, .doc, .docx, .xls, and .xlsx files only</small></p> <p>8) Activities involved at proposed site: (You may select more than 1, Please tick whichever is relevant) * <input type="checkbox"/> Bulk Manufacturing <input type="checkbox"/> Batch Release <input type="checkbox"/> Primary Packing <input type="checkbox"/> Secondary Packing <input type="checkbox"/> Quality Control</p> <p>9) Details of other manufacturers and its activities involved(if any) : Search Manufacturer <input type="text"/> <input type="button" value="ADD"/></p> <table border="1"> <thead> <tr> <th>No.</th> <th>Company Name</th> <th>Activity</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	No.	Company Name	Activity	Action				
No.	Company Name	Activity	Action						
<p>EX6</p>	<p>Explanation: User is required to select/fill the following field marked with *. Users are required to fill the appropriate field.</p>								
<p>FG7</p>									

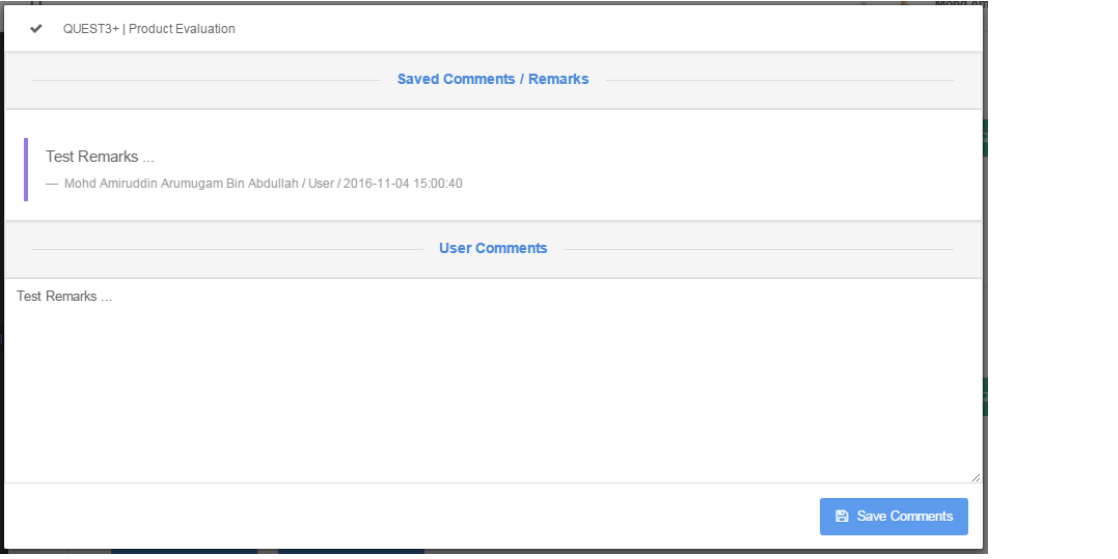
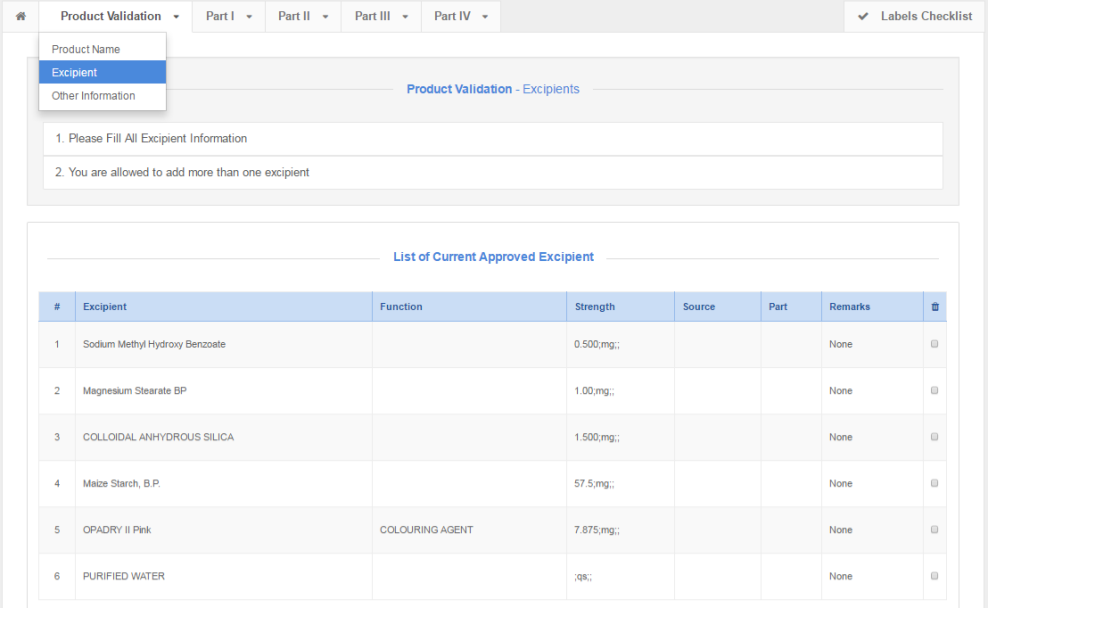
C. DETAILS OF PRODUCT(S) INVOLVED																																							
	<p>1) Please list down all minor changes (if any) and provide justification for each change:</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Registration Number</th> <th>Product Name</th> <th>List of Minor Changes</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL1605169819AC</td> <td>Zuraini NCE Product</td> <td><input type="text"/></td> </tr> </tbody> </table> <p>2) Batch Size and product formulation (including overage, if any) in the new manufacturing site:</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Registration Number</th> <th>Product Name</th> <th>Batch Size</th> <th>Product Formulation</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL1605169819AC</td> <td>Zuraini NCE Product</td> <td><input type="text"/></td> <td><input type="button" value="Choose File"/> No file chosen</td> </tr> </tbody> </table> <p>3) Stability data from the new manufacturing site :</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Registration Number</th> <th>Product Name</th> <th>No. Of Batches</th> <th>Batch Size</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL1605169819AC</td> <td>Zuraini NCE Product</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table> <p>4) Process Validation :</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Registration Number</th> <th>Product Name</th> <th>Development Pharmaceuticals Report</th> <th>Validation Scheme</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL1605169819AC</td> <td>Zuraini NCE Product</td> <td><input type="button" value="✘"/> <input type="button" value="✔"/></td> <td><input type="button" value="✘"/> <input type="button" value="✔"/></td> </tr> </tbody> </table> <p>5) Reasons for the change of Manufacturing Site : *</p> <p><input type="text"/></p> <p>6) Other supporting documents :</p> <p><input type="button" value="Add"/></p> <p><input type="button" value="Choose File"/> Please Select A File <input type="button" value="Remove"/></p> <p><small>▲ Attachment file size limit 5 MB. Please Select .pdf, .jpg, .jpeg, .doc, .docx, .xls, and .xlsx files only</small></p> <p>7) Remarks:</p> <p><input type="text"/></p>	No.	Registration Number	Product Name	List of Minor Changes	1	MAL1605169819AC	Zuraini NCE Product	<input type="text"/>	No.	Registration Number	Product Name	Batch Size	Product Formulation	1	MAL1605169819AC	Zuraini NCE Product	<input type="text"/>	<input type="button" value="Choose File"/> No file chosen	No.	Registration Number	Product Name	No. Of Batches	Batch Size	1	MAL1605169819AC	Zuraini NCE Product	<input type="text"/>	<input type="text"/>	No.	Registration Number	Product Name	Development Pharmaceuticals Report	Validation Scheme	1	MAL1605169819AC	Zuraini NCE Product	<input type="button" value="✘"/> <input type="button" value="✔"/>	<input type="button" value="✘"/> <input type="button" value="✔"/>
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EX7	<p>Explanation:</p> <p>Users are required to fill the appropriate field.</p>																																						
FG8	<p>Submit Pre-Screening Application for Change of Site (COS).</p> <p><input type="button" value="Reset Form"/> <input type="button" value="Submit Application"/></p>																																						
EX8	<p>Explanation:</p> <p>After users has complete filling the form. Click on the Submit Application Button to finish the process.</p>																																						
2.1.2	<p>List of Application</p>																																						

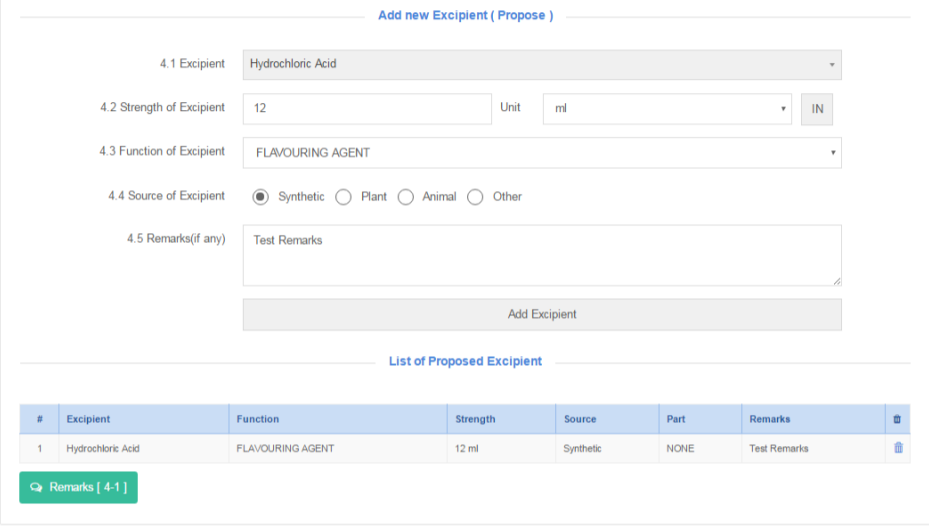
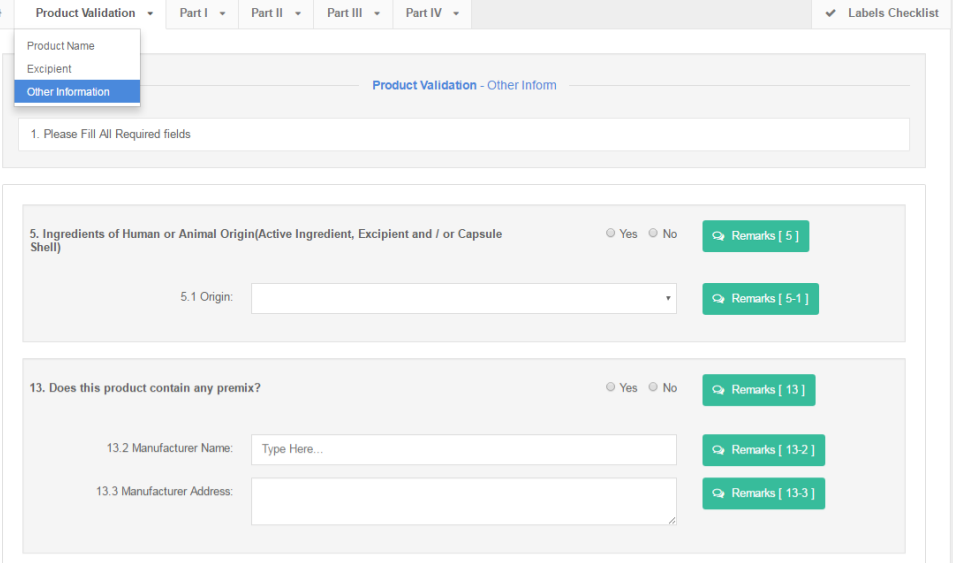
<p>FG9</p>																																																	
<p>EX9</p>	<p>Explanation: Click on side menu 'Change of Site / List of Application'</p>																																																
<p>FG10</p>	 <table border="1"> <thead> <tr> <th>No.</th> <th>COS Type</th> <th>Product Involve</th> <th>Application Date</th> <th>Status</th> <th>Latest Update</th> <th>Times Corresponded</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Type 3</td> <td>1) MAL20122215AS : DICETEL 100MG FILM-COATED TABLET</td> <td>12/10/2016</td> <td>Pending</td> <td></td> <td>0</td> <td>View</td> </tr> <tr> <td>2</td> <td>Type 1</td> <td>1) MAL10100037HA : TYLONE 668MG Water Soluble Powder</td> <td>18/10/2016</td> <td>Rejected</td> <td>18/10/2016</td> <td>0</td> <td>View</td> </tr> <tr> <td>3</td> <td>Type 1</td> <td>1) MAL20132331AE : CAMGESIC TABLET</td> <td>19/10/2016</td> <td>Corresponded</td> <td>19/10/2016</td> <td>1</td> <td>View</td> </tr> <tr> <td>4</td> <td>Type 1</td> <td>1) MAL11100043HA : SUFATRIM 48%w/w Premix</td> <td>20/10/2016</td> <td>Pending</td> <td>20/10/2016</td> <td>1</td> <td>View</td> </tr> <tr> <td>5</td> <td>Type 3</td> <td>1) MAL19985914A : ARFLUR TABLET 100MG (Withdrawal)</td> <td>21/10/2016</td> <td>Pending</td> <td></td> <td>0</td> <td>View</td> </tr> </tbody> </table>	No.	COS Type	Product Involve	Application Date	Status	Latest Update	Times Corresponded		1	Type 3	1) MAL20122215AS : DICETEL 100MG FILM-COATED TABLET	12/10/2016	Pending		0	View	2	Type 1	1) MAL10100037HA : TYLONE 668MG Water Soluble Powder	18/10/2016	Rejected	18/10/2016	0	View	3	Type 1	1) MAL20132331AE : CAMGESIC TABLET	19/10/2016	Corresponded	19/10/2016	1	View	4	Type 1	1) MAL11100043HA : SUFATRIM 48%w/w Premix	20/10/2016	Pending	20/10/2016	1	View	5	Type 3	1) MAL19985914A : ARFLUR TABLET 100MG (Withdrawal)	21/10/2016	Pending		0	View
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<p>EX10</p>	<p>Explanation: FG10 shows a list of submitted application. Click on View Button to view the application details. There are three (3) application status displayed in this view, which is Pending, Corresponded and Rejected Application. Pending: Users can only view the particular submitted Corresponded: Users can view all the particular and can only update/edit the field that was marked by the Evaluator with their remarks. Rejected: Users can view all the particular and remarks form the Evaluator.</p>																																																
<p>2.1.3</p>	<p>Approved Pre-Screening</p>																																																
<p>FG11</p>																																																	

<p>EX11</p>	<p>Explanation: Click on side menu 'Change of Site / Approved Pre-Screening'</p>																																																																																								
<p>FG12</p>	 <p>COS PRE-SCREENING APPROVED APPLICATION</p> <p>Show 10 entries Search: <input type="text"/></p> <table border="1"> <thead> <tr> <th>No.</th> <th>COS Type</th> <th>Product Involve</th> <th>Application Date</th> <th>Status</th> <th>Latest Update</th> <th>Times Corresponded</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Type 2</td> <td>1) MAL1605169819AC : Zuraini NCE Product</td> <td>11-10-2016 09:25 am</td> <td>Approved</td> <td>11-10-2016 09:27 am</td> <td>0</td> <td>View</td> </tr> <tr> <td>2</td> <td>Type 4</td> <td>1) MAL20102048A : GAMUNEX-C, IMMUNE GLOBULIN INJECTION (HUMAN), 10% CAPRYLATE/CHROMATOGRAPHY PURIFIED</td> <td>11-10-2016 10:53 am</td> <td>Approved</td> <td>11-10-2016 11:14 am</td> <td>2</td> <td>View</td> </tr> <tr> <td>3</td> <td>Type 1</td> <td>1) MAL16070005TCR : Zu Natural Product Traditional General 1</td> <td>12-10-2016 11:20 am</td> <td>Approved</td> <td>12-10-2016 11:34 am</td> <td>0</td> <td>View</td> </tr> <tr> <td>4</td> <td>Type 3</td> <td>1) MAL19950840T : INFEE (ORAL LIQUID) 100ML</td> <td>12-10-2016 11:51 am</td> <td>Approved</td> <td>12-10-2016 02:04 pm</td> <td>1</td> <td>View</td> </tr> <tr> <td>5</td> <td>Type 5</td> <td>1) MAL09062130TC : Khasceze Cough Syrup</td> <td>12-10-2016 12:00 pm</td> <td>Approved</td> <td>12-10-2016 02:07 pm</td> <td>0</td> <td>View</td> </tr> <tr> <td>6</td> <td>Type 2</td> <td>1) MAL1605169819AC : Zuraini NCE Product</td> <td>14-10-2016 10:37 am</td> <td>Approved</td> <td>14-10-2016 10:42 am</td> <td>0</td> <td>View</td> </tr> <tr> <td>7</td> <td>Type 1</td> <td>1) MAL20122246AE : GLENIX TABLET 2MG</td> <td>17-10-2016 09:10 am</td> <td>Approved</td> <td>17-10-2016 09:11 am</td> <td>0</td> <td>View</td> </tr> <tr> <td>8</td> <td>Type 3</td> <td>1) MAL16100034HACZ : vet oxytetracycline 500mg/g powder</td> <td>18-10-2016 10:21 am</td> <td>Approved</td> <td>18-10-2016 10:36 am</td> <td>3</td> <td>View</td> </tr> <tr> <td>9</td> <td>Type 4</td> <td>1) MAL16080013ACZ : Human Albumin Solution</td> <td>18-10-2016 10:52 am</td> <td>Approved</td> <td>18-10-2016 11:11 am</td> <td>0</td> <td>View</td> </tr> <tr> <td>10</td> <td>Type 1</td> <td>1) MAL15045044NC : MEDI BOTANICS FISH OIL 1200MG CAPSULE</td> <td>18-10-2016 03:51 pm</td> <td>Approved</td> <td>18-10-2016 04:07 pm</td> <td>1</td> <td>View</td> </tr> </tbody> </table> <p>Showing 1 to 10 of 29 entries Previous 1 2 3 Next</p>	No.	COS Type	Product Involve	Application Date	Status	Latest Update	Times Corresponded		1	Type 2	1) MAL1605169819AC : Zuraini NCE Product	11-10-2016 09:25 am	Approved	11-10-2016 09:27 am	0	View	2	Type 4	1) MAL20102048A : GAMUNEX-C, IMMUNE GLOBULIN INJECTION (HUMAN), 10% CAPRYLATE/CHROMATOGRAPHY PURIFIED	11-10-2016 10:53 am	Approved	11-10-2016 11:14 am	2	View	3	Type 1	1) MAL16070005TCR : Zu Natural Product Traditional General 1	12-10-2016 11:20 am	Approved	12-10-2016 11:34 am	0	View	4	Type 3	1) MAL19950840T : INFEE (ORAL LIQUID) 100ML	12-10-2016 11:51 am	Approved	12-10-2016 02:04 pm	1	View	5	Type 5	1) MAL09062130TC : Khasceze Cough Syrup	12-10-2016 12:00 pm	Approved	12-10-2016 02:07 pm	0	View	6	Type 2	1) MAL1605169819AC : Zuraini NCE Product	14-10-2016 10:37 am	Approved	14-10-2016 10:42 am	0	View	7	Type 1	1) MAL20122246AE : GLENIX TABLET 2MG	17-10-2016 09:10 am	Approved	17-10-2016 09:11 am	0	View	8	Type 3	1) MAL16100034HACZ : vet oxytetracycline 500mg/g powder	18-10-2016 10:21 am	Approved	18-10-2016 10:36 am	3	View	9	Type 4	1) MAL16080013ACZ : Human Albumin Solution	18-10-2016 10:52 am	Approved	18-10-2016 11:11 am	0	View	10	Type 1	1) MAL15045044NC : MEDI BOTANICS FISH OIL 1200MG CAPSULE	18-10-2016 03:51 pm	Approved	18-10-2016 04:07 pm	1	View
No.	COS Type	Product Involve	Application Date	Status	Latest Update	Times Corresponded																																																																																			
1	Type 2	1) MAL1605169819AC : Zuraini NCE Product	11-10-2016 09:25 am	Approved	11-10-2016 09:27 am	0	View																																																																																		
2	Type 4	1) MAL20102048A : GAMUNEX-C, IMMUNE GLOBULIN INJECTION (HUMAN), 10% CAPRYLATE/CHROMATOGRAPHY PURIFIED	11-10-2016 10:53 am	Approved	11-10-2016 11:14 am	2	View																																																																																		
3	Type 1	1) MAL16070005TCR : Zu Natural Product Traditional General 1	12-10-2016 11:20 am	Approved	12-10-2016 11:34 am	0	View																																																																																		
4	Type 3	1) MAL19950840T : INFEE (ORAL LIQUID) 100ML	12-10-2016 11:51 am	Approved	12-10-2016 02:04 pm	1	View																																																																																		
5	Type 5	1) MAL09062130TC : Khasceze Cough Syrup	12-10-2016 12:00 pm	Approved	12-10-2016 02:07 pm	0	View																																																																																		
6	Type 2	1) MAL1605169819AC : Zuraini NCE Product	14-10-2016 10:37 am	Approved	14-10-2016 10:42 am	0	View																																																																																		
7	Type 1	1) MAL20122246AE : GLENIX TABLET 2MG	17-10-2016 09:10 am	Approved	17-10-2016 09:11 am	0	View																																																																																		
8	Type 3	1) MAL16100034HACZ : vet oxytetracycline 500mg/g powder	18-10-2016 10:21 am	Approved	18-10-2016 10:36 am	3	View																																																																																		
9	Type 4	1) MAL16080013ACZ : Human Albumin Solution	18-10-2016 10:52 am	Approved	18-10-2016 11:11 am	0	View																																																																																		
10	Type 1	1) MAL15045044NC : MEDI BOTANICS FISH OIL 1200MG CAPSULE	18-10-2016 03:51 pm	Approved	18-10-2016 04:07 pm	1	View																																																																																		
<p>EX12</p>	<p>Explanation: FG12 show a list of Approved Pre-Screening COS Application. Click View to proceed.</p>																																																																																								
<p>FG13</p>	 <p>COS PRE-SCREENING APPROVED PRODUCT</p> <p>Show 10 entries Search: <input type="text"/></p> <table border="1"> <thead> <tr> <th>No.</th> <th>MAL Number</th> <th>Product Name</th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL1605169819AC</td> <td>Zuraini NCE Product</td> <td>New COS</td> </tr> </tbody> </table> <p>Showing 1 to 1 of 1 entries Previous 1 Next</p>	No.	MAL Number	Product Name		1	MAL1605169819AC	Zuraini NCE Product	New COS																																																																																
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<p>EX13</p>	<p>Explanation: FG13 show a list of product that has been approved in Pre-Screening process. Click on New COS Button to proceed to Workstation.</p>																																																																																								

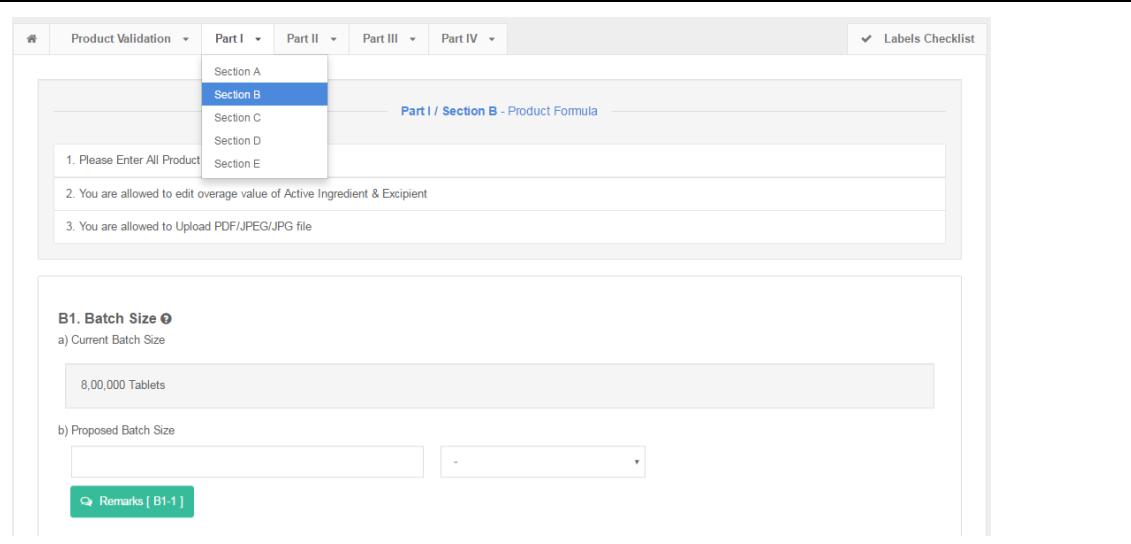
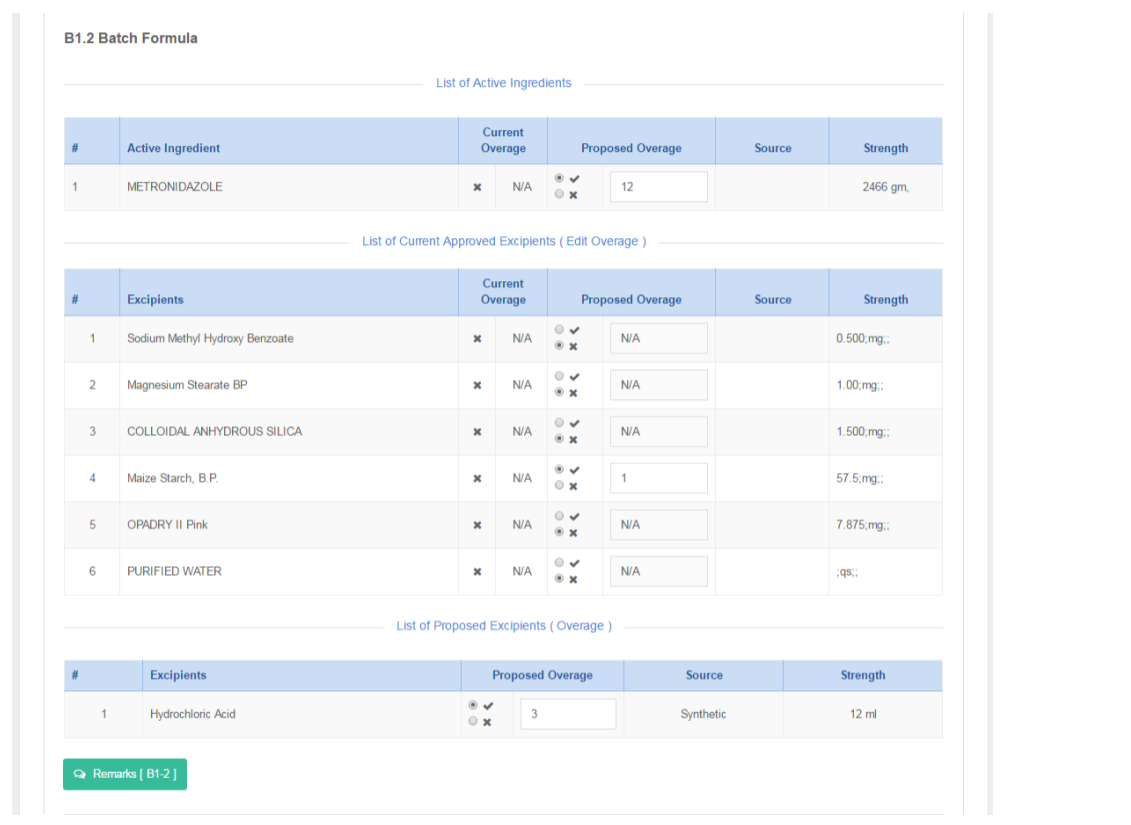
<p>FG14</p>	
<p>EX14</p>	<p>Explanation: FG14 shows the information about the product selected by user for COS Process.</p>
<p>FG15</p>	
<p>EX15</p>	<p>Explanation: Click on Confirm Variation Button to proceed the application to COS Workstation.</p>
<p>FG16</p>	
<p>EX16</p>	<p>Explanation: FG16 shows the Home Screen for COS Workstation.</p>

<p>FG17</p>	<p style="text-align: center;">Involve Variation Types</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Code</th> <th>Variation Title</th> <th>Category</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MaV-5</td> <td>Change of the manufacturing site of the drug product</td> <td>COS - Change Of Site</td> </tr> </tbody> </table> <p style="text-align: center;">Involve Labels</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Code</th> <th>Label Description</th> <th>Label Overlap</th> <th>Correspond</th> <th>Status</th> <th>Go</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>B2</td> <td>Attachment of Batch Manufacturing Formula</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>2</td> <td>D1</td> <td>Label (mock-up) for Immediate Container</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>3</td> <td>D2</td> <td>Label (mock-up) for Outer Carton</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>4</td> <td>D3</td> <td>Proposed Package Insert</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>5</td> <td>E1.2</td> <td>Letter of Authorization from Product Owner</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>6</td> <td>E2.1</td> <td>Letter of Appointment of the Contract Manufacturer from the Product Owner</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>7</td> <td>E2.2</td> <td>Letter of Acceptance from the Contract Manufacturer</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>8</td> <td>E2.3</td> <td>Letter of Appointment of the Repacker from the Product Owner</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>9</td> <td>E2.4</td> <td>Letter of Acceptance from the Repacker</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>10</td> <td>E3.1</td> <td>Certificate of Pharmaceutical Product (CPP)</td> <td>–</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> </tbody> </table>	No.	Code	Variation Title	Category	1	MaV-5	Change of the manufacturing site of the drug product	COS - Change Of Site	No.	Code	Label Description	Label Overlap	Correspond	Status	Go	1	B2	Attachment of Batch Manufacturing Formula	–	N/A	▲	🔗	2	D1	Label (mock-up) for Immediate Container	–	N/A	▲	🔗	3	D2	Label (mock-up) for Outer Carton	–	N/A	▲	🔗	4	D3	Proposed Package Insert	–	N/A	▲	🔗	5	E1.2	Letter of Authorization from Product Owner	–	N/A	▲	🔗	6	E2.1	Letter of Appointment of the Contract Manufacturer from the Product Owner	–	N/A	▲	🔗	7	E2.2	Letter of Acceptance from the Contract Manufacturer	–	N/A	▲	🔗	8	E2.3	Letter of Appointment of the Repacker from the Product Owner	–	N/A	▲	🔗	9	E2.4	Letter of Acceptance from the Repacker	–	N/A	▲	🔗	10	E3.1	Certificate of Pharmaceutical Product (CPP)	–	N/A	▲	🔗
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<p>FG18</p>																																																																																						
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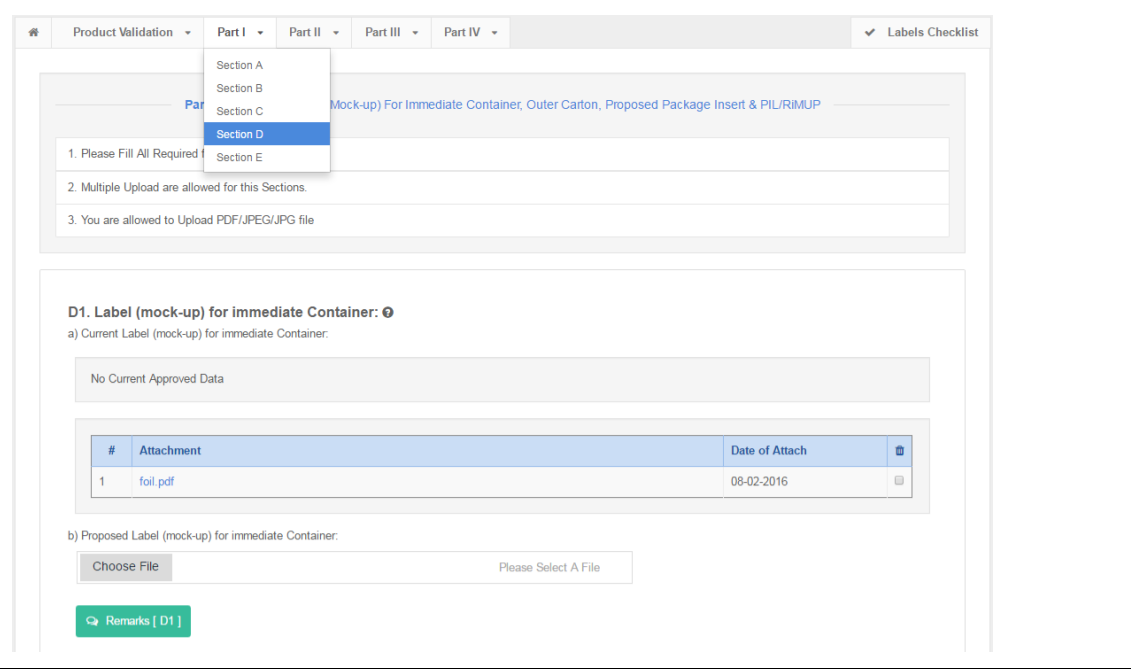
	<p>User can leave remarks for the Evaluator by clicking the Remarks Button on the right side of each field.</p>																																																								
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<p>EX19</p>	<p>Explanation: FG19 shows User Remarks Popup window. Fill remarks in the field provided and click on Save Comments button. Click anywhere outside the popup window to close the popup window.</p>																																																								
<p>FG20</p>	 <table border="1" data-bbox="300 1361 1217 1664"> <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>🗑️</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>🗑️</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>🗑️</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>🗑️</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>🗑️</td> </tr> <tr> <td>6</td> <td>PURIFIED WATER</td> <td></td> <td>.08,;</td> <td></td> <td></td> <td>None</td> <td>🗑️</td> </tr> </tbody> </table>	#	Excipient	Function	Strength	Source	Part	Remarks		1	Sodium Methyl Hydroxy Benzoate		0.500,mg;;			None	🗑️	2	Magnesium Stearate BP		1.00,mg;;			None	🗑️	3	COLLOIDAL ANHYDROUS SILICA		1.500,mg;;			None	🗑️	4	Maize Starch, B.P.		57.5,mg;;			None	🗑️	5	OPADRY II Pink	COLOURING AGENT	7.875,mg;;			None	🗑️	6	PURIFIED WATER		.08,;			None	🗑️
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<p>EX20</p>	<p>Explanation: Click on Product Validation / Excipient. FG20 show a list of current approved excipient for the product.</p>																																																								

<p>FG21</p>	
<p>EX21</p>	<p>Explanation: Fill the following field: 4.1 Excipient 4.2 Strength of Excipient 4.3 Function of Excipient 4.4 Source of Excipient 4.5 Remarks(if any) Then click on the Add Excipient Button.</p>
<p>FG22</p>	
<p>EX22</p>	<p>Explanation: Click on Product Validation / Other Information. Fill the required field.</p>

<p>FG23</p>	<p>A4. Product Description ⓘ</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>EX23</p>	<p>Explanation:</p> <p>FG23 shows one of the fields available in the COS 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>FG24</p>	<p>A21. ATC Code ⓘ</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</p> <p>C07DA06</p> <p>Remarks [A21]</p>
<p>EX24</p>	<p>Explanation:</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>FG25</p>																																																																	
<p>EX25</p>	<p>Explanation: 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>FG26</p>	 <p>B1.2 Batch Formula</p> <p>List of Active Ingredients</p> <table border="1"> <thead> <tr> <th>#</th> <th>Active Ingredient</th> <th>Current Overage</th> <th>Proposed Overage</th> <th>Source</th> <th>Strength</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>METRONIDAZOLE</td> <td>x N/A</td> <td>12</td> <td></td> <td>2466 gm.</td> </tr> </tbody> </table> <p>List of Current Approved Excipients (Edit Overage)</p> <table border="1"> <thead> <tr> <th>#</th> <th>Excipients</th> <th>Current Overage</th> <th>Proposed Overage</th> <th>Source</th> <th>Strength</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Sodium Methyl Hydroxy Benzoate</td> <td>x N/A</td> <td>N/A</td> <td></td> <td>0.500,mg,;</td> </tr> <tr> <td>2</td> <td>Magnesium Stearate BP</td> <td>x N/A</td> <td>N/A</td> <td></td> <td>1.00,mg,;</td> </tr> <tr> <td>3</td> <td>COLLOIDAL ANHYDROUS SILICA</td> <td>x N/A</td> <td>N/A</td> <td></td> <td>1.500,mg,;</td> </tr> <tr> <td>4</td> <td>Maize Starch, B.P.</td> <td>x N/A</td> <td>1</td> <td></td> <td>57.5,mg,;</td> </tr> <tr> <td>5</td> <td>OPADRY II Pink</td> <td>x N/A</td> <td>N/A</td> <td></td> <td>7.875,mg,;</td> </tr> <tr> <td>6</td> <td>PURIFIED WATER</td> <td>x N/A</td> <td>N/A</td> <td></td> <td>:qs,;</td> </tr> </tbody> </table> <p>List of Proposed Excipients (Overage)</p> <table border="1"> <thead> <tr> <th>#</th> <th>Excipients</th> <th>Proposed Overage</th> <th>Source</th> <th>Strength</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hydrochloric Acid</td> <td>3</td> <td>Synthetic</td> <td>12 ml</td> </tr> </tbody> </table>	#	Active Ingredient	Current Overage	Proposed Overage	Source	Strength	1	METRONIDAZOLE	x N/A	12		2466 gm.	#	Excipients	Current Overage	Proposed Overage	Source	Strength	1	Sodium Methyl Hydroxy Benzoate	x N/A	N/A		0.500,mg,;	2	Magnesium Stearate BP	x N/A	N/A		1.00,mg,;	3	COLLOIDAL ANHYDROUS SILICA	x N/A	N/A		1.500,mg,;	4	Maize Starch, B.P.	x N/A	1		57.5,mg,;	5	OPADRY II Pink	x N/A	N/A		7.875,mg,;	6	PURIFIED WATER	x N/A	N/A		:qs,;	#	Excipients	Proposed Overage	Source	Strength	1	Hydrochloric Acid	3	Synthetic	12 ml
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<p>EX26</p>	<p>Explanation: User is require to fill all the Proposed Overage column in the table shown in FG18</p>																																																																

<p>FG27</p>	<p>B2. Batch Manufacturing Formula</p> <p>a) Current Batch Manufacturing Formula</p> <div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div> <p>b) Proposed Batch Manufacturing Formula</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Choose File Chrysanthemum.jpg</p> <div style="display: flex; justify-content: flex-end; gap: 10px;"> 👁️ 🗑️ </div> <p style="background-color: #28a745; color: white; padding: 2px 5px; display: inline-block;">Remarks [B2]</p> </div>																																																				
<p>EX27</p>	<p>Explanation:</p> <p>Click on the Choose File button to select a file to be uploaded in the system.</p> <p>User can View the uploaded file by clicking on the blue eye-icon button.</p> <p>Click on the red dustbin-icon button to remove the uploaded file.</p>																																																				
<p>FG28</p>	<div style="border: 1px solid #ccc; padding: 5px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> Product Validation Part I Part II Part III Part IV Labels Checklist </div> <div style="margin-top: 10px;"> <p>Part I / Section C - Particulars of packing</p> <ol style="list-style-type: none"> Click "ADD" button after ... repeat these steps if there is more than one(1) pack size. To delete an entry from the list, click on the "DELETE" button. For editing, click on the "EDIT" button. Those field with symbol * is a compulsory fields. If those fields are not filled, submission of application is not permitted. </div> <div style="margin-top: 10px;"> <p>a) Current Particular of Packing</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>C1. Pack Size</th> <th>Field</th> <th>Data</th> <th></th> </tr> </thead> <tbody> <tr> <td rowspan="6">1</td> <td rowspan="6">1000Tablet GRAMS [WEIGHT]</td> <td>C2. Immediate Container Type</td> <td>PLASTIC</td> <td></td> </tr> <tr> <td>C3. Container Type Description</td> <td>HDPE PLASTIC container</td> <td></td> </tr> <tr> <td>C4. Barcode / Serial No.</td> <td>300200201507</td> <td></td> </tr> <tr> <td>C5. Recommended Distributor's Price</td> <td>RM 30.00</td> <td></td> </tr> <tr> <td>C6. Recommended Retail Price</td> <td>RM 40.00</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> </div> <div style="margin-top: 10px;"> <p>b) Proposed Particular of Packing</p> <p>C1. Pack Size* : <input type="text" value="12"/> Unit <input type="text" value="KILOGRAMS"/></p> <p>C2. Immediate Container Type* : <input type="text" value="PAPER"/> If Other, please specify <input type="text"/></p> <p>C3. Container Type Description* : <input type="text" value="Desc"/></p> <p>C4. Barcode / Serial No. (if applicable) : <input type="text" value="123456789"/></p> <p>C5. Recommended Distributor's Price* : <input type="text" value="80"/></p> <p>C6. Recommended Retail Price* : <input type="text" value="90"/></p> <p>List of Pack Size Add Pack Size</p> <div style="background-color: #28a745; color: white; padding: 2px 5px; text-align: center;">Success! Packing Particular has been Added</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>#</th> <th>C1. Pack Size</th> <th>Field</th> <th>Data</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td rowspan="6">1</td> <td rowspan="6">12 KILOGRAMS [Weight]</td> <td>C2. Immediate Container Type</td> <td>PAPER []</td> <td></td> </tr> <tr> <td>C3. Container Type Description</td> <td>Desc</td> <td></td> </tr> <tr> <td>C4. Barcode / Serial No.</td> <td>123456789</td> <td></td> </tr> <tr> <td>C5. Recommended Distributor's Price</td> <td>RM 80.00</td> <td></td> </tr> <tr> <td>C6. Recommended Retail Price</td> <td>RM 90.00</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> </div> </div>	#	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						#	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					
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<p>EX28</p>	<p>Explanation:</p> <p>Click on Part 1/ Section C</p> <p>Fill all the required field marked with * then click on the Add Pack Size button to add new proposed Pack Size.</p>																																																				

<p>FG29</p>	 <p>The screenshot shows a web application interface for 'Product Validation'. At the top, there are dropdown menus for 'Part I', 'Part II', 'Part III', and 'Part IV', along with a 'Labels Checklist' button. A dropdown menu is open under 'Part I', showing options for Section A, B, C, D, and E, with 'Section D' highlighted. Below this, there are three numbered instructions: '1. Please Fill All Required...', '2. Multiple Upload are allowed for this Sections.', and '3. You are allowed to Upload PDF/JPEG/JPG file'. The main section is titled 'D1. Label (mock-up) for immediate Container:'. It contains two sub-sections: 'a) Current Label (mock-up) for immediate Container:' which shows 'No Current Approved Data' and a table of attachments; and 'b) Proposed Label (mock-up) for immediate Container:' which has a 'Choose File' button and the text 'Please Select A File'. At the bottom, there is a green button labeled 'Remarks [D1]'.</p>
<p>EX29</p>	<p>Explanation: Click on Part 1 / Section D FG29 show a part of Section D. User can view current attachment files by clicking on the filename in the Current label table. Click on the Choose file Button to upload new files for COS. Fill the required field D1-D5</p>

FG30

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

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]

EX30	Explanation: Click on Part 1 / Section E / E1 – E2. Key-in the followings:- E1 upload attachment file E2 upload attachment file
-------------	--

FG31

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

E3. Certificate of Pharmaceutical Product (CPP) Help

E3.1. Certificate of Pharmaceutical: ⊕

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 ⊕

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? ⊕

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? ⊕

a) Current Answer and Remark:

Yes

b) Proposed Answer and Remark:

Yes NO

Remarks [E3-4]

E3.5. Date of issue of CPP ⊕

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 ⊕

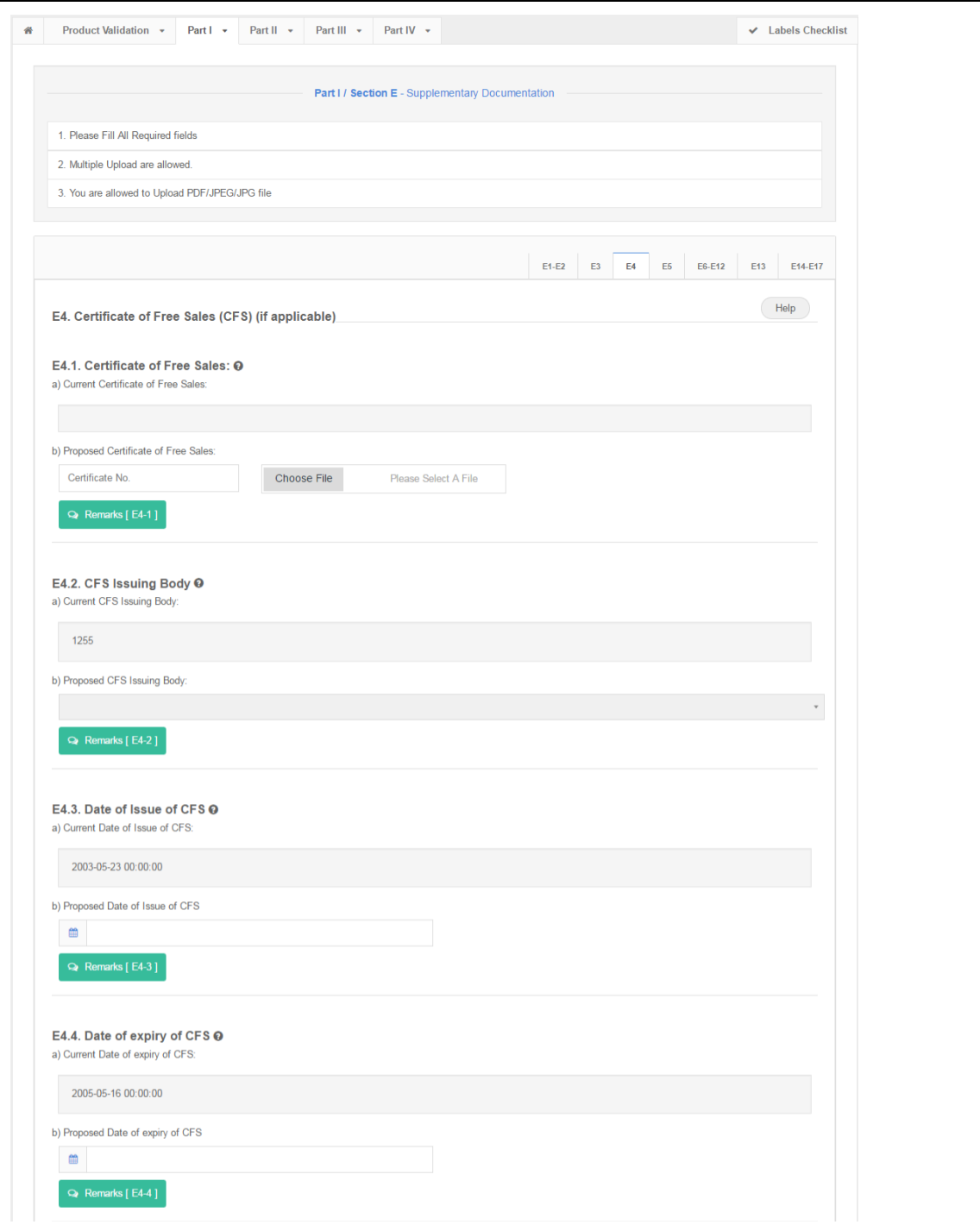
a) Current Date of expiry of CPP:

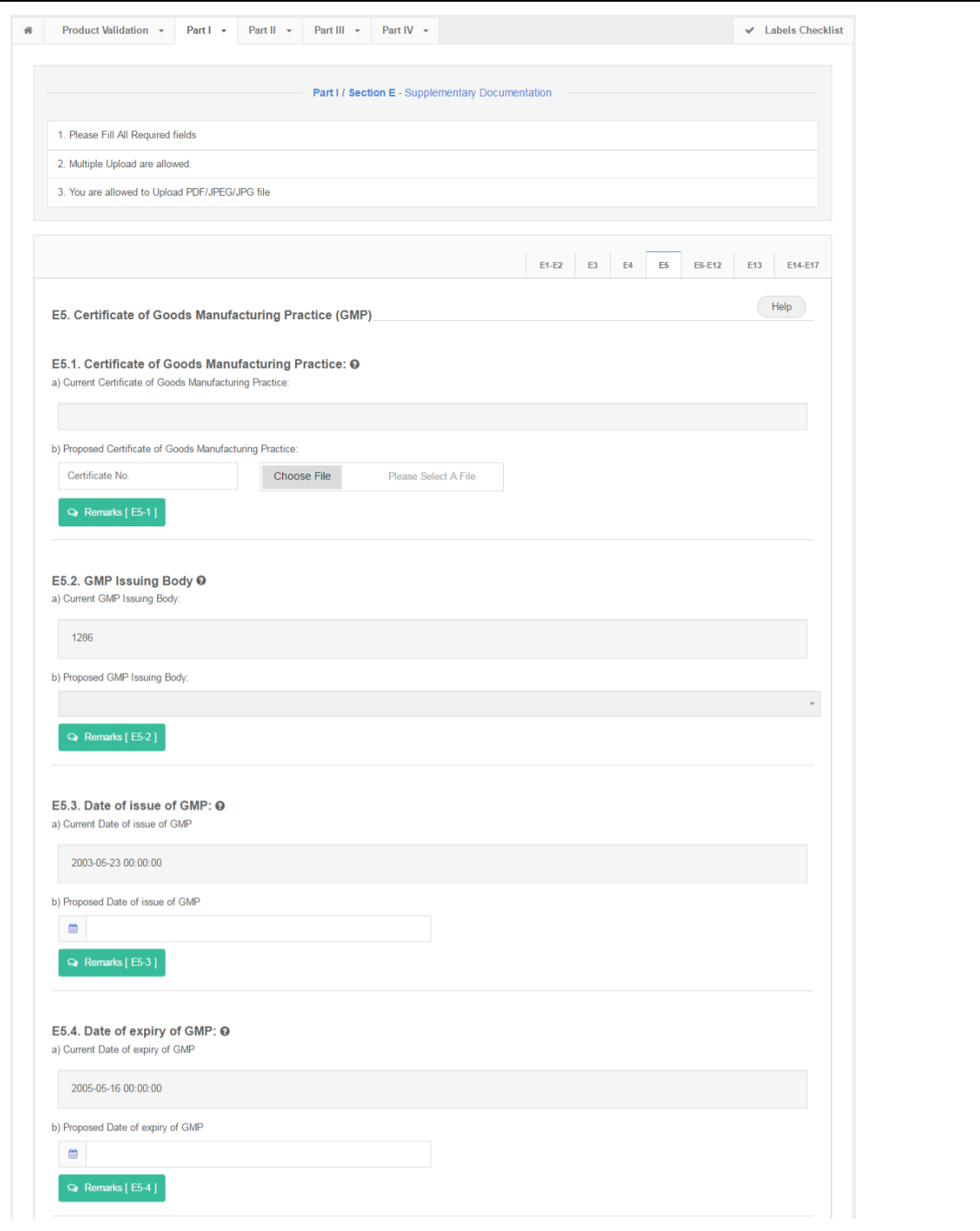
2005-05-16 00:00:00

b) Proposed Date of expiry of CPP:

Remarks [E3-6]

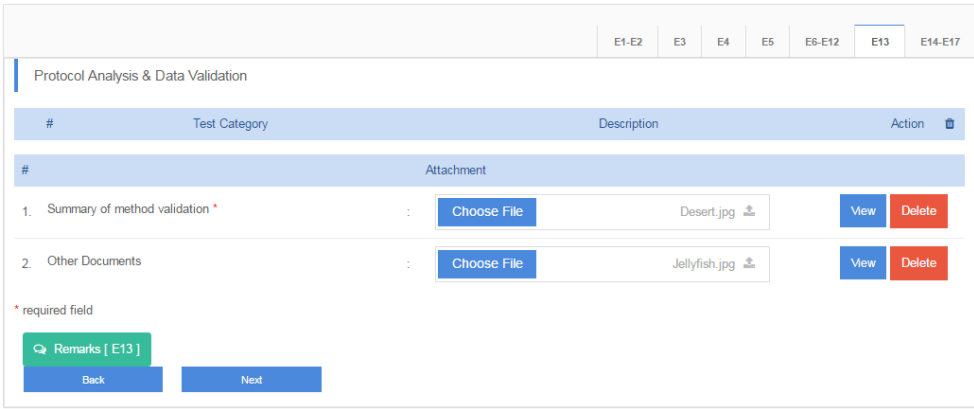
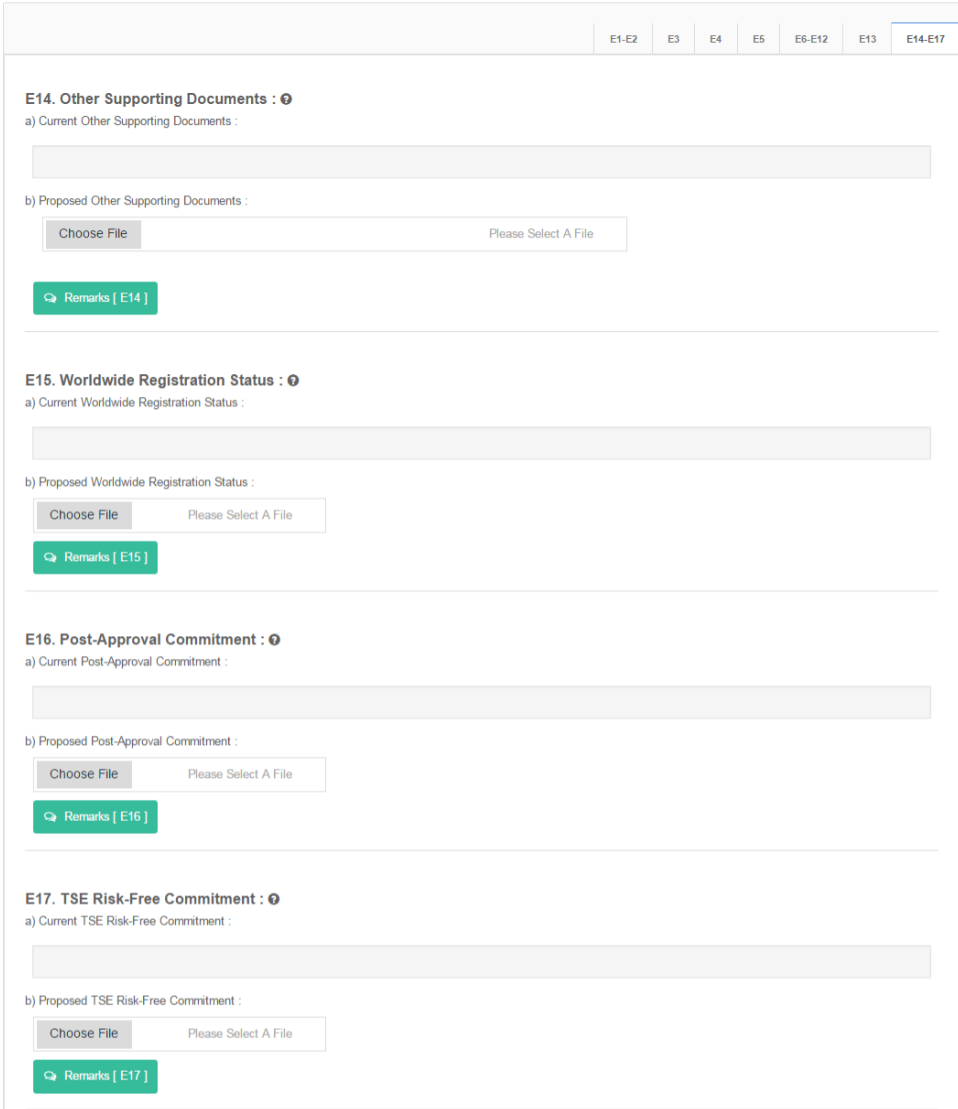
EX31	Explanation: Click on Part 1 / Section E / E3. Key-in the followings:- E3.1 upload attachment file E3.2 fill in issuing body - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list. E3.3 fill in reason E3.4 fill in reason E3.5 fill in date E3.6 fill in date
-------------	--

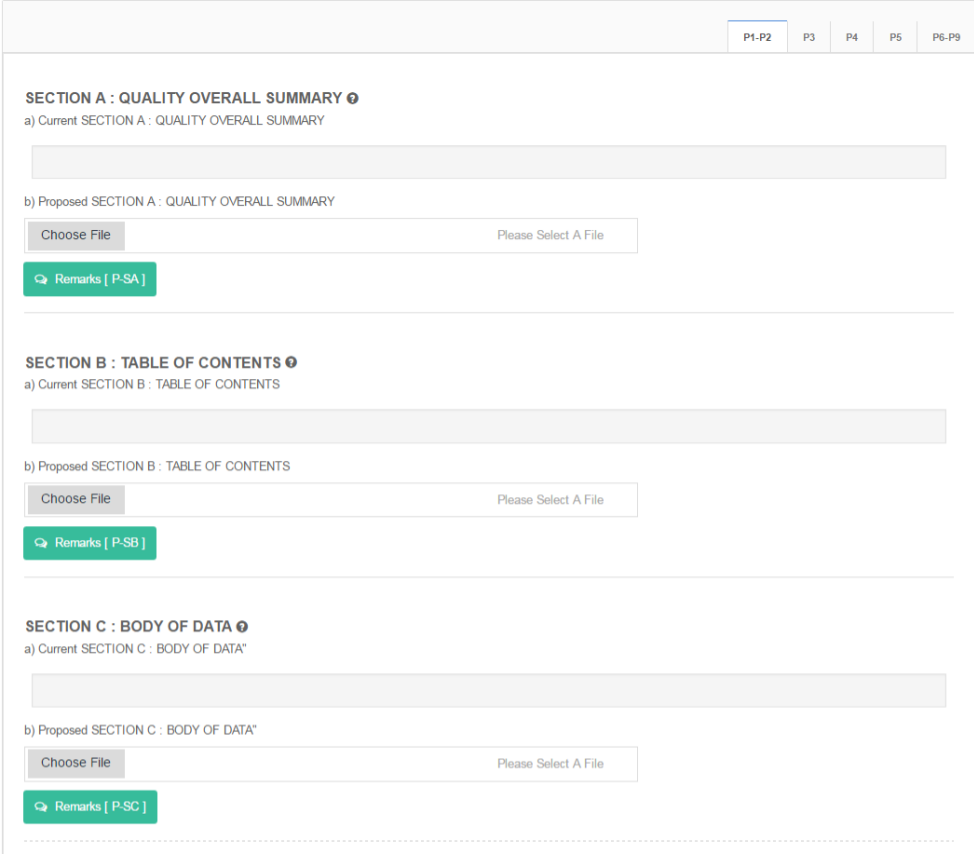
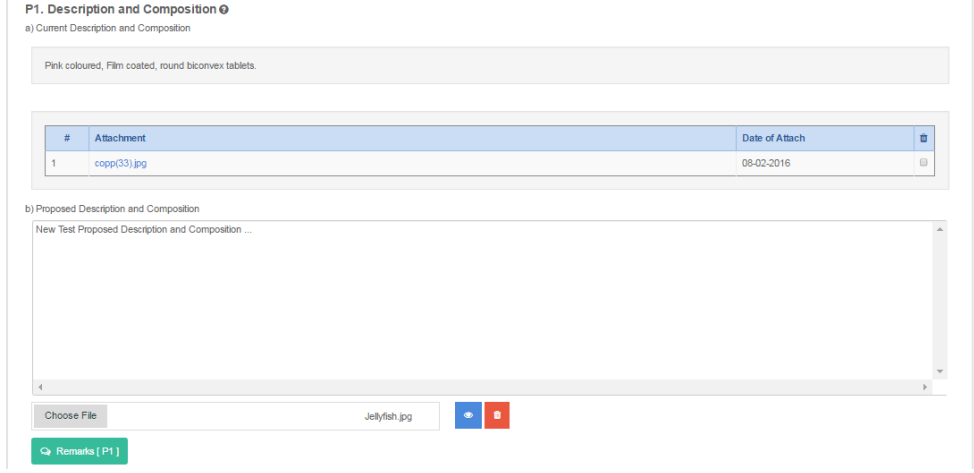
<p>FG32</p>	
<p>EX32</p>	<p>Explanation:</p> <p>Click on Part 1 / Section E / E4. Key-in the followings:-</p> <p>E4.1 upload attachment file</p> <p>E4.2 fill in issuing body</p> <ul style="list-style-type: none"> - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list <p>E4.3 fill in date</p> <p>E4.4 fill in date</p>

FG33	
EX33	<p>Explanation:</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"> - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list <p>E5.3 fill in date</p> <p>E5.4 fill in date</p>

<p>FG34</p>	<p>E7. Other Manufacturer(s) Involved : ⓘ</p> <p>a) Current Other Manufacturer(s) Involved:</p> <table border="1"> <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"> <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>EX34</p>	<p>Explanation:</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>FG35</p>	<p>E8. Importer : ⓘ</p> <p>a) Current Importer Involved:</p> <table border="1"> <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"> <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																			
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No.	Manufacturer Name	Manufacturer Address																			
1	GERMAX SDN. BHD.	NO:10, JALAN PJU 3/48, SUNWAY DAMANSARA TECHNOLOGY PARK																			
<p>EX35</p>	<p>Explanation:</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>FG36</p>	<p>E9. Store Address: ⓘ</p> <p>a) Current Store Involved:</p> <table border="1" data-bbox="304 315 1209 383"> <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: <input type="text" value="NUFERA BIO TECH SDN BHD : SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 ..."/></p> <p>Store Address: <input type="text" value="SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA"/></p> <p style="text-align: center;">ADD</p> <table border="1" data-bbox="304 546 1209 613"> <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>Remove</td> </tr> </tbody> </table> <p>Remarks [E9]</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,	Remove
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,	Remove												
<p>EX36</p>	<p>Explanation:</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>FG37</p>	<p>E10. Summary of Product Characteristic / Product Data Sheet (if applicable): ⓘ</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><input type="button" value="Choose File"/> Penguins.jpg <input type="button" value="View"/> <input type="button" value="Remove"/></p> <p>Remarks [E10]</p> <hr/> <p>E11. Company Core Data Sheet (CCDS) (if applicable): ⓘ</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><input type="button" value="Choose File"/> Koala.jpg <input type="button" value="View"/> <input type="button" value="Remove"/></p> <p>Remarks [E11]</p> <hr/> <p>E12. Analysis Protocol: ⓘ</p> <p>a) Current Analysis Protocol:</p> <p> </p> <p>b) Proposed Company Analysis Protocol:</p> <p><input type="button" value="Choose File"/> Penguins.jpg <input type="button" value="View"/> <input type="button" value="Remove"/></p> <p>Remarks [E12]</p>														
<p>EX37</p>	<p>Explanation:</p> <p>Click on Choose File button to select and upload attachment file for E10, E11, and E12.</p>														

FG38	
EX38	<p>Explanation:</p> <p>Click on Part 1/ Section E / E13.</p> <p>Click Choose File button to select and upload attachment.</p>
FG39	

<p>EX39</p>	<p>Explanation: Click on Part 1 / Section E / E14 – E17. Click Choose File button to select and upload attachment.</p>						
<p>FG40</p>	 <p>The screenshot shows a web interface with a top navigation bar containing tabs for P1-P2, P3, P4, P5, and P6-P9. Below this, there are three sections:</p> <ul style="list-style-type: none"> SECTION A : QUALITY OVERALL SUMMARY <ul style="list-style-type: none"> a) Current SECTION A : QUALITY OVERALL SUMMARY (text area) b) Proposed SECTION A : QUALITY OVERALL SUMMARY <ul style="list-style-type: none"> Choose File (button) Please Select A File (text) Remarks [P-SA] (button) SECTION B : TABLE OF CONTENTS <ul style="list-style-type: none"> a) Current SECTION B : TABLE OF CONTENTS (text area) b) Proposed SECTION B : TABLE OF CONTENTS <ul style="list-style-type: none"> Choose File (button) Please Select A File (text) Remarks [P-SB] (button) SECTION C : BODY OF DATA <ul style="list-style-type: none"> a) Current SECTION C : BODY OF DATA (text area) b) Proposed SECTION C : BODY OF DATA <ul style="list-style-type: none"> Choose File (button) Please Select A File (text) Remarks [P-SC] (button) 						
<p>EX40</p>	<p>Explanation: Click Choose File button to select and upload attachment.</p>						
<p>FG41</p>	 <p>The screenshot shows the 'P1. Description and Composition' section:</p> <ul style="list-style-type: none"> a) Current Description and Composition: Pink coloured, Film coated, round biconvex tablets. Attachment Table: <table border="1"> <thead> <tr> <th>#</th> <th>Attachment</th> <th>Date of Attach</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>copp(33).jpg</td> <td>08-02-2016</td> </tr> </tbody> </table> b) Proposed Description and Composition: New Test Proposed Description and Composition ... (text area) Choose File (button) Jellyfish.jpg (text) [+] [-] (buttons) Remarks [P1] (button) 	#	Attachment	Date of Attach	1	copp(33).jpg	08-02-2016
#	Attachment	Date of Attach					
1	copp(33).jpg	08-02-2016					
<p>EX41</p>	<p>Explanation: Type or paste text on the text area and click on Choose File Button to upload attachment.</p>						

FG42	<p>P2. Pharmaceutical Development</p> <hr/> <p>P2.1 Information on Development Studies ⓘ</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 Please Select A File</p> <p>Remarks [P2-1]</p>
EX42	<p>Explanation:</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>

FG43

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:

SLNO	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

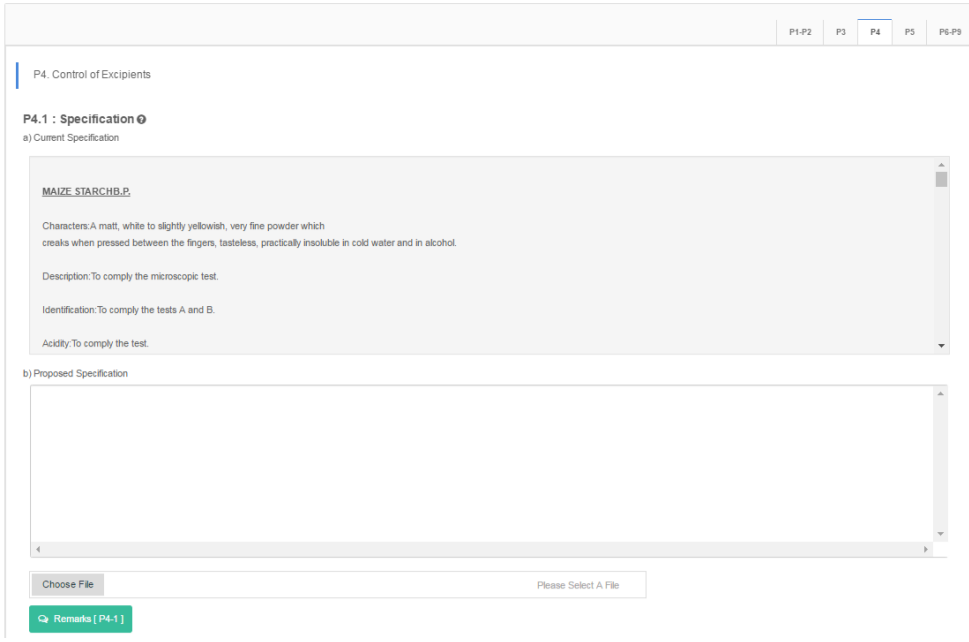
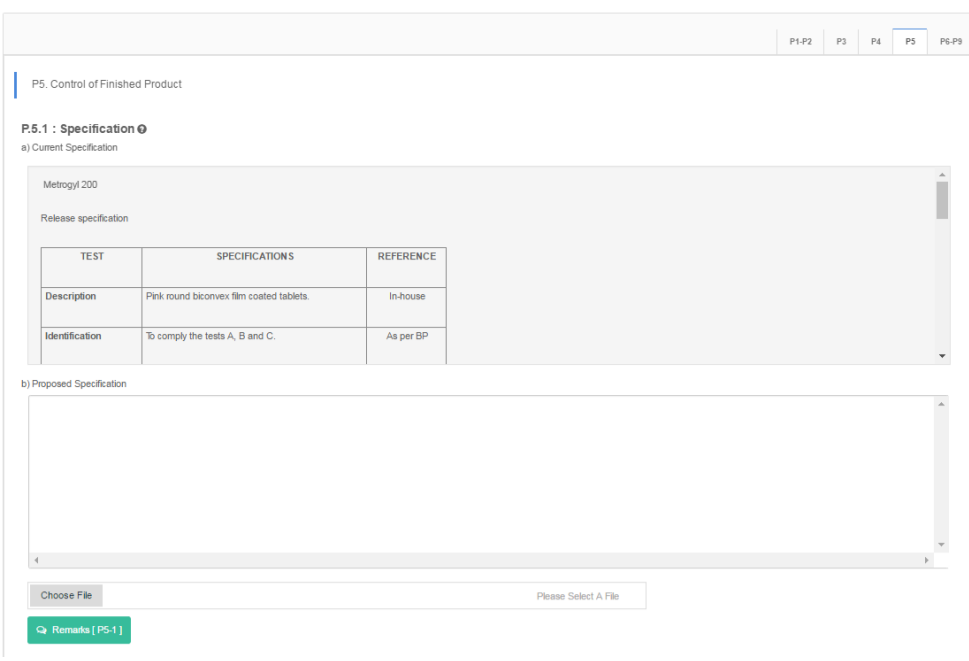
b) Proposed Control of Critical Steps and Intermediate

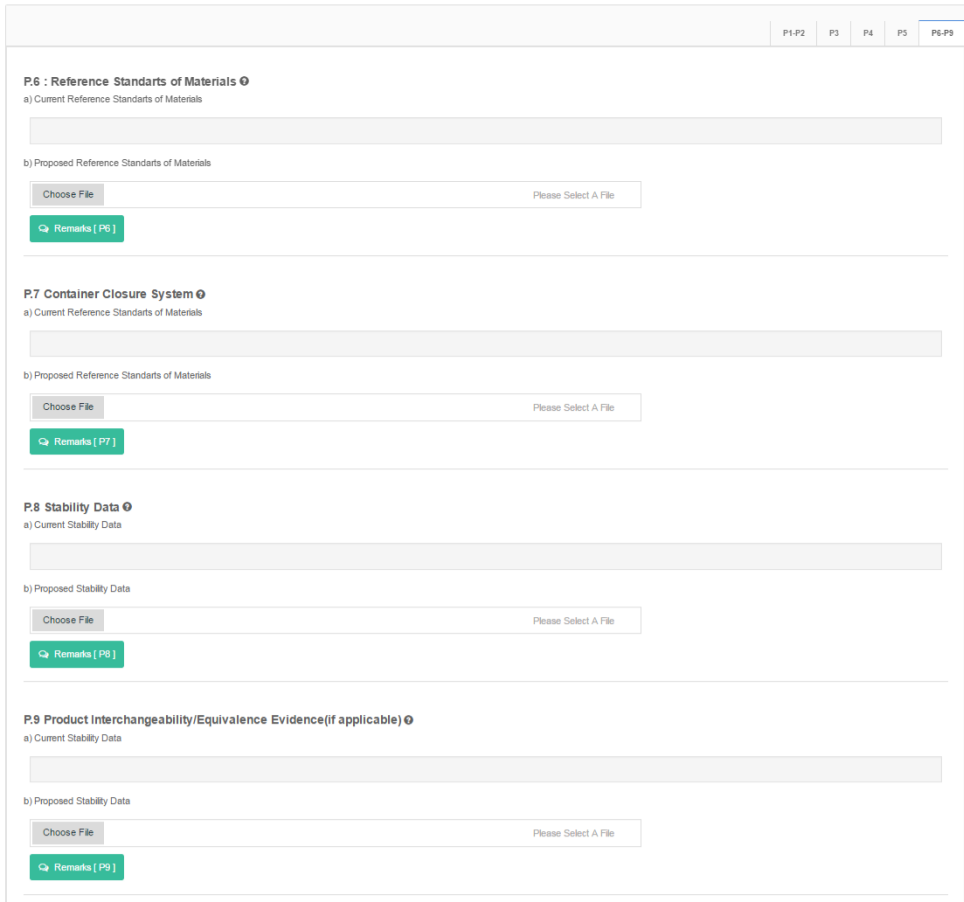
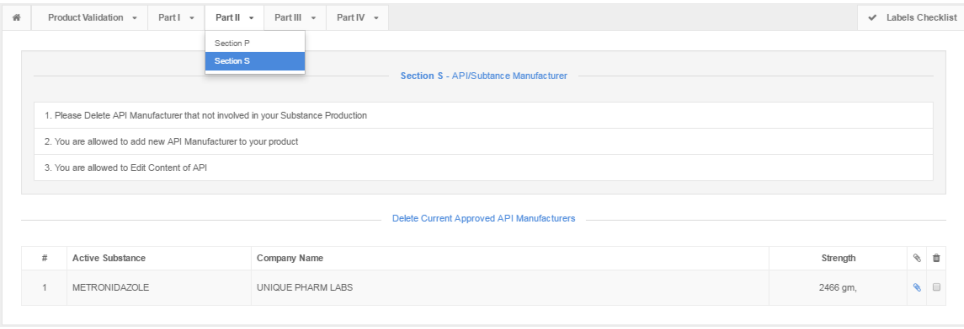
Please Select A File

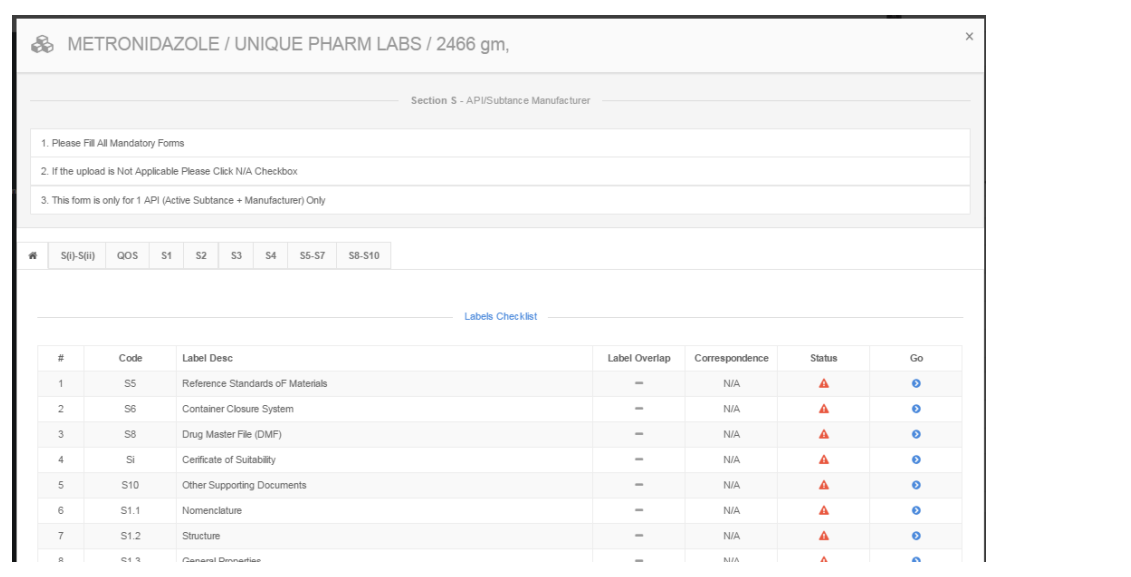
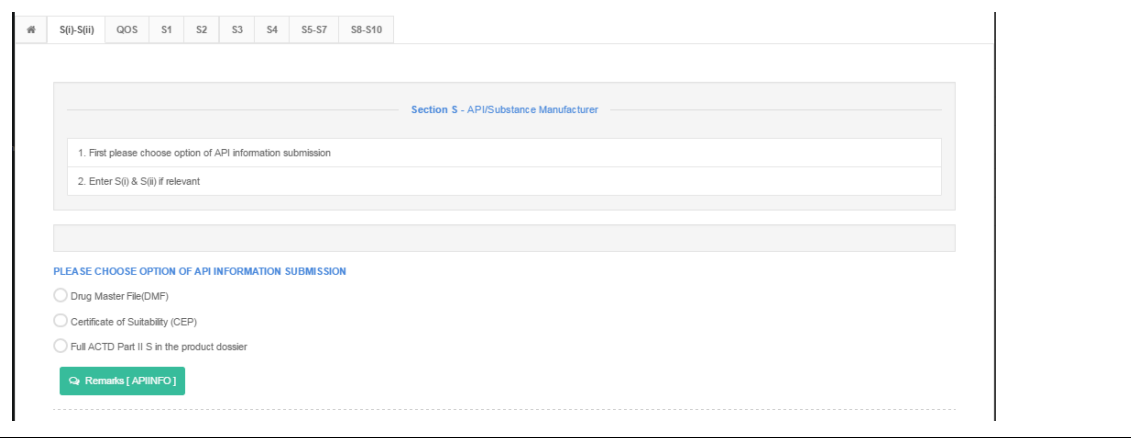
Remarks [P3-4]

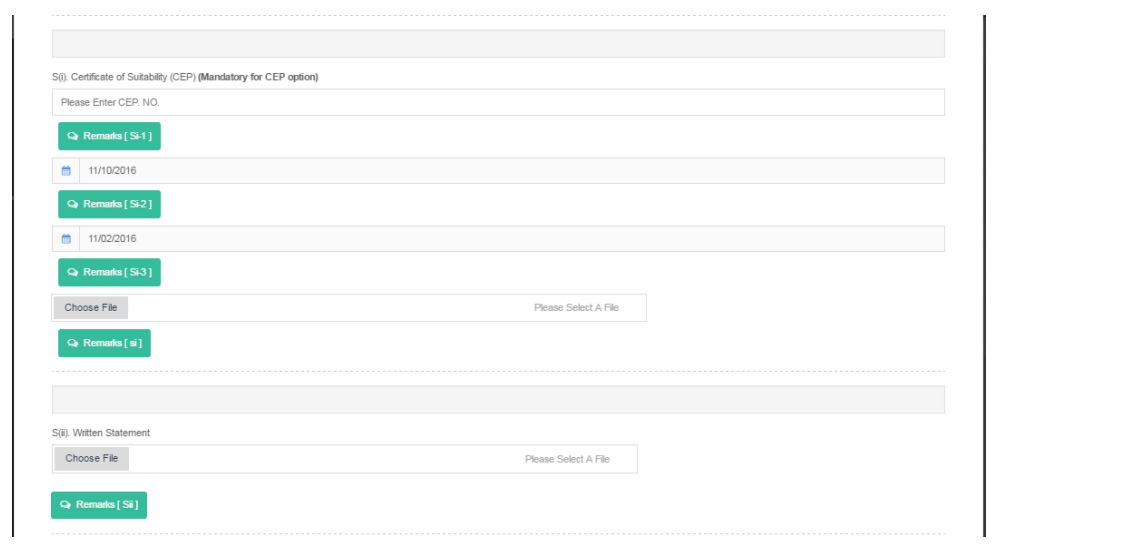
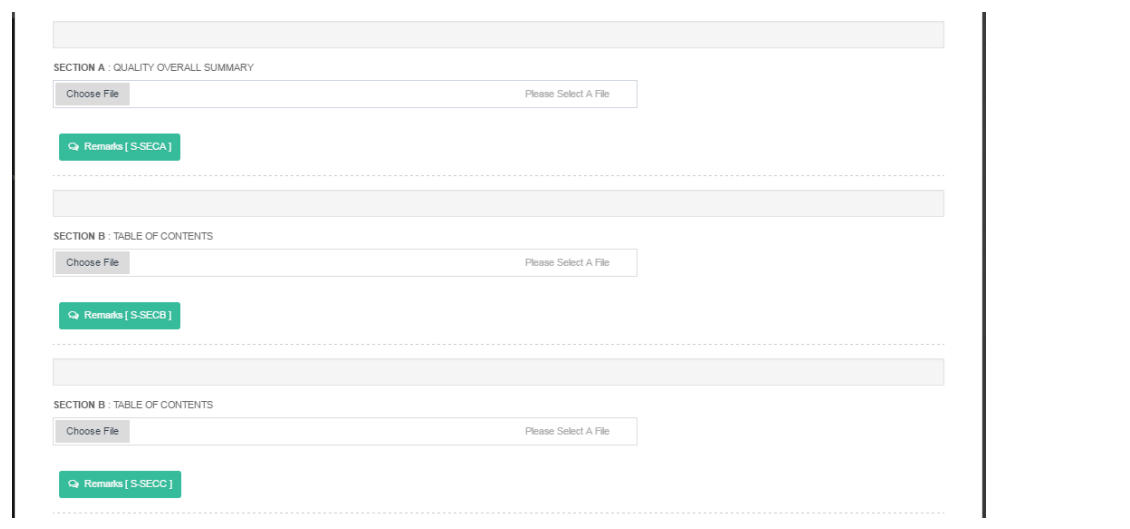
EX43

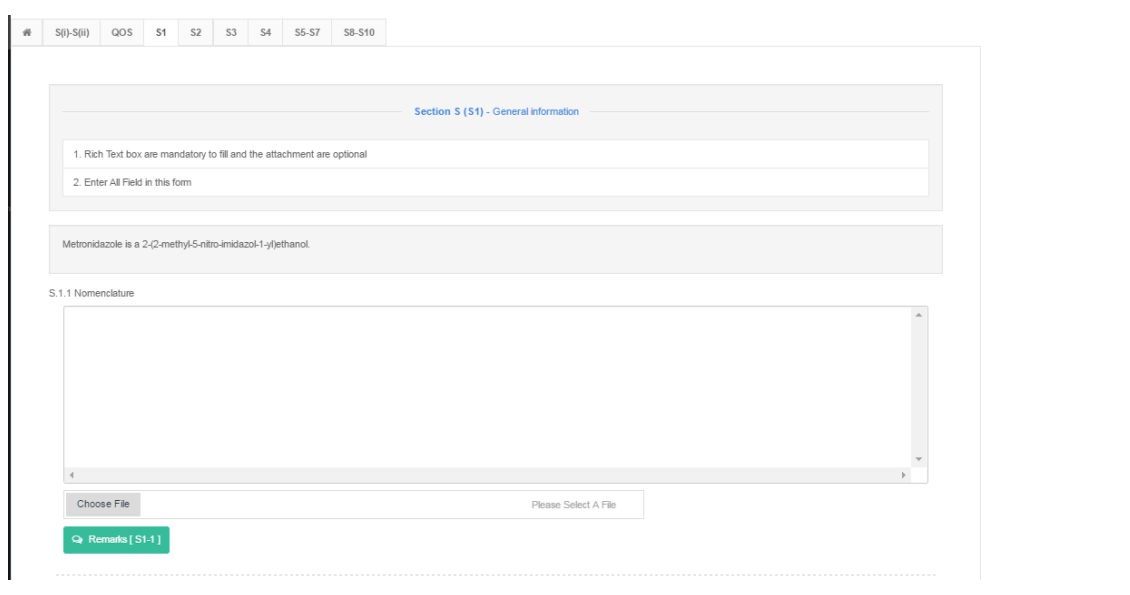
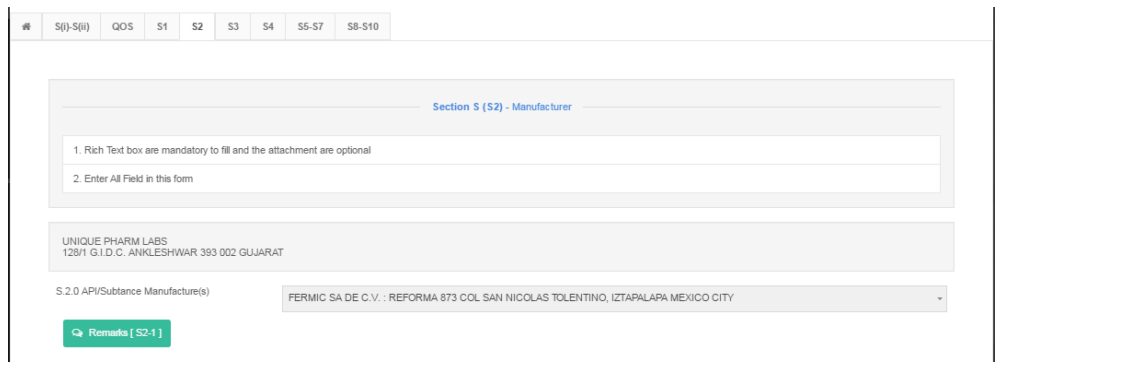
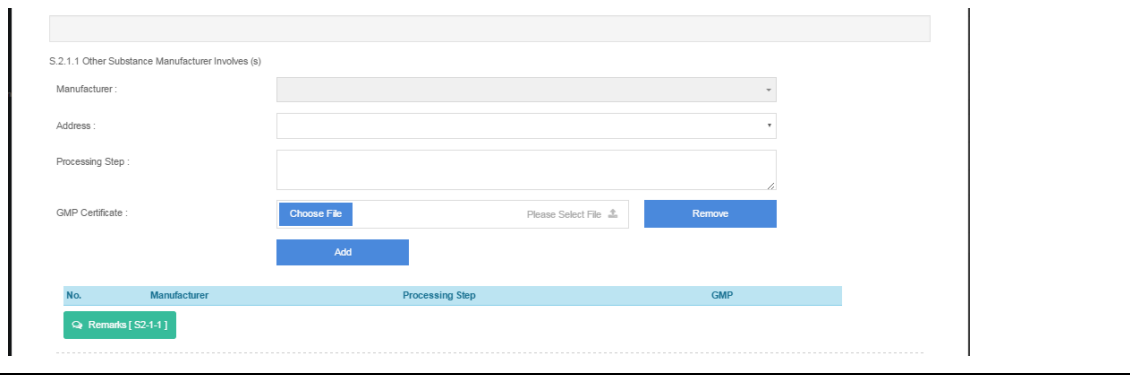
Explanation:
Type or paste text on the text area and click on Choose File Button to upload attachment.
Key-in for the following P3.2 – P3.4.

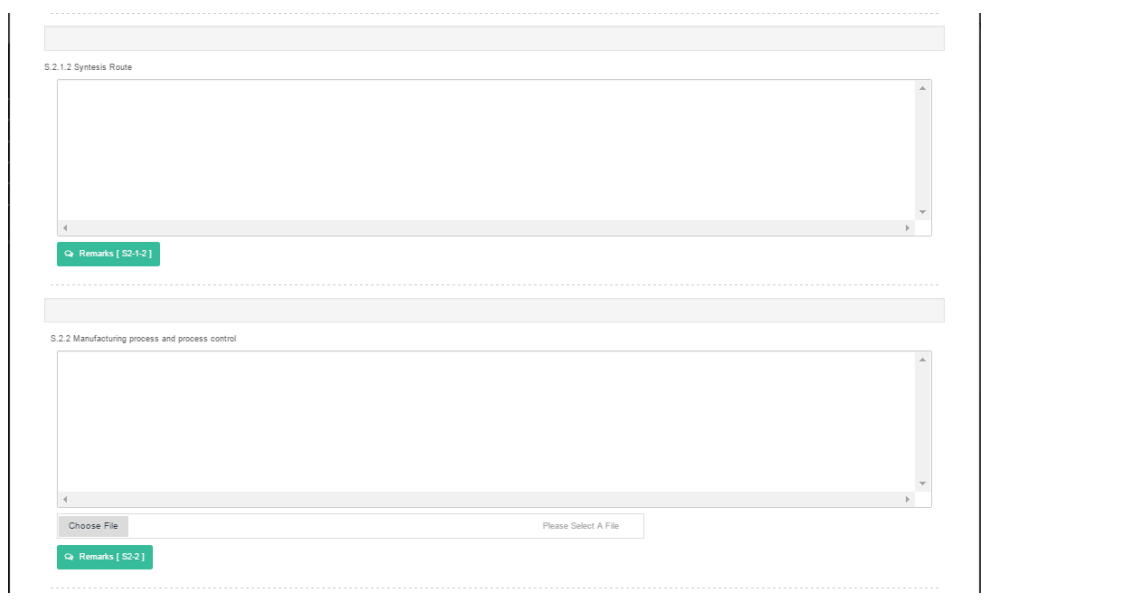
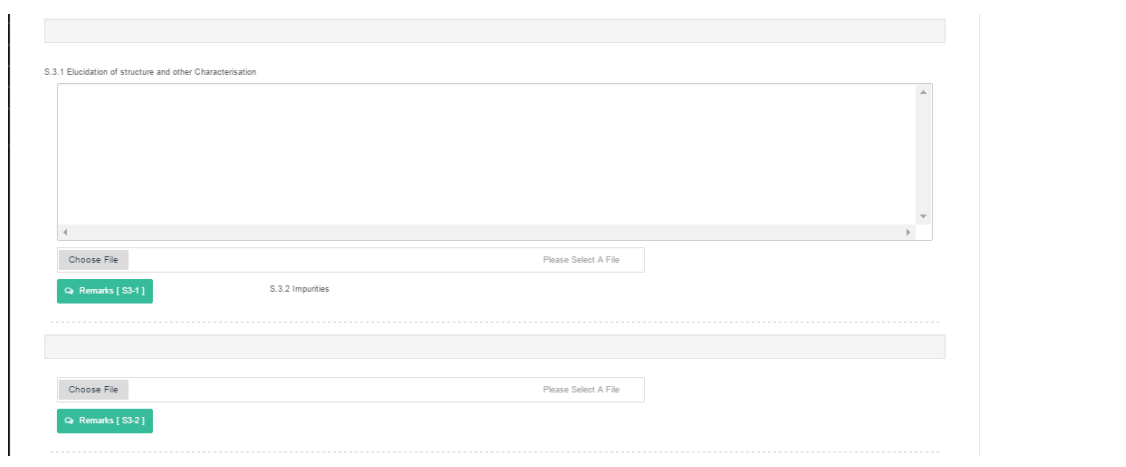
<p>FG44</p>										
<p>EX44</p>	<p>Explanation: Type or paste text on the text area and click on Choose File Button to upload attachment. Key-in for the following P4.1 – P4.6.</p>									
<p>FG45</p>	 <table border="1" data-bbox="300 1310 715 1429"> <thead> <tr> <th>TEST</th> <th>SPECIFICATIONS</th> <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>EX45</p>	<p>Explanation: 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>									

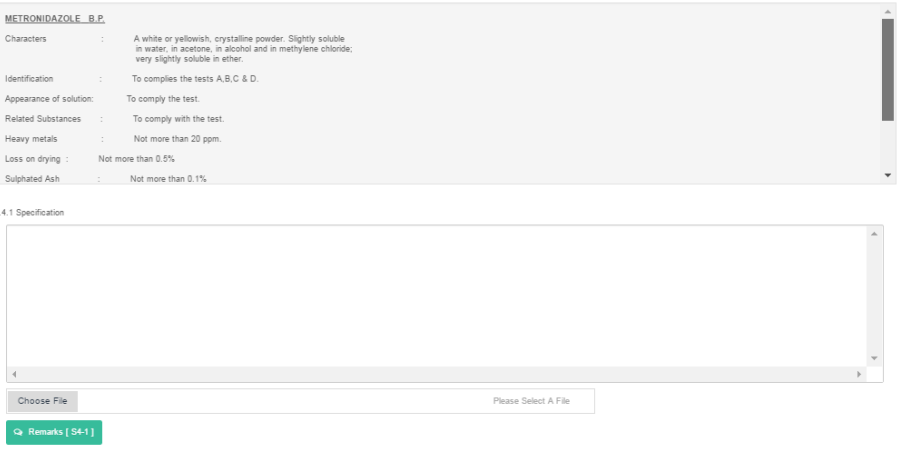
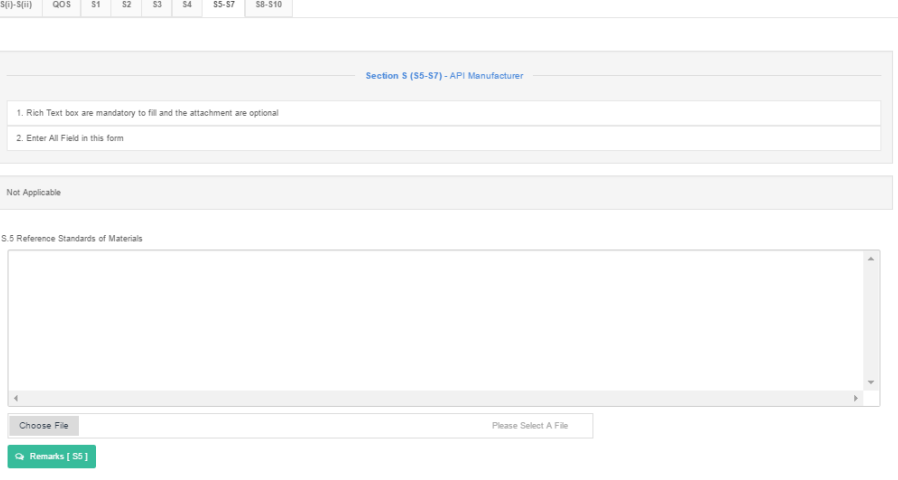
<p>FG46</p>	
<p>EX46</p>	<p>Explanation: Click on Choose File button to upload attachment for P6 – P9.</p>
<p>FG47</p>	
<p>EX47</p>	<p>Explanation: Click on Part 2 / Section S Click on the clip-icon to open the popup form.</p>

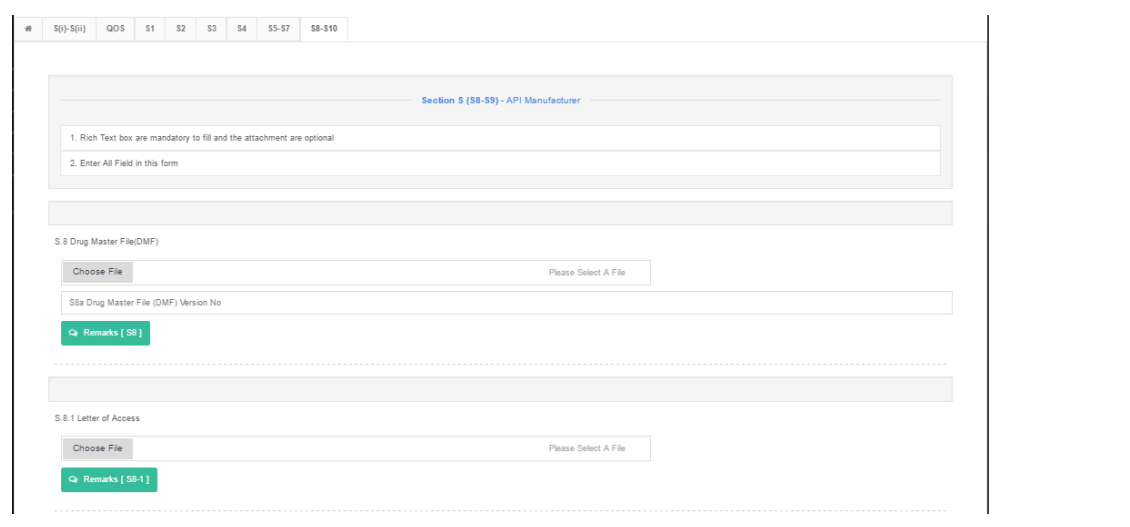
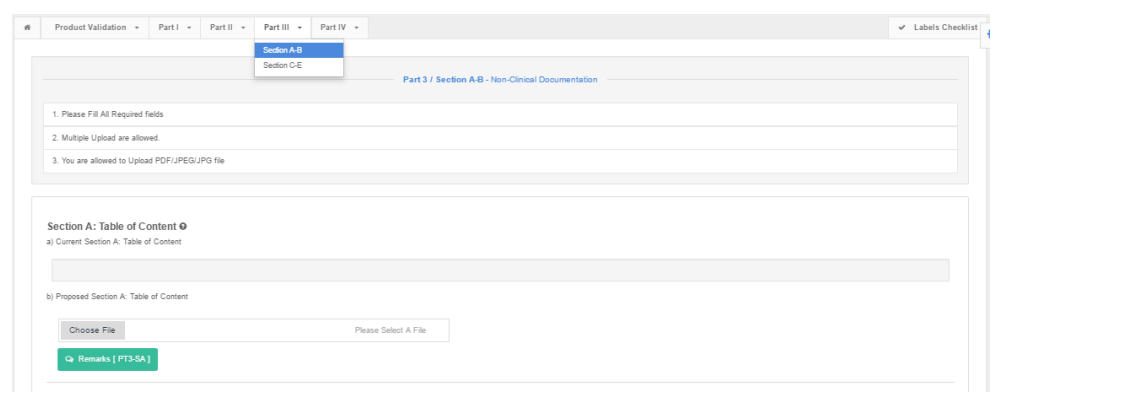
<p>FG48</p>	 <p>Section S - API/Substance Manufacturer</p> <p>1. Please Fill All Mandatory Forms 2. If the upload is Not Applicable Please Click N/A Checkbox 3. This form is only for 1 API (Active Substance + Manufacturer) Only</p> <p># S(i)-S(ii) QOS S1 S2 S3 S4 S5-S7 S8-S10</p> <p>Labels Checklist</p> <table border="1"> <thead> <tr> <th>#</th> <th>Code</th> <th>Label Desc</th> <th>Label Overlap</th> <th>Correspondence</th> <th>Status</th> <th>Go</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>S5</td> <td>Reference Standards of Materials</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>2</td> <td>S6</td> <td>Container Closure System</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</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> </tr> <tr> <td>4</td> <td>S1</td> <td>Certificate of Suitability</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>5</td> <td>S10</td> <td>Other Supporting Documents</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>6</td> <td>S1.1</td> <td>Nomenclature</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>7</td> <td>S1.2</td> <td>Structure</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> <tr> <td>8</td> <td>S1.3</td> <td>General Description</td> <td>—</td> <td>N/A</td> <td>▲</td> <td>🔗</td> </tr> </tbody> </table>	#	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	S1	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	▲	🔗
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8	S1.3	General Description	—	N/A	▲	🔗																																																										
<p>EX48</p>	<p>Explanation: FG48 shows a popup form for Section S.</p>																																																															
<p>FG49</p>	 <p>Section S - API/Substance Manufacturer</p> <p>1. First please choose option of API information submission 2. Enter S(i) & S(ii) if relevant</p> <p>PLEASE CHOOSE OPTION OF API INFORMATION SUBMISSION</p> <p><input type="radio"/> Drug Master File(DMF) <input type="radio"/> Certificate of Suitability (CEP) <input type="radio"/> Full ACTD Part II S in the product dossier</p> <p>Remarks [APIINFO]</p>																																																															
<p>EX49</p>	<p>Explanation: Click on S(i)-S(ii) Select API Information</p>																																																															

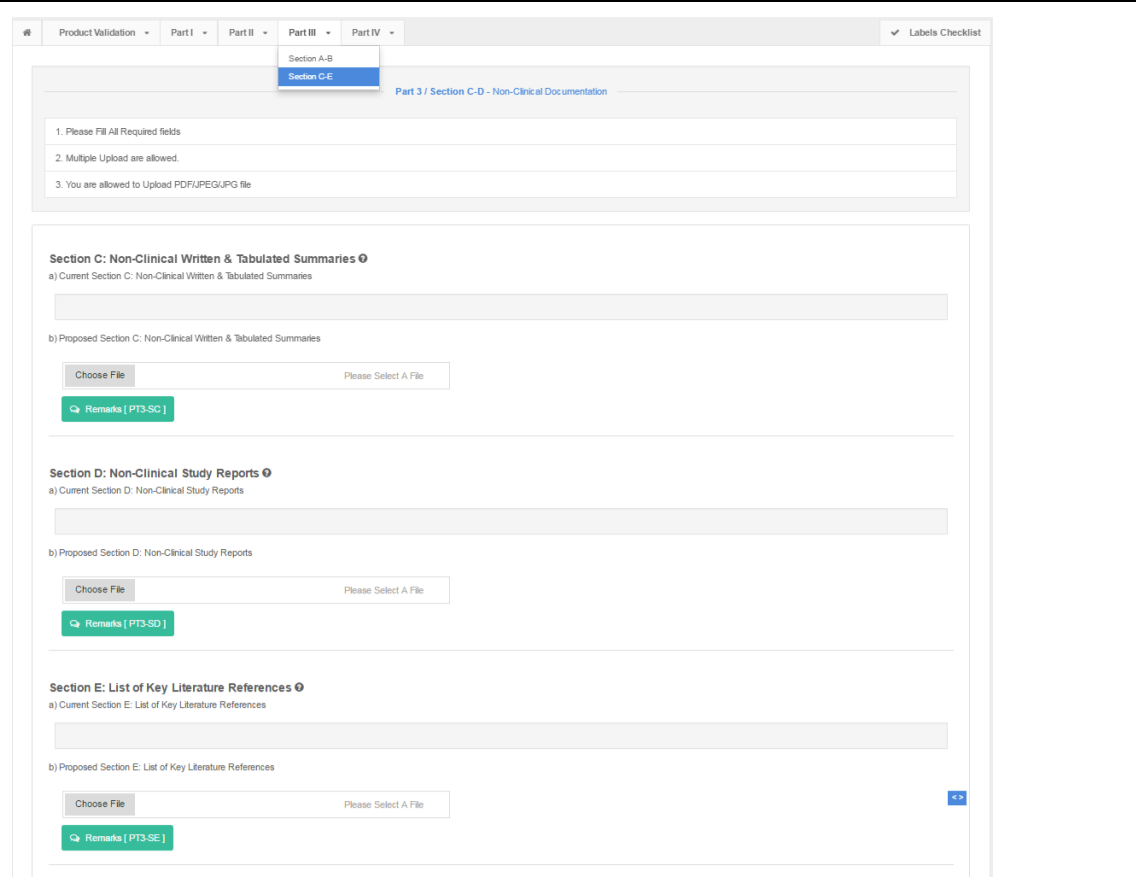
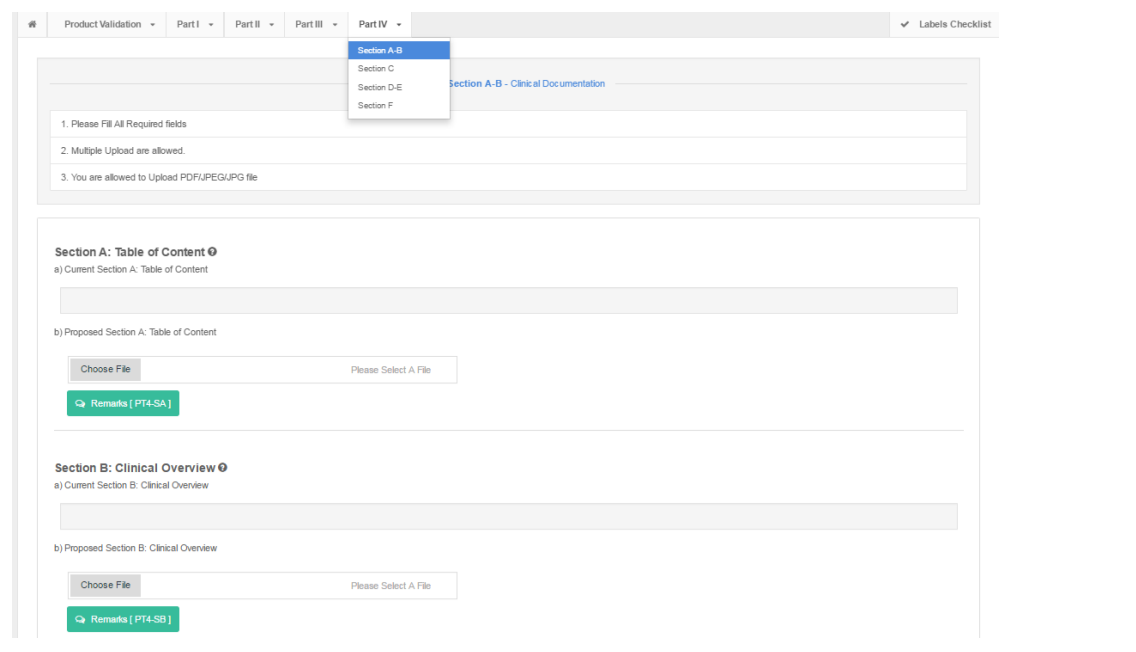
<p>FG50</p>	
<p>EX50</p>	<p>Explanation: Select Date by clicking on the calendar-icon. Click on Choose File button to upload attachment</p>
<p>FG51</p>	
<p>EX51</p>	<p>Explanation: Click on QOS Click on Choose File button to upload attachment</p>

<p>FG52</p>	
<p>EX52</p>	<p>Explanation: 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>FG53</p>	
<p>EX53</p>	<p>Explanation: Click on the dropdown option to search for API Substance Manufacturer.</p>
<p>FG54</p>	
<p>EX54</p>	<p>Explanation: Click on Manufacturer field to search for a manufacturer. Select Address and key-in Processing Step.</p>

	<p>Upload GMP by clicking on the Choose File button Click on ADD button to add the selected manufacturer.</p>
<p>FG55</p>	
<p>EX55</p>	<p>Explanation: Type or paste text into the text area. Click on Choose File button to upload attachment.</p>
<p>FG56</p>	
<p>EX56</p>	<p>Explanation: Click on S3 Type or paste text into the text area. Click on Choose File button to upload attachment.</p>

<p>FG57</p>	
<p>EX57</p>	<p>Explanation: 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>FG58</p>	
<p>EX58</p>	<p>Explanation: 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>FG59</p>	
<p>EX59</p>	<p>Explanation: 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>FG60</p>	
<p>EX60</p>	<p>Explanation: 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>FG61</p>	
<p>EX61</p>	<p>Explanation: Click on Choose File button to select and upload attachment.</p>
<p>FG62</p>	
<p>EX62</p>	<p>Explanation: Click on Choose File button to select and upload attachment.</p>

FG63

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

Section A-B
Section C
 Section D-E
 Section F

Section C - Clinical Documentation

1. Please Fill All Required fields
 2. Multiple Upload are allowed.
 3. You are allowed to Upload PDF/JPEG/JPG file

Section C: Clinical Summary

C1. Summary of Biopharmaceutics Studies and Associated Analytical Methods

a) Current Summary of Biopharmaceutics Studies and Associated Analytical Methods

b) Proposed Summary of Biopharmaceutics Studies and Associated Analytical Methods

Choose File Please Select A File

Remarks [PT4-C1]

C2. Summary of Clinical Pharmacology Studies

a) Current Summary of Clinical Pharmacology Studies

b) Proposed Summary of Clinical Pharmacology Studies

Choose File Please Select A File

Remarks [PT4-C2]

C3. Summary of Clinical Efficacy

a) Current Summary of Clinical Efficacy

b) Proposed Summary of Clinical Efficacy

Choose File Please Select A File

Remarks [PT4-C3]

C4. Summary of Clinical Safety

a) Current Summary of Clinical Safety

b) Proposed Summary of Clinical Safety

Choose File Please Select A File

Remarks [PT4-C4]

C5. Synopsis of Individual Studies

a) Current Synopsis of Individual Studies

b) Proposed Synopsis of Individual Studies

Choose File Please Select A File

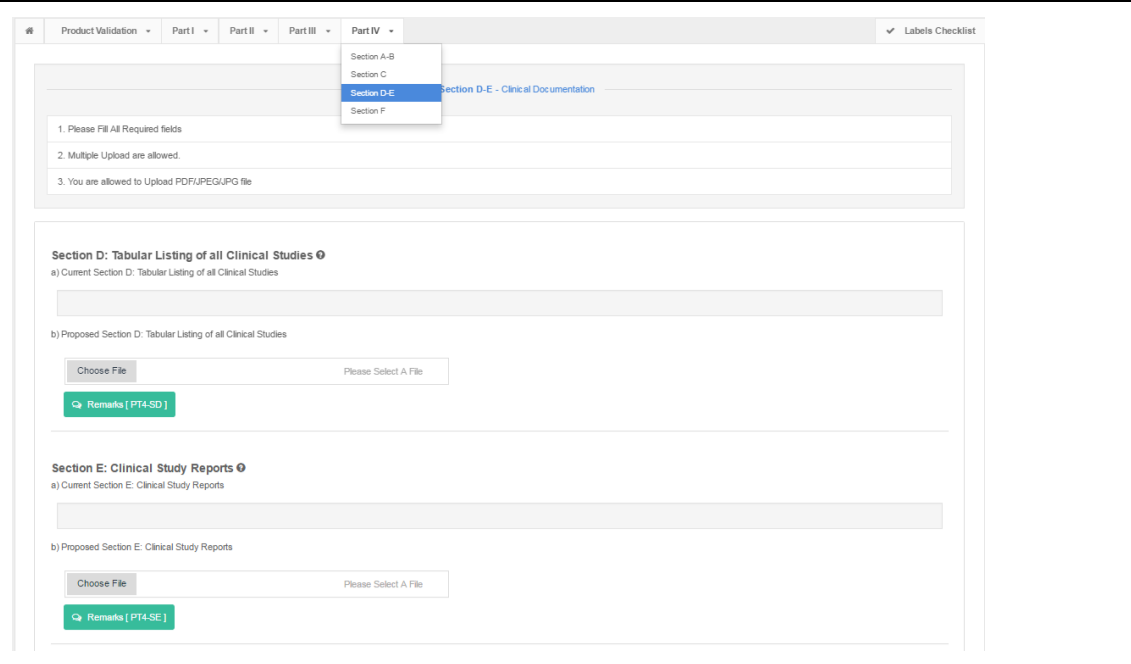
Remarks [PT4-C5]

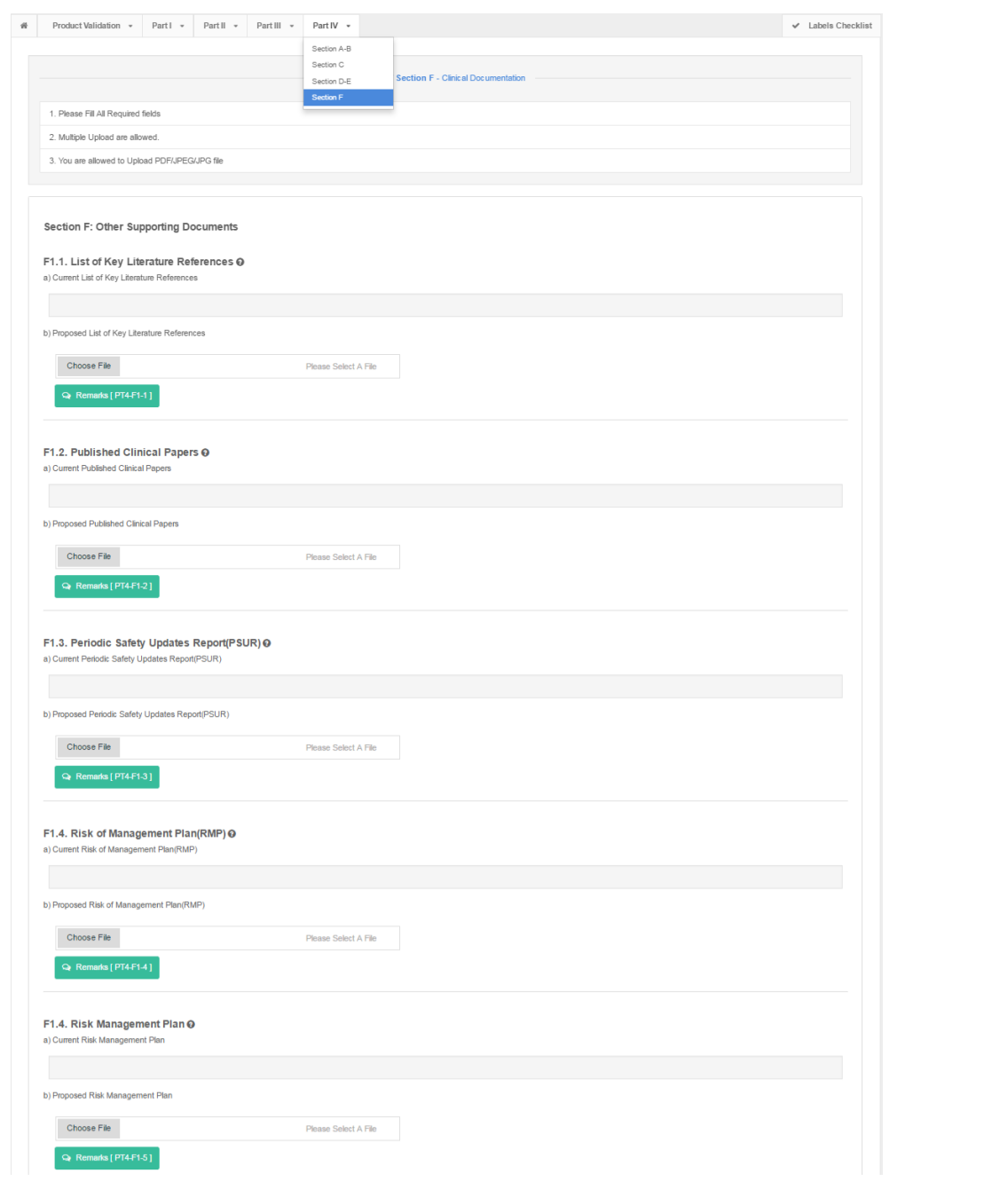
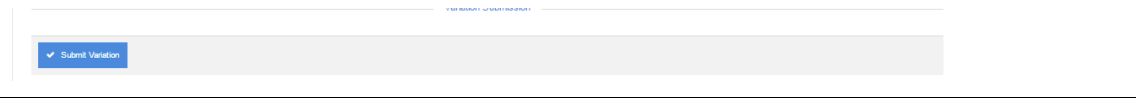
EX53

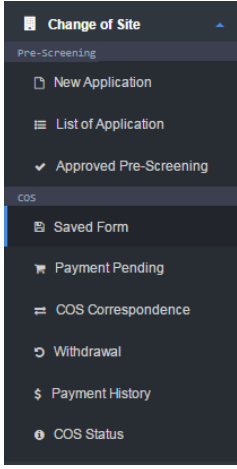
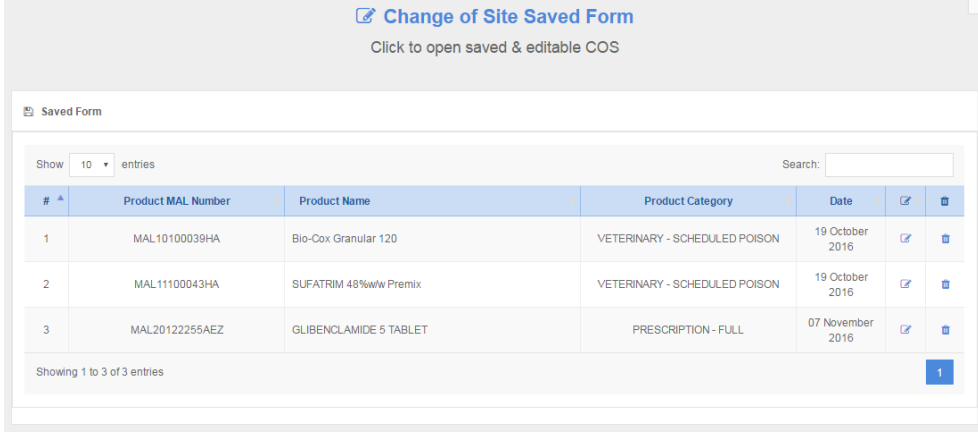
Explanation:

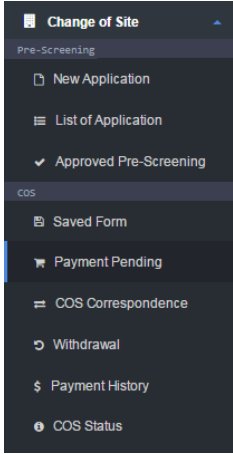
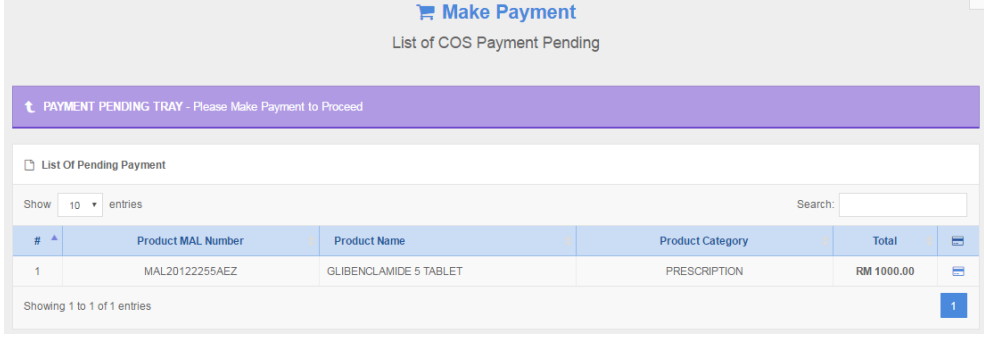
Click on Part 4 / Section C

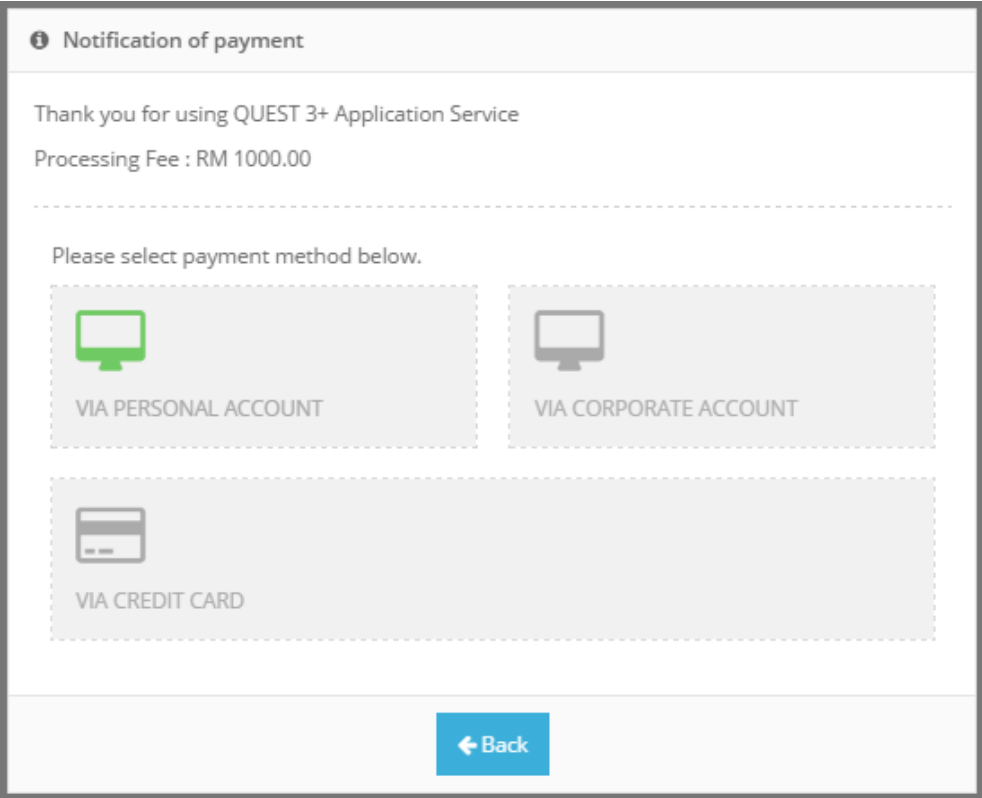
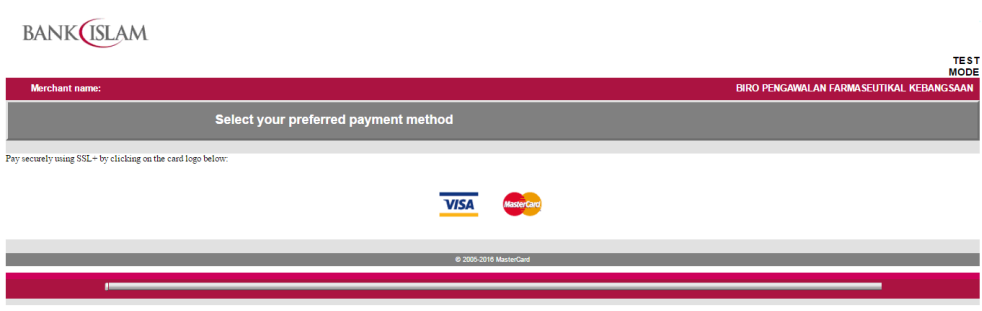
Click on Choose File button to select and upload attachment.

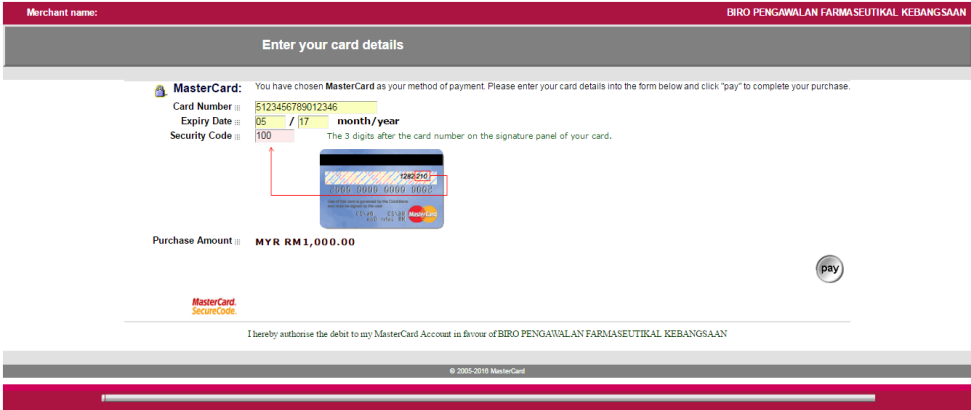
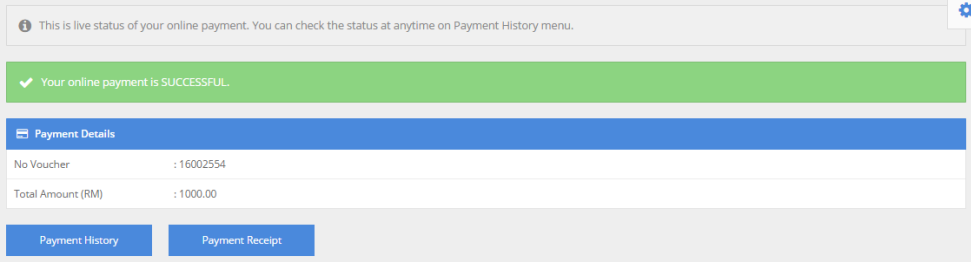
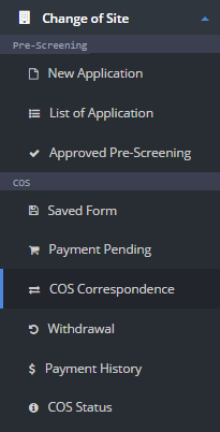
<p>FG64</p>	
<p>EX64</p>	<p>Explanation: Click on Part 4 / Section D-E Click on Choose File button to select and upload attachment.</p>

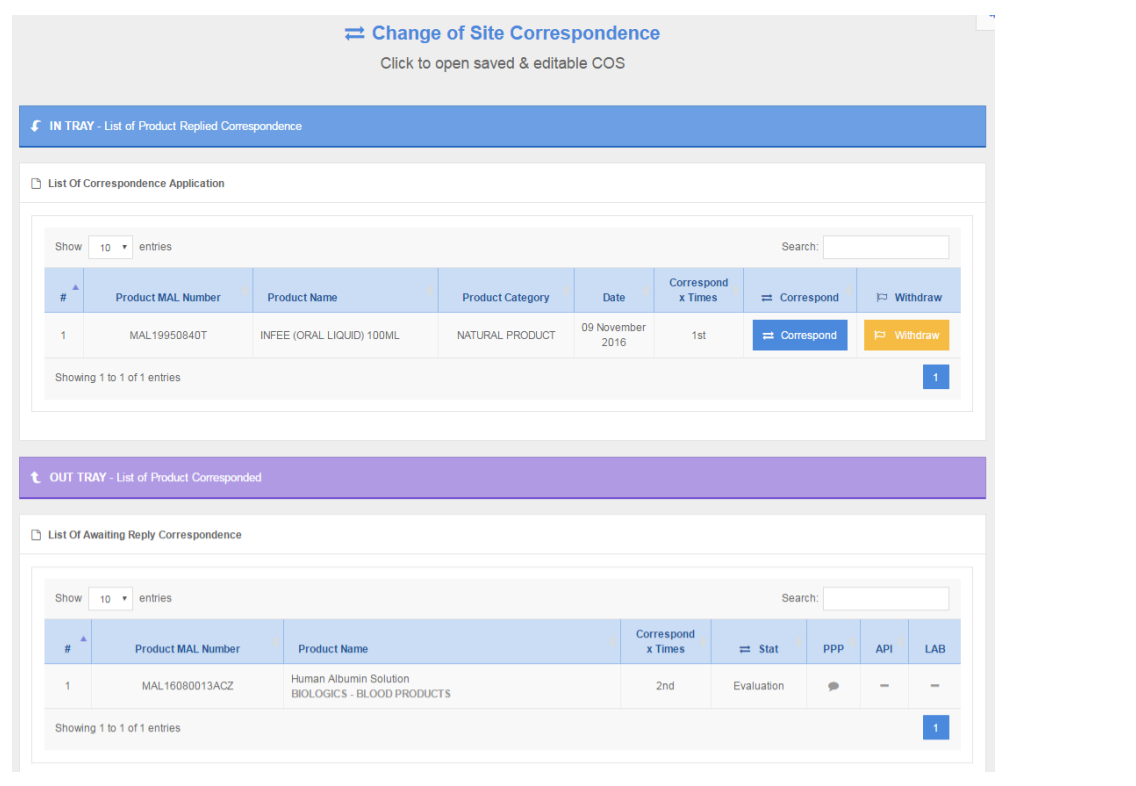
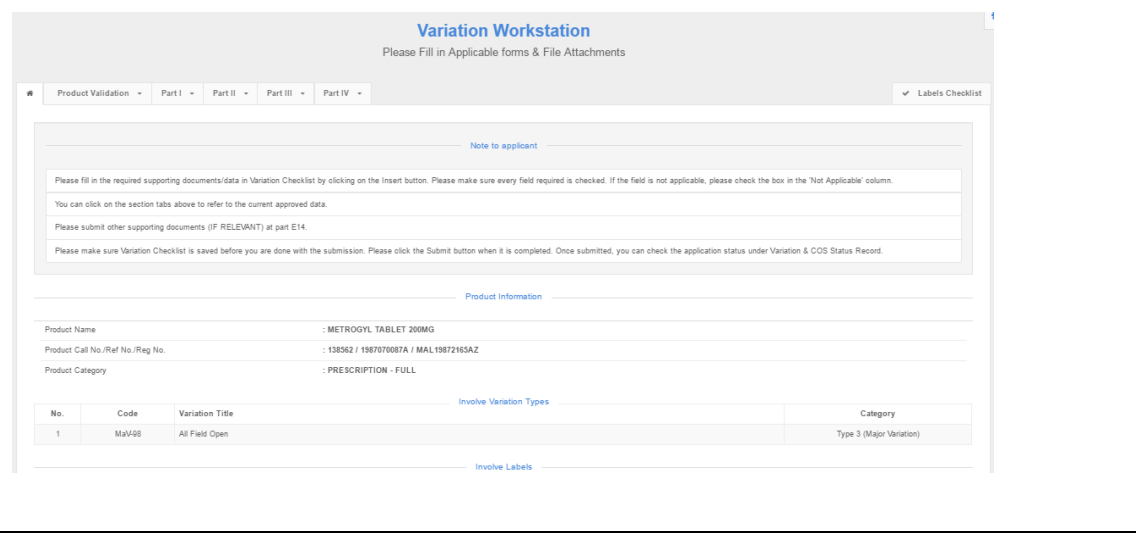
<p>FG65</p>	
<p>EX65</p>	<p>Explanation: Click on Part 4 / Section F Click on Choose File button to select and upload attachment.</p>
<p>FG66</p>	
<p>EX66</p>	<p>Explanation: After finish filling all the required fields. Click on home-icon and scroll down to bottom of page. Click on Submit Variation button as shown in FG66</p>
<p>Saved Form</p>	

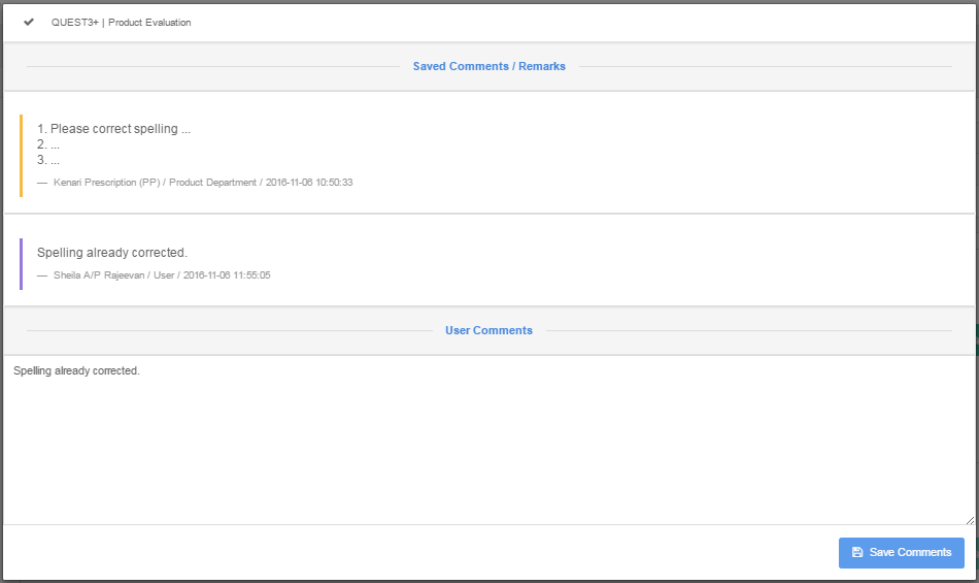
<p>FG67</p>																													
<p>EX67</p>	<p>Explanation: Click on Change of Site / Saved Form</p>																												
<p>FG68</p>	 <table border="1"> <thead> <tr> <th>#</th> <th>Product MAL Number</th> <th>Product Name</th> <th>Product Category</th> <th>Date</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL10100039HA</td> <td>Bio-Cox Granular 120</td> <td>VETERINARY - SCHEDULED POISON</td> <td>19 October 2016</td> <td></td> <td></td> </tr> <tr> <td>2</td> <td>MAL11100043HA</td> <td>SUFATRIM 48%w/w Premix</td> <td>VETERINARY - SCHEDULED POISON</td> <td>19 October 2016</td> <td></td> <td></td> </tr> <tr> <td>3</td> <td>MAL20122255AEZ</td> <td>GLIBENCLAMIDE 5 TABLET</td> <td>PRESCRIPTION - FULL</td> <td>07 November 2016</td> <td></td> <td></td> </tr> </tbody> </table>	#	Product MAL Number	Product Name	Product Category	Date			1	MAL10100039HA	Bio-Cox Granular 120	VETERINARY - SCHEDULED POISON	19 October 2016			2	MAL11100043HA	SUFATRIM 48%w/w Premix	VETERINARY - SCHEDULED POISON	19 October 2016			3	MAL20122255AEZ	GLIBENCLAMIDE 5 TABLET	PRESCRIPTION - FULL	07 November 2016		
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3	MAL20122255AEZ	GLIBENCLAMIDE 5 TABLET	PRESCRIPTION - FULL	07 November 2016																									
<p>EX68</p>	<p>Explanation: FG68 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>																												
<p>2.3</p>	<p>Payment Pending</p>																												

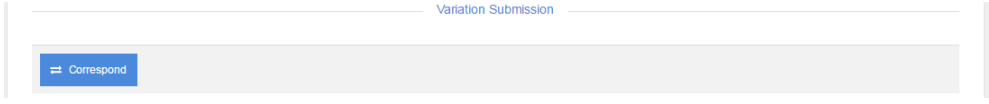
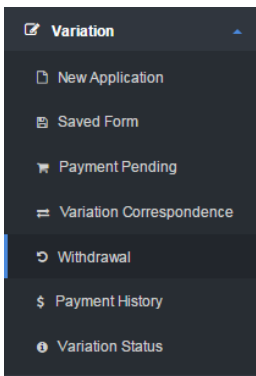
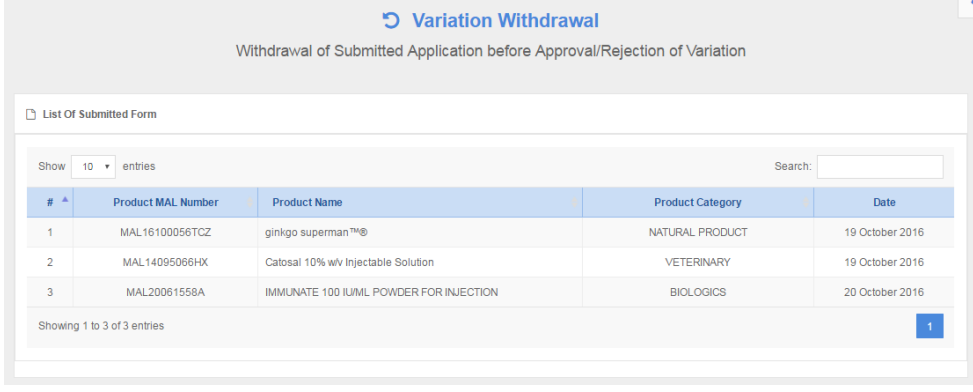
<p>FG69</p>	
<p>EX69</p>	<p>Explanation: Click on Change of Site / Payment Pending</p>
<p>FG70</p>	
<p>EX70</p>	<p>Explanation: FG70 shows a list Variation Application with Pending payment status. Click on the credit card-icon to proceed with payment.</p>

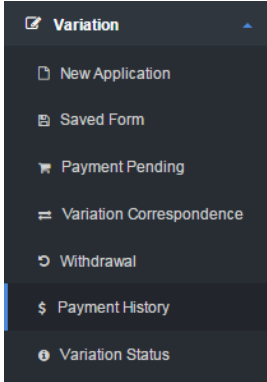
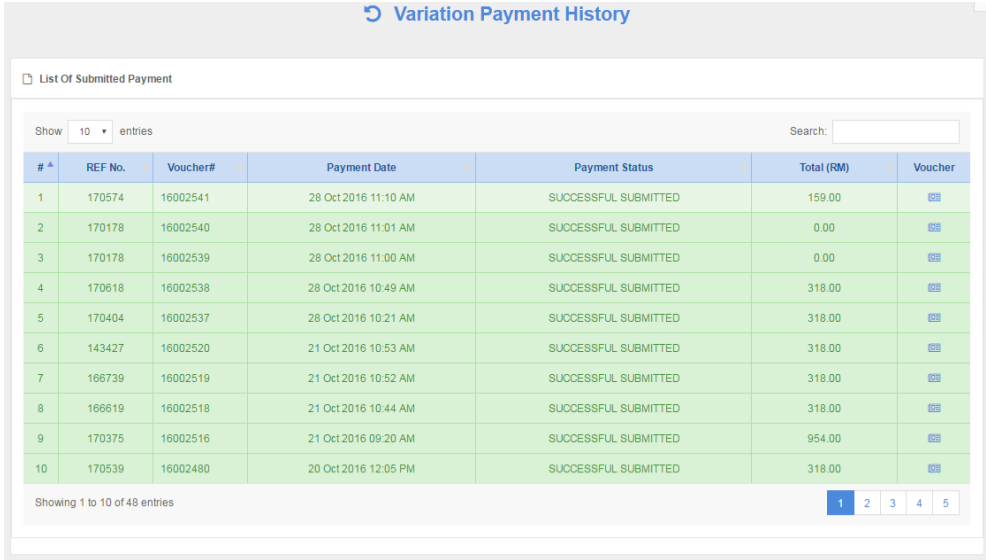
<p>FG71</p>	
<p>EX71</p>	<p>Explanation: FG71 shows list of available payment method. Click on Payment Method icon to continue.</p>
<p>FG72</p>	
<p>EX72</p>	<p>Explanation: Select preferred payment method by clicking on the icon.</p>

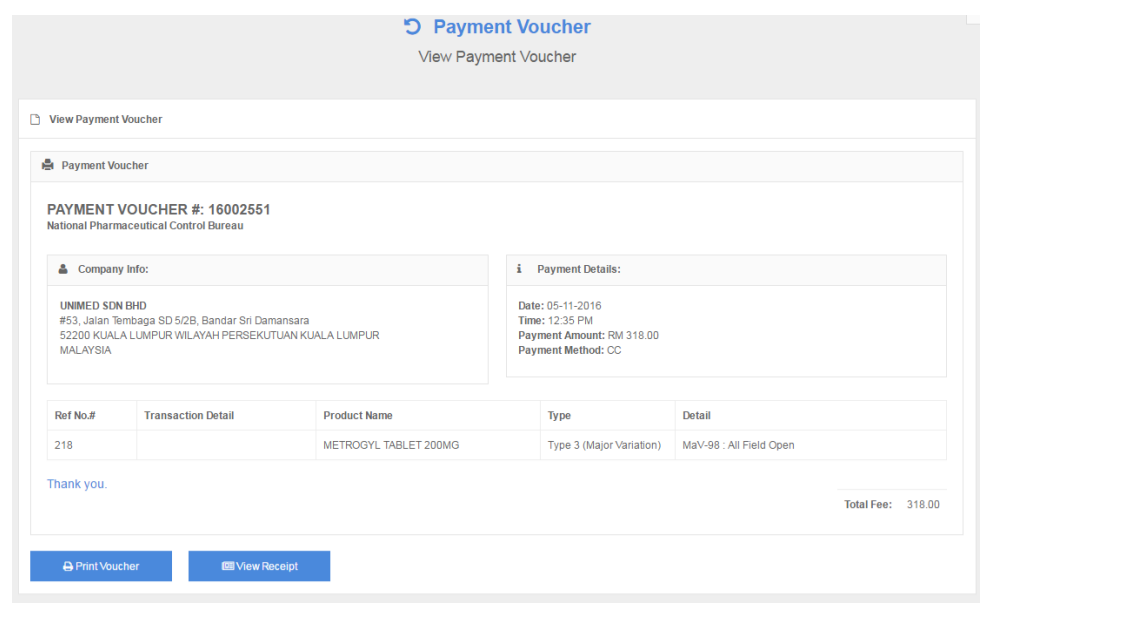
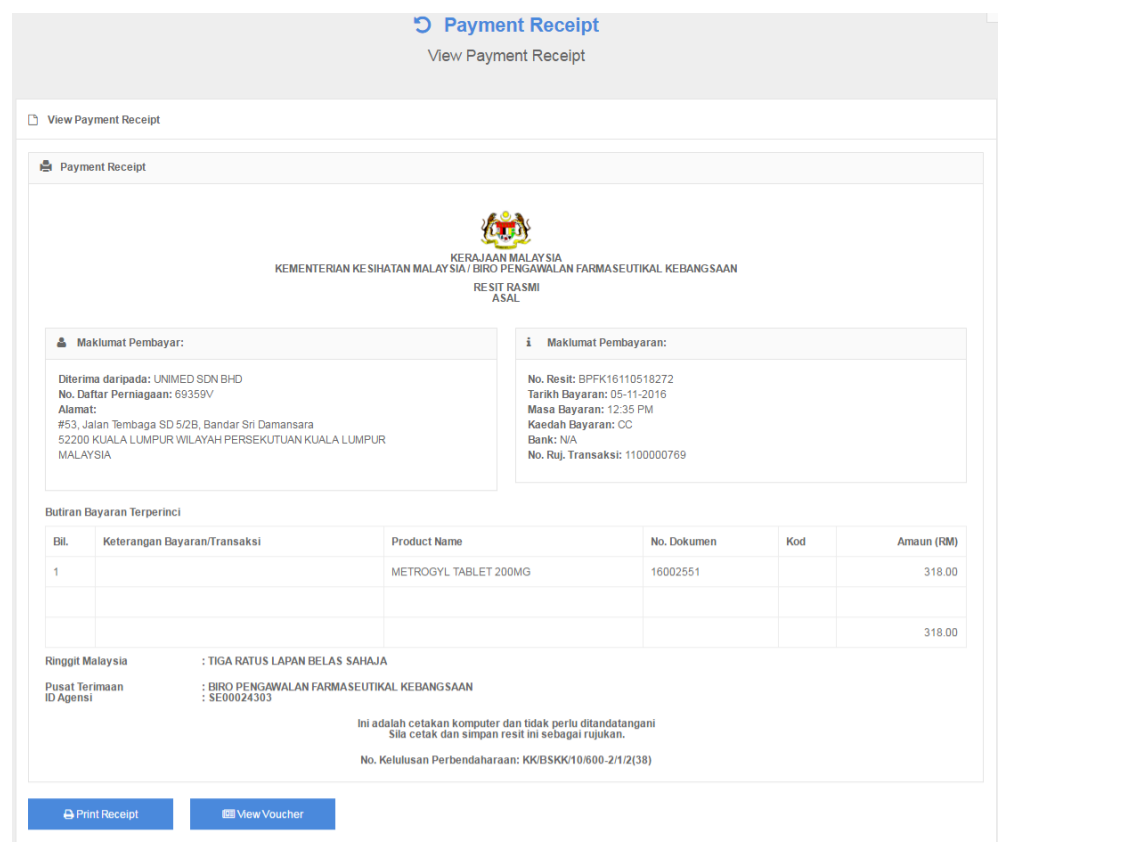
<p>FG73</p>	
<p>EX73</p>	<p>Explanation: Enter card details and click pay button.</p>
<p>FG74</p>	
<p>EX74</p>	<p>Explanation: FG74 show the result of previous payment. Click on Payment History to go to Payment History page. Click on Payment Receipt button to view receipt.</p>
<p>2.4</p>	<p>COS Correspondence</p>
<p>FG75</p>	
<p>EX75</p>	<p>Explanation: Click on Change of Site / COS Correspondence</p>

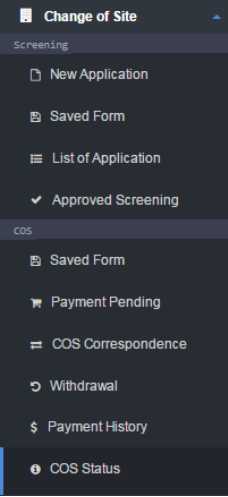
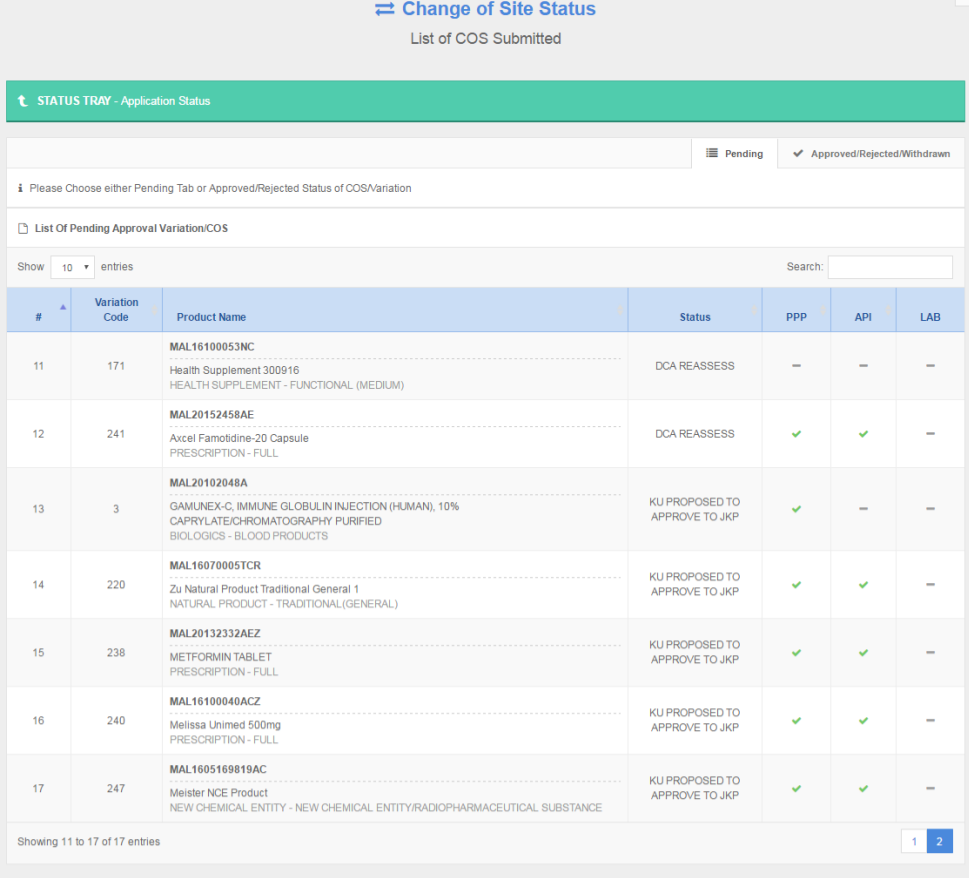
<p>FG76</p>	 <p>Change of Site Correspondence Click to open saved & editable COS</p> <p>IN TRAY - List of Product Replied Correspondence</p> <p>List Of Correspondence Application</p> <p>Show 10 entries Search: []</p> <table border="1"> <thead> <tr> <th>#</th> <th>Product MAL Number</th> <th>Product Name</th> <th>Product Category</th> <th>Date</th> <th>Correspond x Times</th> <th>Correspond</th> <th>Withdraw</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL19950840T</td> <td>INFEE (ORAL LIQUID) 100ML</td> <td>NATURAL PRODUCT</td> <td>09 November 2016</td> <td>1st</td> <td>Correspond</td> <td>Withdraw</td> </tr> </tbody> </table> <p>Showing 1 to 1 of 1 entries</p> <p>OUT TRAY - List of Product Corresponded</p> <p>List Of Awaiting Reply Correspondence</p> <p>Show 10 entries Search: []</p> <table border="1"> <thead> <tr> <th>#</th> <th>Product MAL Number</th> <th>Product Name</th> <th>Correspond x Times</th> <th>Stat</th> <th>PPP</th> <th>API</th> <th>LAB</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MAL16080013ACZ</td> <td>Human Albumin Solution BIOLOGICS - BLOOD PRODUCTS</td> <td>2nd</td> <td>Evaluation</td> <td></td> <td>-</td> <td>-</td> </tr> </tbody> </table> <p>Showing 1 to 1 of 1 entries</p>	#	Product MAL Number	Product Name	Product Category	Date	Correspond x Times	Correspond	Withdraw	1	MAL19950840T	INFEE (ORAL LIQUID) 100ML	NATURAL PRODUCT	09 November 2016	1st	Correspond	Withdraw	#	Product MAL Number	Product Name	Correspond x Times	Stat	PPP	API	LAB	1	MAL16080013ACZ	Human Albumin Solution BIOLOGICS - BLOOD PRODUCTS	2nd	Evaluation		-	-
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<p>EX76</p>	<p>Explanation:</p> <p>The IN TRAY table shows a list of Variation Application that needs to be correspond/replied by the user/applicant .</p> <p>The OUT TRAY table shows a list of Variation Application that has been replied by user/applicants.</p> <p>Click on the Correspond button to reply correspondence.</p> <p>Click on the Withdraw button to withdraw/cancel the application. Refer (FG74 – FG75, EX74 – EX75)</p>																																
<p>FG77</p>	 <p>Variation Workstation Please Fill in Applicable forms & File Attachments</p> <p>Product Validation - Part I - Part II - Part III - Part IV - Labels Checklist</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>You can click on the section tabs above to refer to the current approved data.</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 & COS Status Record.</p> <p>Product Information</p> <p>Product Name : METROGYL TABLET 200MG Product Call No./Ref No./Reg No. : 138562 / 1987070087A / MAL19872165AZ Product Category : PRESCRIPTION - FULL</p> <p>Involve Variation Types</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Code</th> <th>Variation Title</th> <th>Category</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MaV98</td> <td>All Field Open</td> <td>Type 3 (Major Variation)</td> </tr> </tbody> </table> <p>Involve Labels</p>	No.	Code	Variation Title	Category	1	MaV98	All Field Open	Type 3 (Major Variation)																								
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<p>EX77</p>	<p>Explanation:</p> <p>FG77 shows a Variation Workstation Opened when user click on Correspond button in FG68.</p>																																

<p>FG78</p>	<p>1.1 Brand Name:</p> <p>a) Current Approved Brand Name:</p> <p>N</p> <p>b) Proposed Brand Name:</p> <p>New Meister Brand</p> <p>Remarks [1-1]</p>																				
<p>EX78</p>	<p>Explanation:</p> <p>User/applicants can only edit/ammends or make changes on label marked as reject by Evaluator.</p> <p>Click on the remarks button to view comments/remarks from the Evaluator.</p>																				
<p>FG79</p>																					
<p>EX79</p>	<p>Explanation:</p> <p>FG79 shows a popup form appear when user click on Remarks buuton. User can see the remarks/comments from the evaluator</p> <p>User can reply to the comments by typing appropriate comments on the textarea provided and click on Save Comments button.</p> <p>Click anywhere outside the popup box to close.</p>																				
<p>FG80</p>	<p>D1. Label (mock-up) for immediate Container: ①</p> <p>a) Current Label (mock-up) for immediate Container:</p> <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> <p>b) Proposed Label (mock-up) for immediate Container:</p> <p>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>Remarks [D1]</p>	#	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>EX80</p>	<p>Explanation:</p> <p>FG80 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>FG81</p>																					
<p>EX81</p>	<p>Explanation:</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>EX82</p>	<p>Explanation:</p> <p>Click on Variation / Withdrawal</p>																				
<p>FG83</p>	 <table border="1" data-bbox="288 1458 1222 1576"> <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>	#	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>EX83</p>	<p>Explanation:</p> <p>FG83 shows a list of withdrawn Variation Application.</p>																				
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<p>EX84</p>	<p>Explanation: Click on Variation / Payment History</p>																																																																													
<p>FG85</p>	 <p>Variation Payment History</p> <p>List Of Submitted Payment</p> <p>Show 10 entries Search: <input type="text"/></p> <table border="1"> <thead> <tr> <th>#</th> <th>REF No.</th> <th>Voucher#</th> <th>Payment Date</th> <th>Payment Status</th> <th>Total (RM)</th> <th>Voucher</th> </tr> </thead> <tbody> <tr><td>1</td><td>170574</td><td>16002541</td><td>28 Oct 2016 11:10 AM</td><td>SUCCESSFUL SUBMITTED</td><td>159.00</td><td></td></tr> <tr><td>2</td><td>170178</td><td>16002540</td><td>28 Oct 2016 11:01 AM</td><td>SUCCESSFUL SUBMITTED</td><td>0.00</td><td></td></tr> <tr><td>3</td><td>170178</td><td>16002539</td><td>28 Oct 2016 11:00 AM</td><td>SUCCESSFUL SUBMITTED</td><td>0.00</td><td></td></tr> <tr><td>4</td><td>170618</td><td>16002538</td><td>28 Oct 2016 10:49 AM</td><td>SUCCESSFUL SUBMITTED</td><td>318.00</td><td></td></tr> <tr><td>5</td><td>170404</td><td>16002537</td><td>28 Oct 2016 10:21 AM</td><td>SUCCESSFUL SUBMITTED</td><td>318.00</td><td></td></tr> <tr><td>6</td><td>143427</td><td>16002520</td><td>21 Oct 2016 10:53 AM</td><td>SUCCESSFUL SUBMITTED</td><td>318.00</td><td></td></tr> <tr><td>7</td><td>166739</td><td>16002519</td><td>21 Oct 2016 10:52 AM</td><td>SUCCESSFUL SUBMITTED</td><td>318.00</td><td></td></tr> <tr><td>8</td><td>166619</td><td>16002518</td><td>21 Oct 2016 10:44 AM</td><td>SUCCESSFUL SUBMITTED</td><td>318.00</td><td></td></tr> <tr><td>9</td><td>170375</td><td>16002516</td><td>21 Oct 2016 09:20 AM</td><td>SUCCESSFUL SUBMITTED</td><td>954.00</td><td></td></tr> <tr><td>10</td><td>170539</td><td>16002480</td><td>20 Oct 2016 12:05 PM</td><td>SUCCESSFUL SUBMITTED</td><td>318.00</td><td></td></tr> </tbody> </table> <p>Showing 1 to 10 of 48 entries 1 2 3 4 5</p>	#	REF No.	Voucher#	Payment Date	Payment Status	Total (RM)	Voucher	1	170574	16002541	28 Oct 2016 11:10 AM	SUCCESSFUL SUBMITTED	159.00		2	170178	16002540	28 Oct 2016 11:01 AM	SUCCESSFUL SUBMITTED	0.00		3	170178	16002539	28 Oct 2016 11:00 AM	SUCCESSFUL SUBMITTED	0.00		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	
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<p>EX85</p>	<p>Explanation: FG85 show a list of payment made by user. Click on the card-icon to view payment Voucher.</p>																																																																													

<p>FG86</p>	 <p>The screenshot shows the 'Payment Voucher' interface. At the top, it says 'Payment Voucher' and 'View Payment Voucher'. Below that, it displays 'PAYMENT VOUCHER #: 16002551' from the 'National Pharmaceutical Control Bureau'. There are two main sections: 'Company Info' for UNIMED SDN BHD and 'Payment Details' showing a date of 05-11-2016, time of 12:35 PM, payment amount of RM 318.00, and payment method of CC. A table lists transaction details for 'METROGYL TABLET 200MG'. At the bottom, there are buttons for 'Print Voucher' and 'View Receipt', and a 'Total Fee: 318.00'.</p>
<p>EX86</p>	<p>Explanation: FG86 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>FG87</p>	 <p>The screenshot shows the 'Payment Receipt' interface. It features the Malaysian national emblem and text: 'KERAJAAN MALAYSIA, KEMENTERIAN KESEHATAN MALAYSIA / BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN, RESIT RASMI ASAL'. It contains two 'Maklumat Pembayaran' sections. The first lists the payee 'UNIMED SDN BHD'. The second lists receipt details: 'No. Resit: BPFK16110518272', 'Tarikh Bayaran: 05-11-2016', 'Masa Bayaran: 12:35 PM', 'Kaedah Bayaran: CC', 'Bank: N/A', and 'No. Ruj. Transaksi: 1100000769'. A table titled 'Butiran Bayaran Terperinci' shows one transaction for 'METROGYL TABLET 200MG' with a total amount of 318.00. At the bottom, there are buttons for 'Print Receipt' and 'View Voucher', and a note in Malay: 'Ini adalah cetakan komputer dan tidak perlu ditandatangani. Sila cetak dan simpan resit ini sebagai rujukan. No. Kelulusan Perbendaharaan: KK/BSKK/10/600-2/1/2(38)'.</p>
<p>EX87</p>	<p>Explanation: FG87 show a sample Receipt. Click on Print Receipt button to print the receipt.</p>

	Click on View Voucher button to view voucher.																																																								
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EX88	<p>Explanation: Click on Change of Site / COS Status</p>																																																								
FG89	 <p>Change of Site Status List of COS Submitted</p> <p>STATUS TRAY - Application Status</p> <p> <input type="checkbox"/> Pending <input checked="" type="checkbox"/> Approved/Rejected/Withdrawn </p> <p>Please Choose either Pending Tab or Approved/Rejected Status of COS/Variation</p> <p>List Of Pending Approval Variation/COS</p> <p>Show 10 entries Search: <input type="text"/></p> <table border="1"> <thead> <tr> <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>11</td> <td>171</td> <td>MAL16100053NC Health Supplement 300916 HEALTH SUPPLEMENT - FUNCTIONAL (MEDIUM)</td> <td>DCA REASSESS</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>12</td> <td>241</td> <td>MAL20152458AE Axcel Famotidine-20 Capsule PRESCRIPTION - FULL</td> <td>DCA REASSESS</td> <td>✓</td> <td>✓</td> <td>-</td> </tr> <tr> <td>13</td> <td>3</td> <td>MAL20102048A GAMUNEX-C, IMMUNE GLOBULIN INJECTION (HUMAN), 10% CAPRYLATE/CHROMATOGRAPHY PURIFIED BIOLOGICS - BLOOD PRODUCTS</td> <td>KU PROPOSED TO APPROVE TO JKP</td> <td>✓</td> <td>-</td> <td>-</td> </tr> <tr> <td>14</td> <td>220</td> <td>MAL16070005TCR Zu Natural Product Traditional General 1 NATURAL PRODUCT - TRADITIONAL (GENERAL)</td> <td>KU PROPOSED TO APPROVE TO JKP</td> <td>✓</td> <td>✓</td> <td>-</td> </tr> <tr> <td>15</td> <td>238</td> <td>MAL20132332AEZ METFORMIN TABLET PRESCRIPTION - FULL</td> <td>KU PROPOSED TO APPROVE TO JKP</td> <td>✓</td> <td>✓</td> <td>-</td> </tr> <tr> <td>16</td> <td>240</td> <td>MAL16100040ACZ Melissa Unimed 500mg PRESCRIPTION - FULL</td> <td>KU PROPOSED TO APPROVE TO JKP</td> <td>✓</td> <td>✓</td> <td>-</td> </tr> <tr> <td>17</td> <td>247</td> <td>MAL1605169819AC Meister NCE Product NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE</td> <td>KU PROPOSED TO APPROVE TO JKP</td> <td>✓</td> <td>✓</td> <td>-</td> </tr> </tbody> </table> <p>Showing 11 to 17 of 17 entries</p> <p>1 2</p>	#	Variation Code	Product Name	Status	PPP	API	LAB	11	171	MAL16100053NC Health Supplement 300916 HEALTH SUPPLEMENT - FUNCTIONAL (MEDIUM)	DCA REASSESS	-	-	-	12	241	MAL20152458AE Axcel Famotidine-20 Capsule PRESCRIPTION - FULL	DCA REASSESS	✓	✓	-	13	3	MAL20102048A GAMUNEX-C, IMMUNE GLOBULIN INJECTION (HUMAN), 10% CAPRYLATE/CHROMATOGRAPHY PURIFIED BIOLOGICS - BLOOD PRODUCTS	KU PROPOSED TO APPROVE TO JKP	✓	-	-	14	220	MAL16070005TCR Zu Natural Product Traditional General 1 NATURAL PRODUCT - TRADITIONAL (GENERAL)	KU PROPOSED TO APPROVE TO JKP	✓	✓	-	15	238	MAL20132332AEZ METFORMIN TABLET PRESCRIPTION - FULL	KU PROPOSED TO APPROVE TO JKP	✓	✓	-	16	240	MAL16100040ACZ Melissa Unimed 500mg PRESCRIPTION - FULL	KU PROPOSED TO APPROVE TO JKP	✓	✓	-	17	247	MAL1605169819AC Meister NCE Product NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHARMACEUTICAL SUBSTANCE	KU PROPOSED TO APPROVE TO JKP	✓	✓	-
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EX89	<p>Explanation: FG89 shows a list of variation application with their status.</p>																																																								

	Click on Approved/Withdrawn/Rejected tab button to view Approved, Withdrawn, or Rejected variation application.
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