National Pharmaceutical Control Bureau
Ministry of Health Malaysia

USER MANUAL

QUEST 3+ System

Module: **Variation**

(Front-End)

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Version 2.1

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Table of Contents

INTRODUCTION 6

1.0 QUEST3+ Front-end login 8

2.0 NEW APPLICATION FORM 9

INTRODUCTION

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

1. Application for Variation Application
2. Variation payment
3. Variation Correspondence

Pre-requisite:

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

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

Contact Person

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

Administrative Enquiries:

Name: Cik Nurulfajar Mohd Jamid
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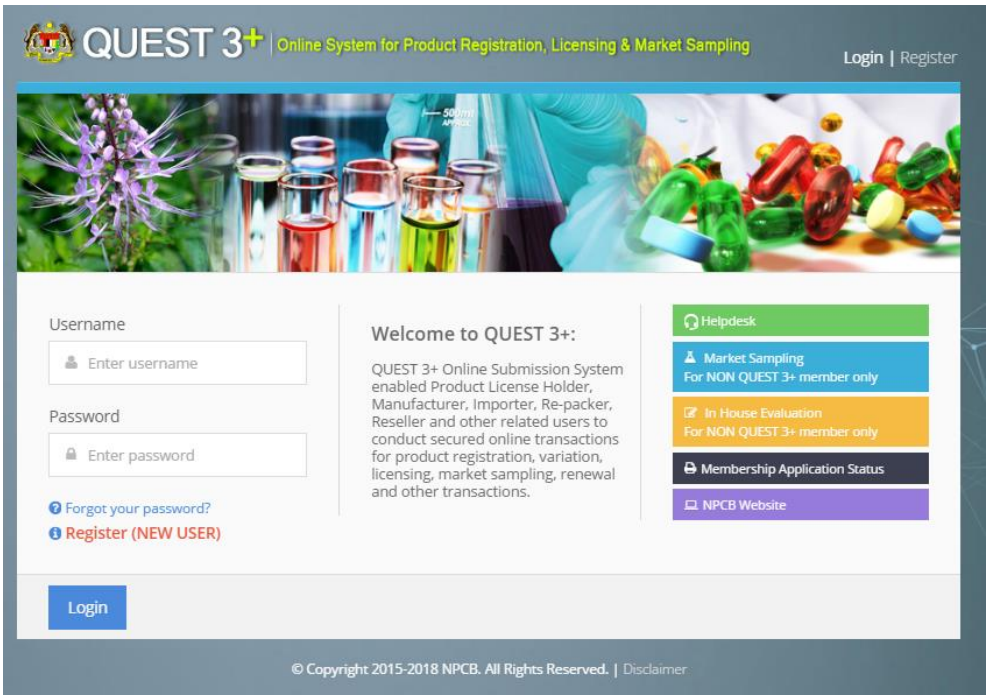
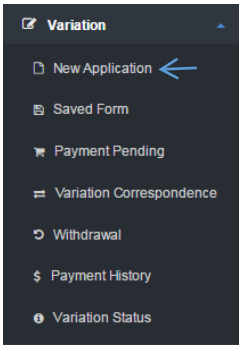
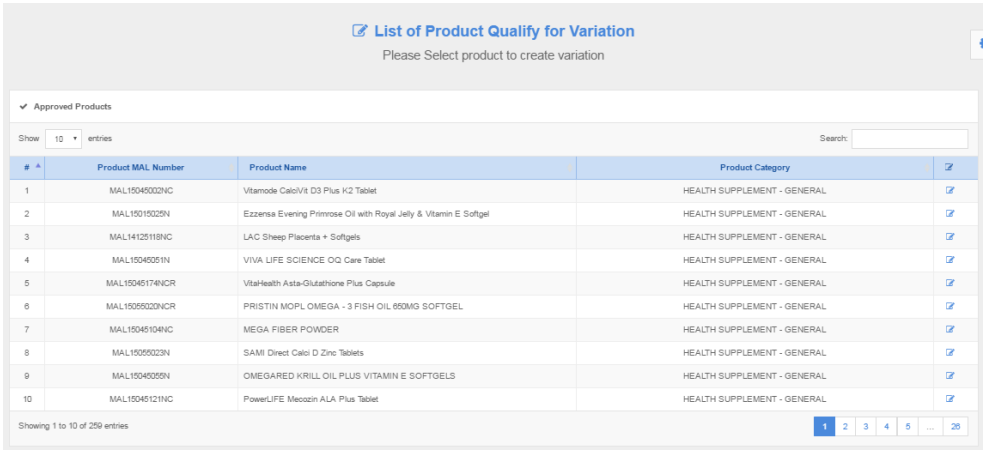
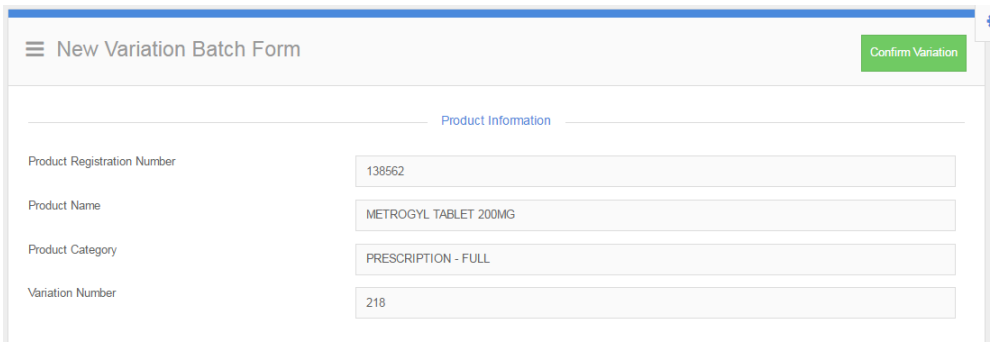
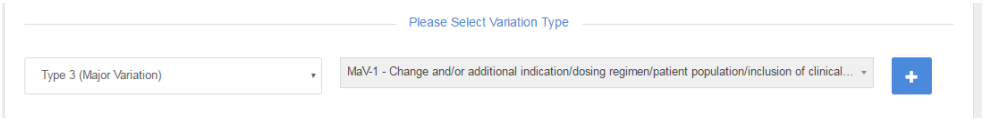
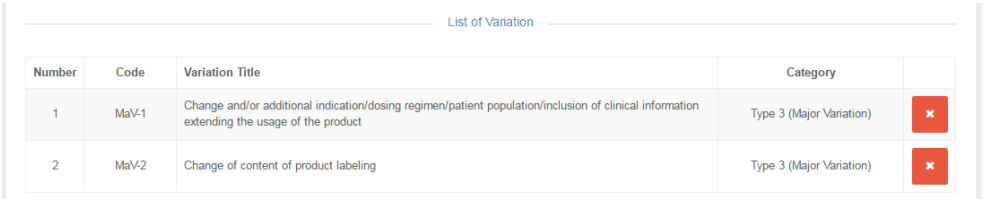
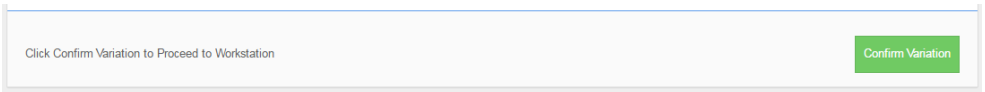
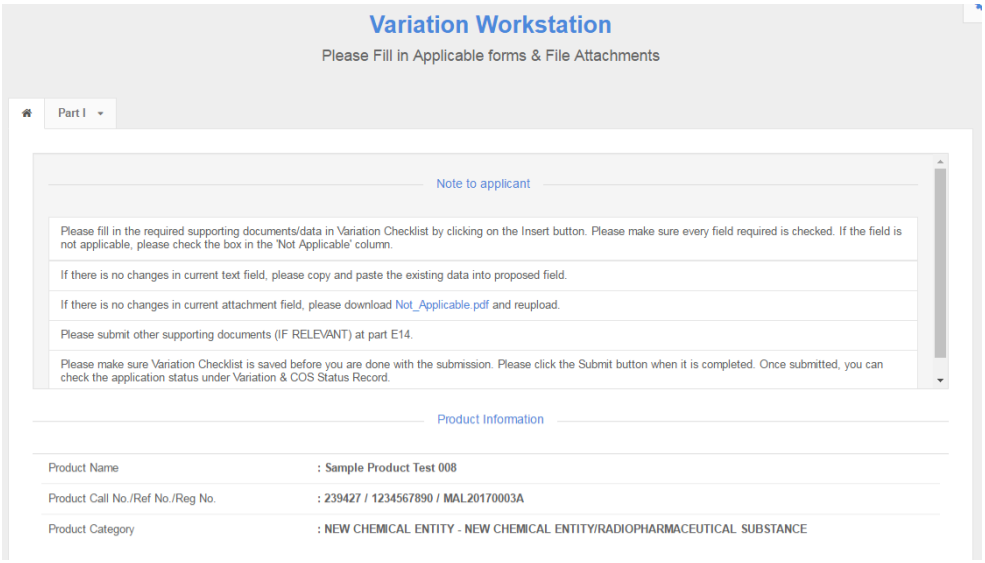
Email: hazree@mypersada.com
Telephone: +60 3-6141 8151

1.0 QUEST3+ Front-end login

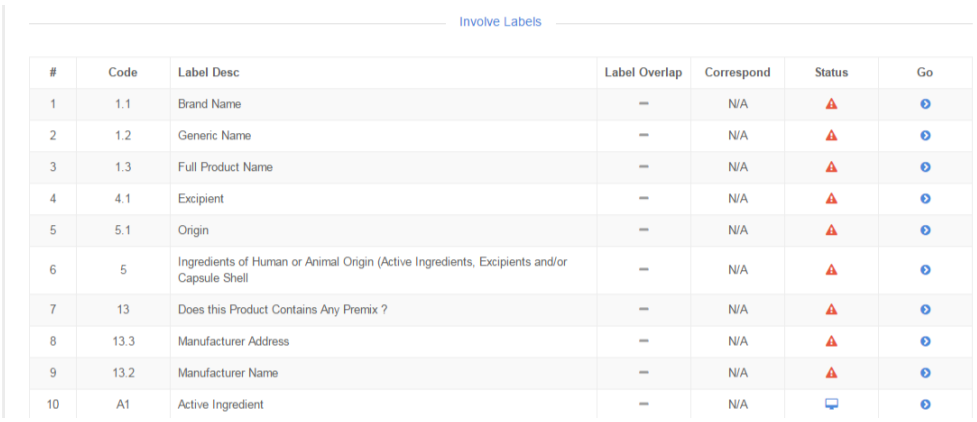
#	SCREENSHOTS / EXPLANATION
1	**Login**
FG1	
EX1	**Explanation:** To access the Quest 3+ system, user need to use the URL as below: https://quest3plus.bpfk.gov.my/front-end Figure 1 as the above will appear and the user will need to enter the following information: 1. User Name: User ID 2. Password: Enter Password. 3. Click Login

2.0 Variation

#	SCREENSHOTS / EXPLANATION
2.1	**Variation Application**
2.1.1	New Application
FG2	
EX2	**Explanation:** Click on side menu '**Variation / New Application**'
FG3	
EX3	**Explanation:** FG3 show a list of approved product in a company. Click on the edit icon to proceed to Variation Workstation.
FG4	
EX4	**Explanation:**

	FG4 shows the information about the product selected by user for Variation Process.
FG5	
EX5	**Explanation:** User can select more than one (1) Variation title by clicking the + button after selecting an option from the dropdown list.
FG6	
EX6	**Explanation:** FG6 shows a list of Variation Title added by user for a Variation application. User can click on the X button to remove the added Variation Title.
FG7	
EX7	**Explanation:** Click on Confirm Variation Button to proceed the application to Variation Workstation.
FG8	
EX8	**Explanation:** FG8 shows the Home Screen for Variation Workstation.

FG9



#	Code	Label Desc	Label Overlap	Correspond	Status	Go
1	1.1	Brand Name	-	N/A		
2	1.2	Generic Name	-	N/A		
3	1.3	Full Product Name	-	N/A		
4	4.1	Excipient	-	N/A		
5	5.1	Origin	-	N/A		
6	5	Ingredients of Human or Animal Origin (Active Ingredients, Excipients and/or Capsule Shell	-	N/A		
7	13	Does this Product Contains Any Premix ?	-	N/A		
8	13.3	Manufacturer Address	-	N/A		
9	13.2	Manufacturer Name	-	N/A		
10	A1	Active Ingredient	-	N/A		

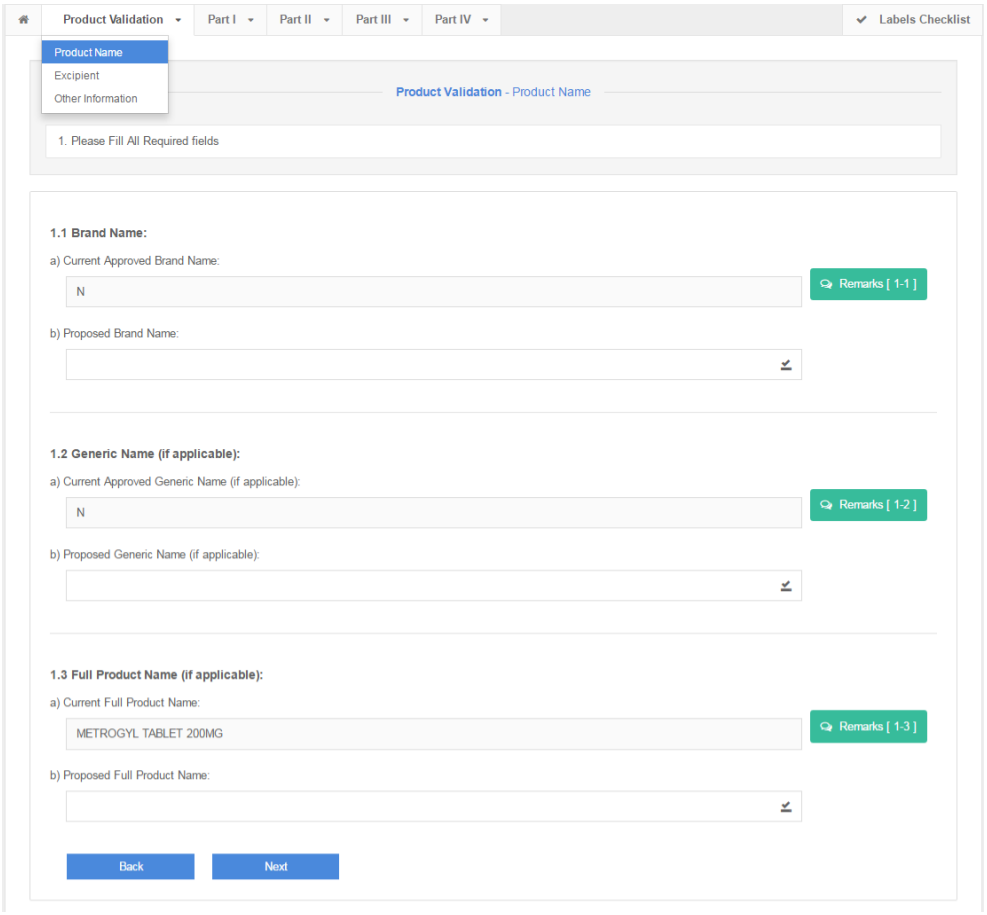
EX9

Explanation:

FG9 show a part of label involved in a Variation Application.

**Some Labels are not applicable/available in some Variation Titles.

FG10



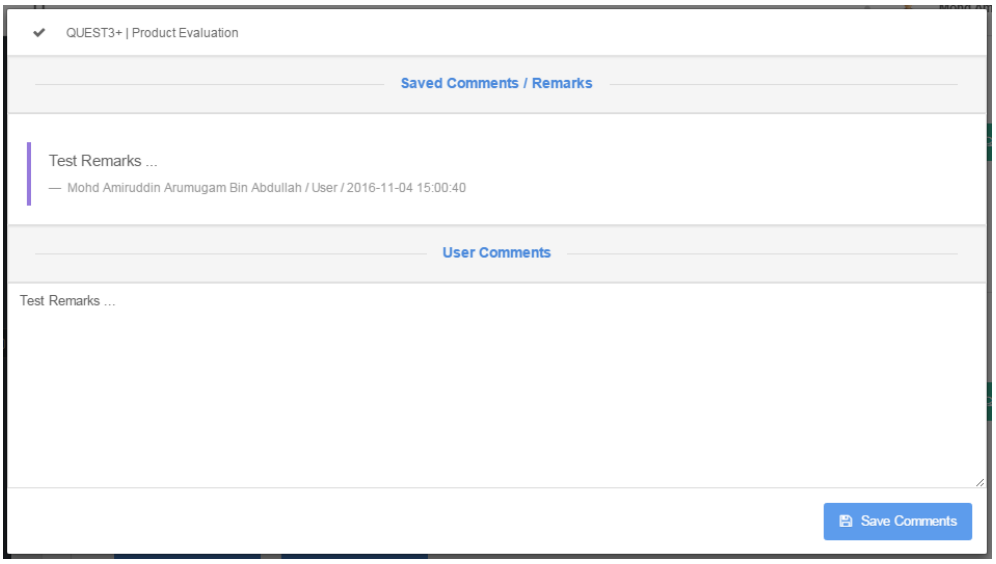
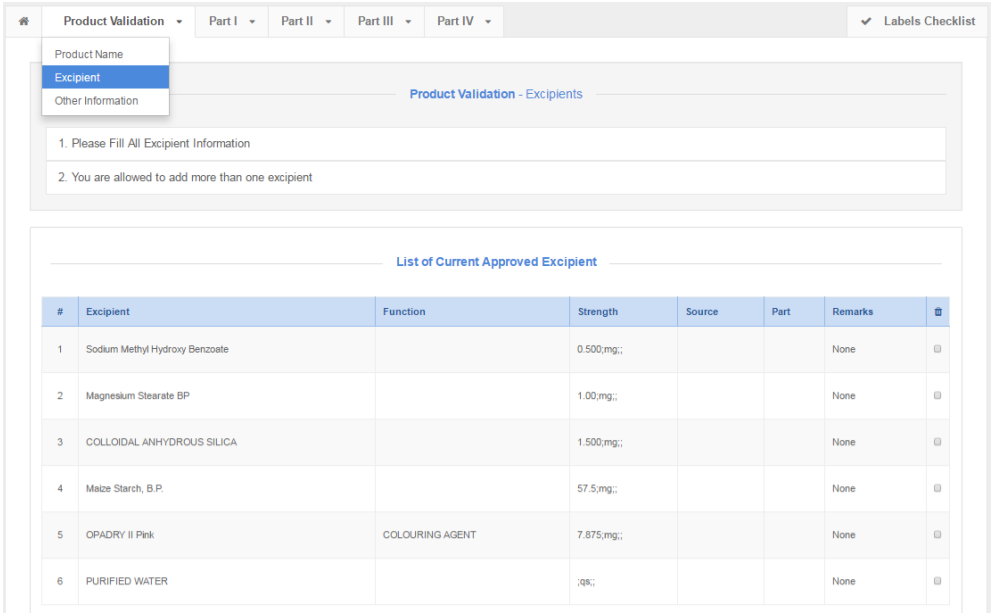
EX10

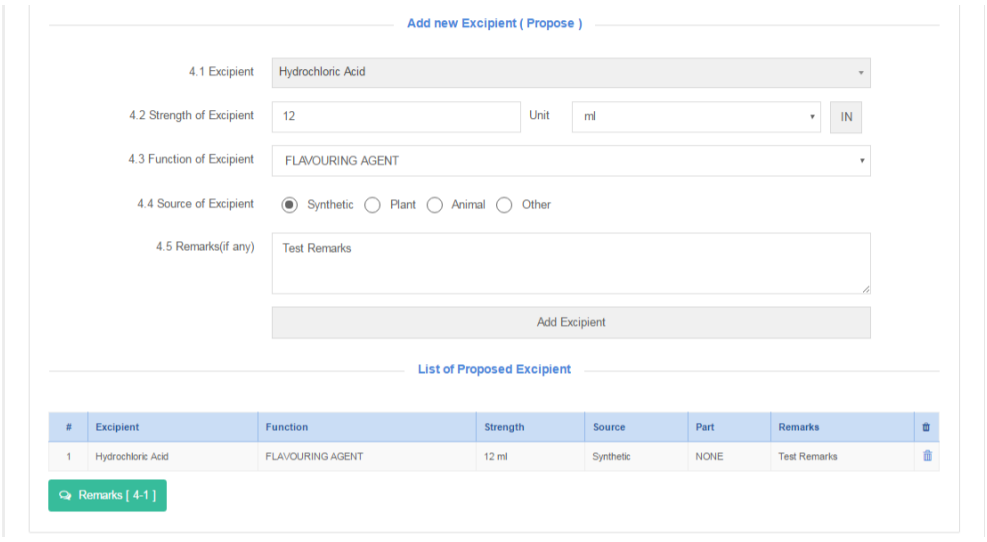
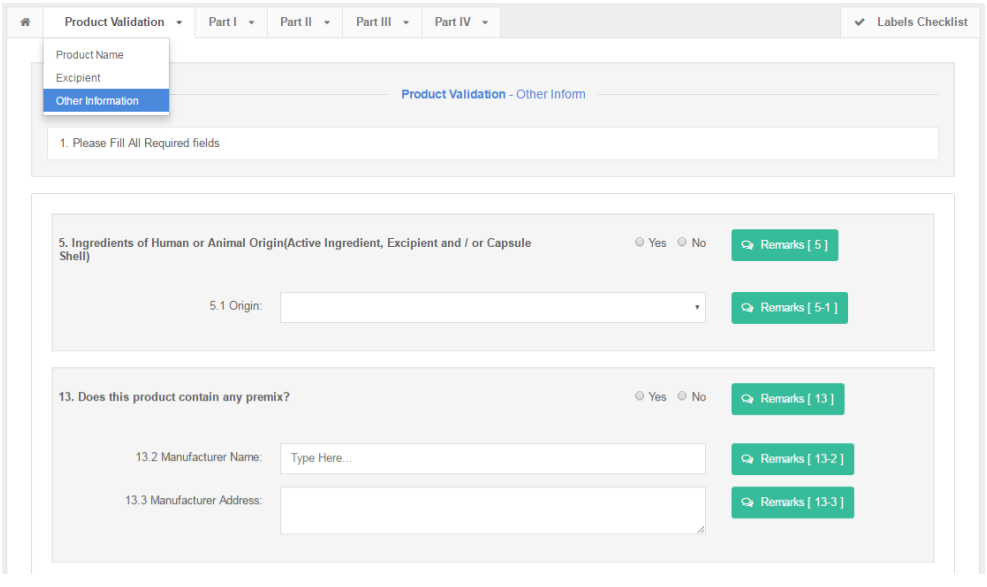
Explanation:

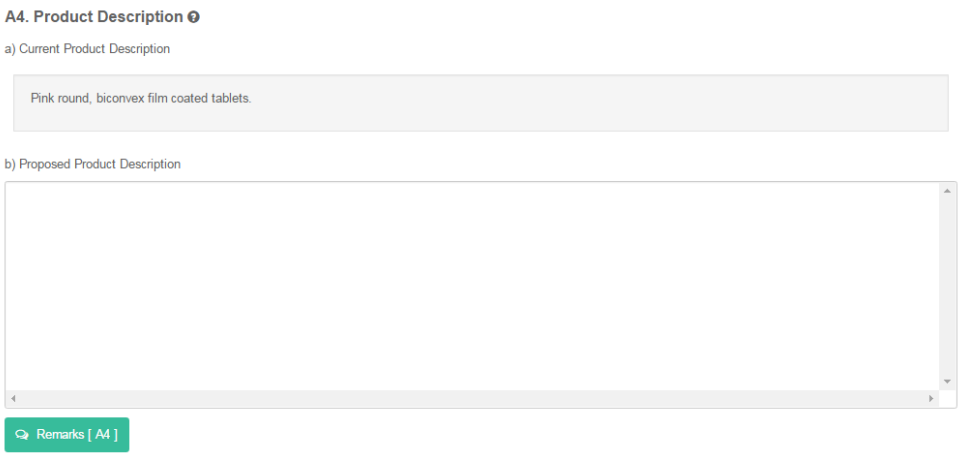
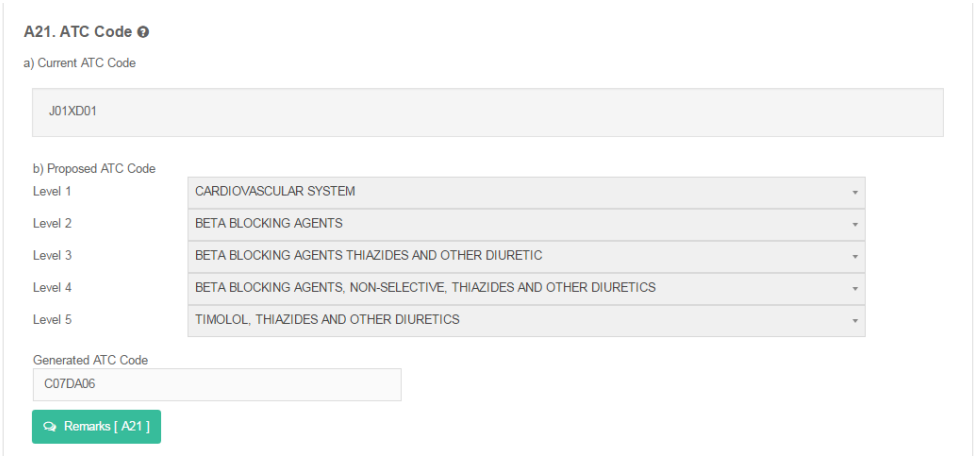
Click on Product Validation / Product Name.

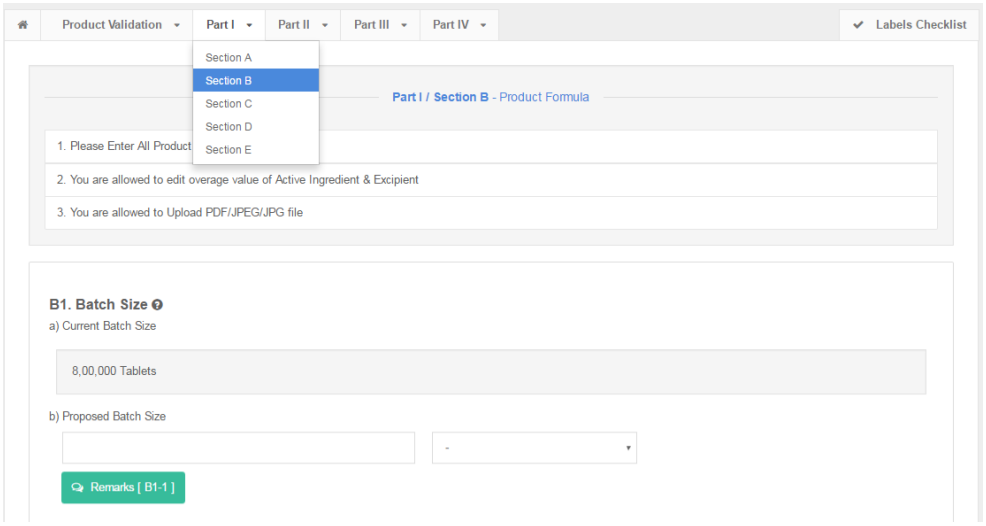
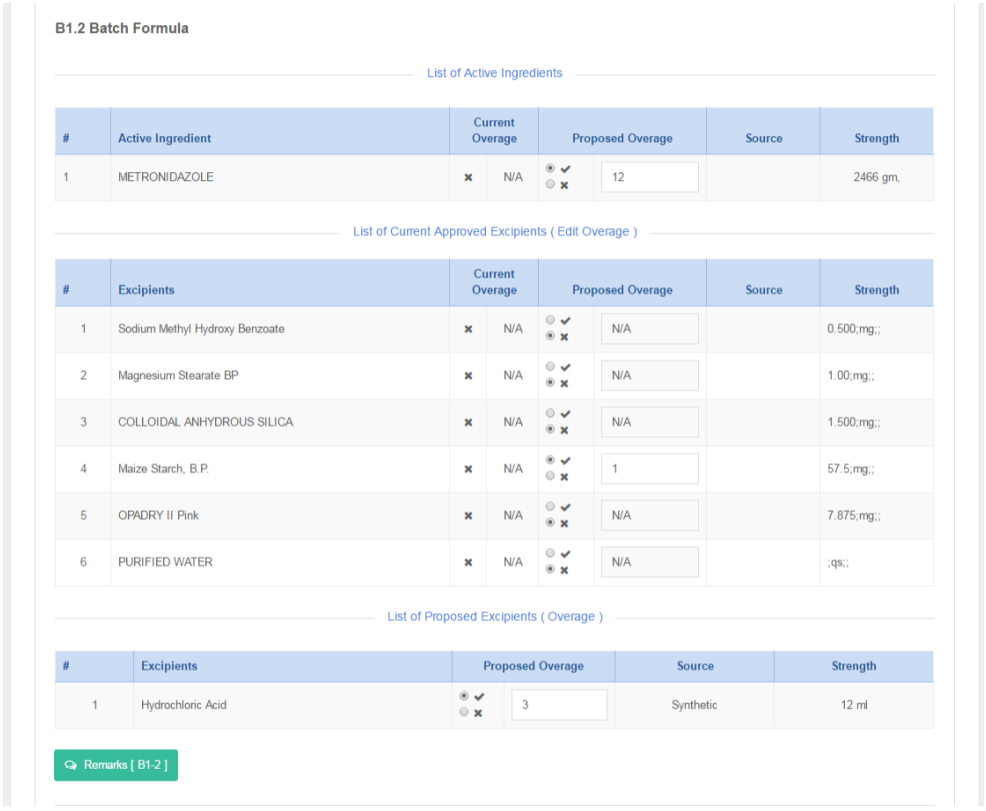
Fill the required particular in the text box.

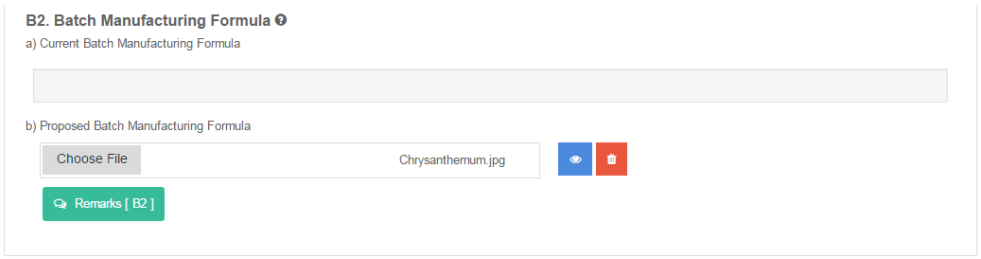
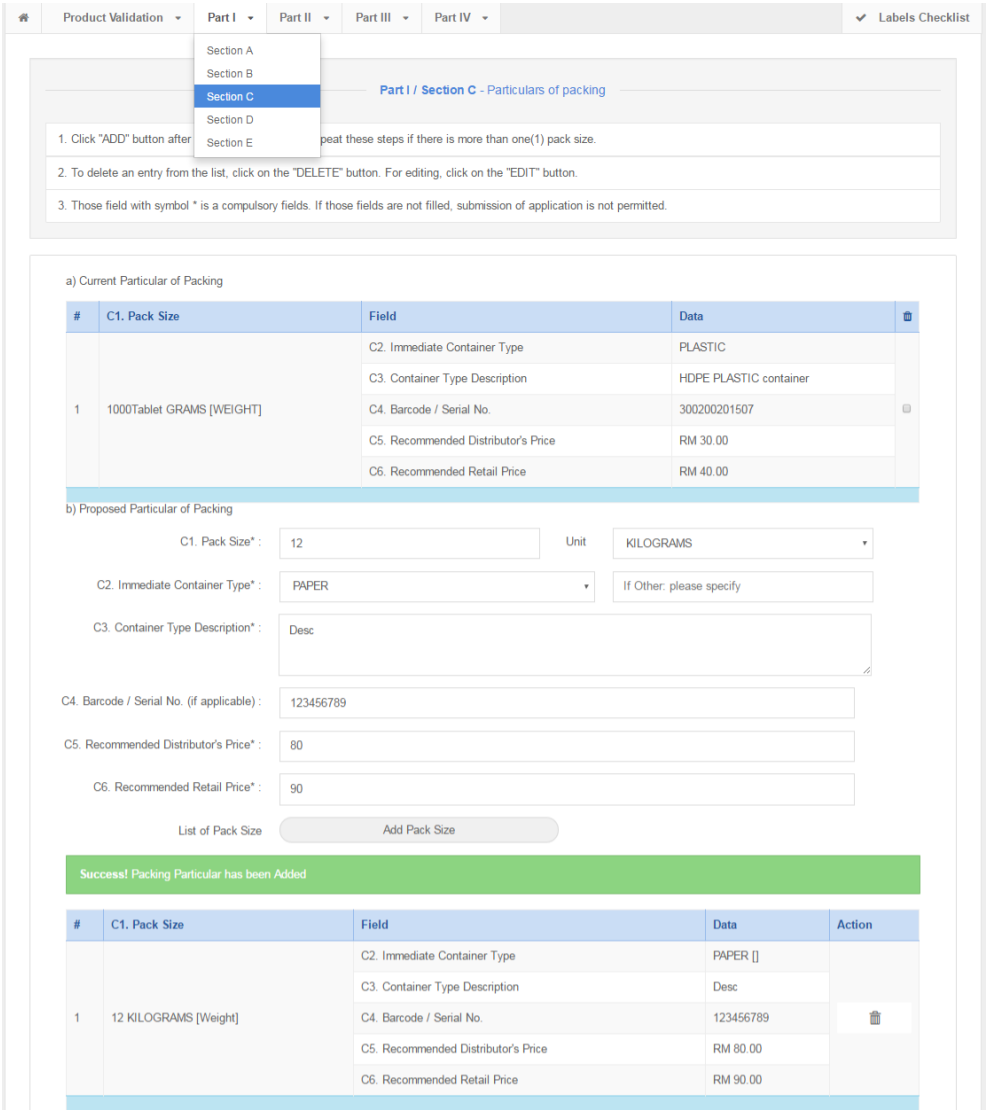
User can leave remarks for the Evaluator by clicking the Remarks Button on the right side of each field.

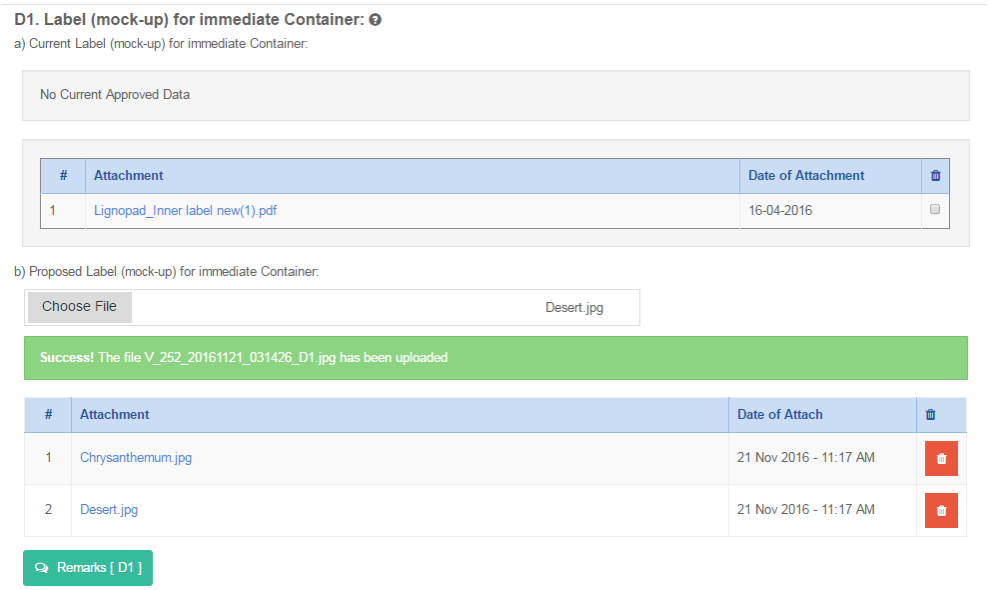
FG11	
EX11	**Explanation:** FG11 shows User Remarks Popup window. Fill remarks in the field provided and click on Save Comments button. Click anywhere outside the popup window to close the popup window.
FG12	
EX12	**Explanation:** Click on Product Validation / Excipient. FG12 show a list of current approved excipient for the product. User can click on checkbox on the trash-icon column to propose delete current approved excipient.

FG13	
EX13	**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. Click on the trash-icon located on each row to delete added proposed excipient.
FG14	
EX14	**Explanation:** Click on Product Validation / Other Information. Fill the required field.

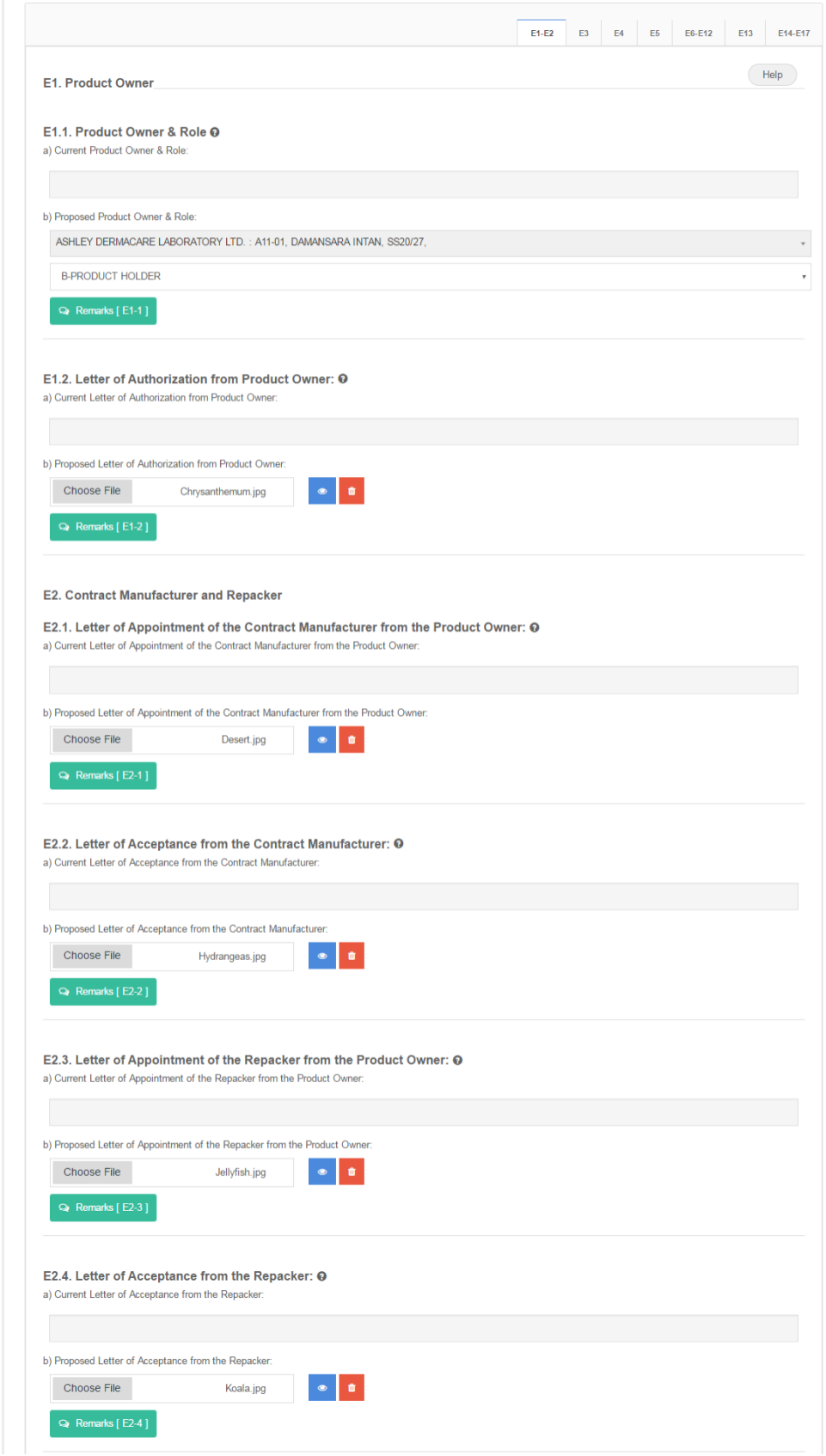
FG15	
EX15	**Explanation:** FG15 shows one of the field available in the Variation Title. User can view the current data on part a) User can fill the new data on the text area on part b) Click on Remarks button to leave a remark to Evaluator. Fill the following field A4 – A20
FG16	
EX16	**Explanation:** To fill label A21. ATC Code, user need to select the ATC code starting from Level. Click to select ATC Code.

FG17	
EX17	**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.
FG18	
EX18	**Explanation:** User is require to fill all the Proposed Overage column in the table shown in FG18

FG19	
EX19	**Explanation:** Click on the Choose File button to select a file to be uploaded in the system. User can View the uploaded file by clicking on the blue eye-icon button. Click on the red dustbin-icon button to remove the uploaded file.
FG20	
EX20	**Explanation:** Click on Part 1/ Section C Fill all the required field marked with * then click on the Add Pack Size button to add new proposed Pack Size.

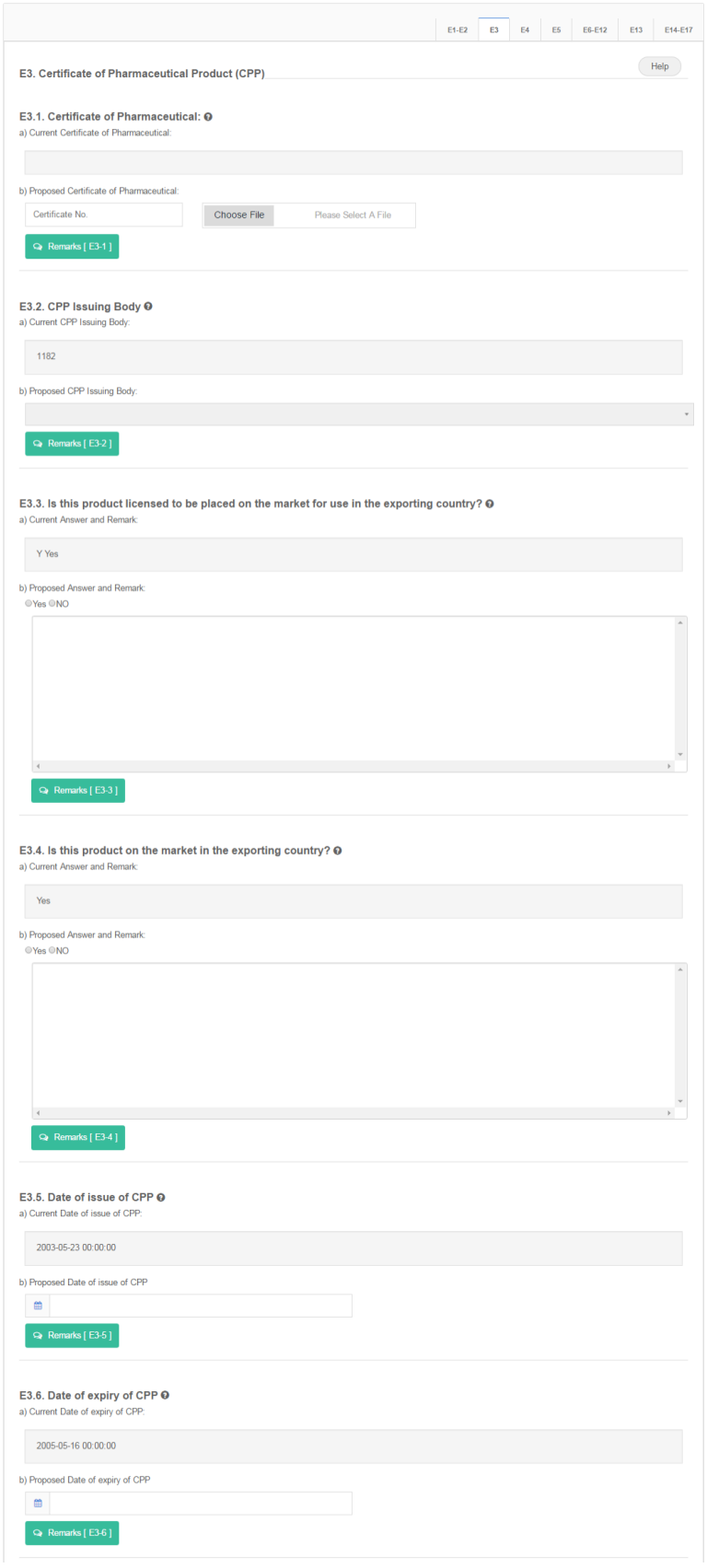
	User can click on checkbox on the trash-icon column to propose delete current approved pack size. Click on the trash-icon located on the action column on each row to delete added proposed pack size.
FG21	
EX21	**Explanation:** Click on Part 1 / Section D FG21 show a part of Section D. User can view current attachment files by clicking on the filename in the Current label table. Click on the Choose file Button to upload new files for Variation. User can click on checkbox on the trash-icon column to propose delete current approved attachments. Click on the red trash-icon button to remove uploaded attachments. Multiple file attachment are available in some Field/Label. Fill the required field D1-D5

FG22

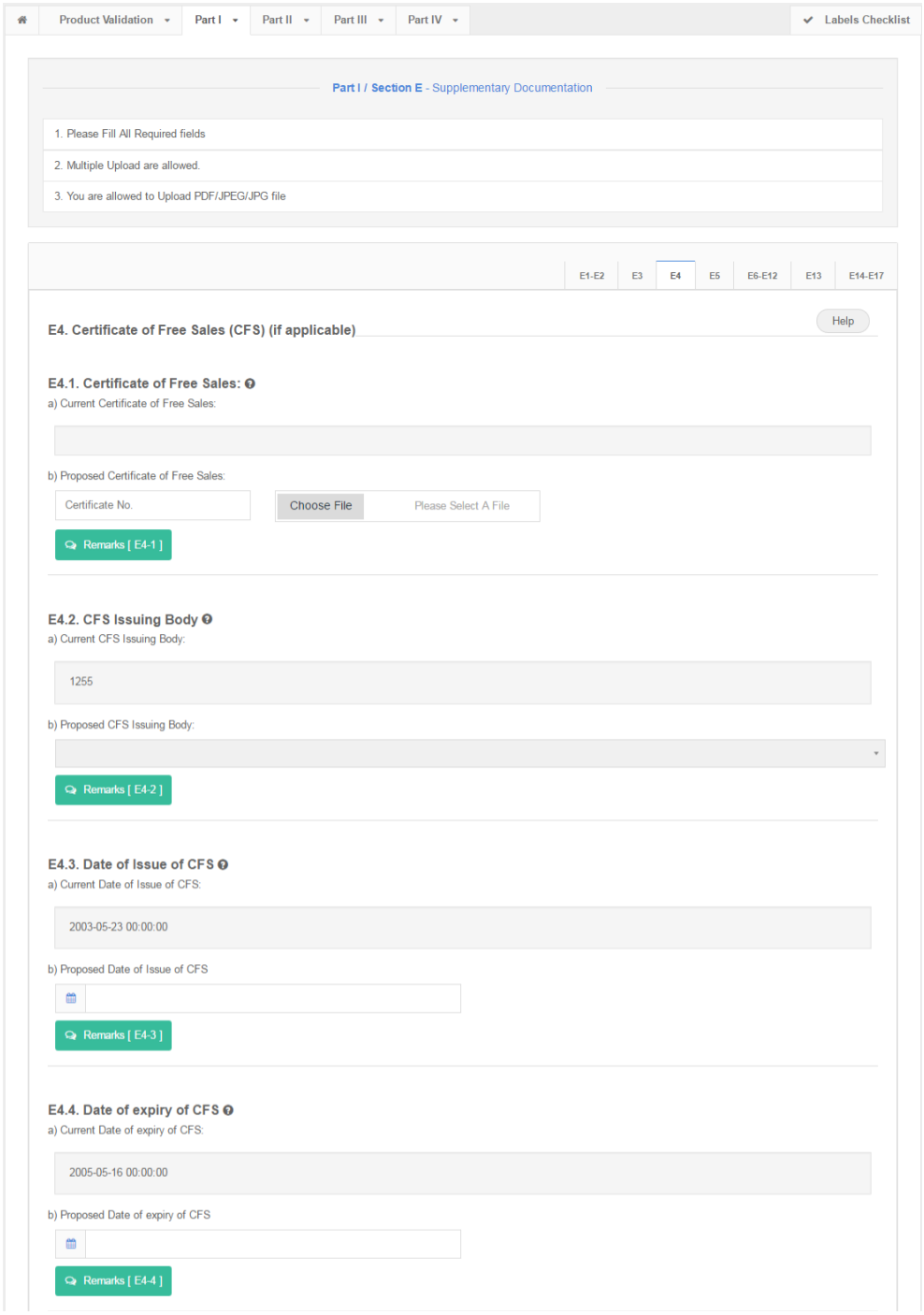

E1-E2
E3
E4
E5
E6-E12
E13
E14-E17
E1. Product Owner
Help
E1.1. Product Owner & Role
a) Current Product Owner & Role:
b) Proposed Product Owner & Role:
ASHLEY DERMACARE LABORATORY LTD. : A11-01, DAMANSARA INTAN, SS20/27,
B-PRODUCT HOLDER
Remarks [E1-1]
E1.2. Letter of Authorization from Product Owner:
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]

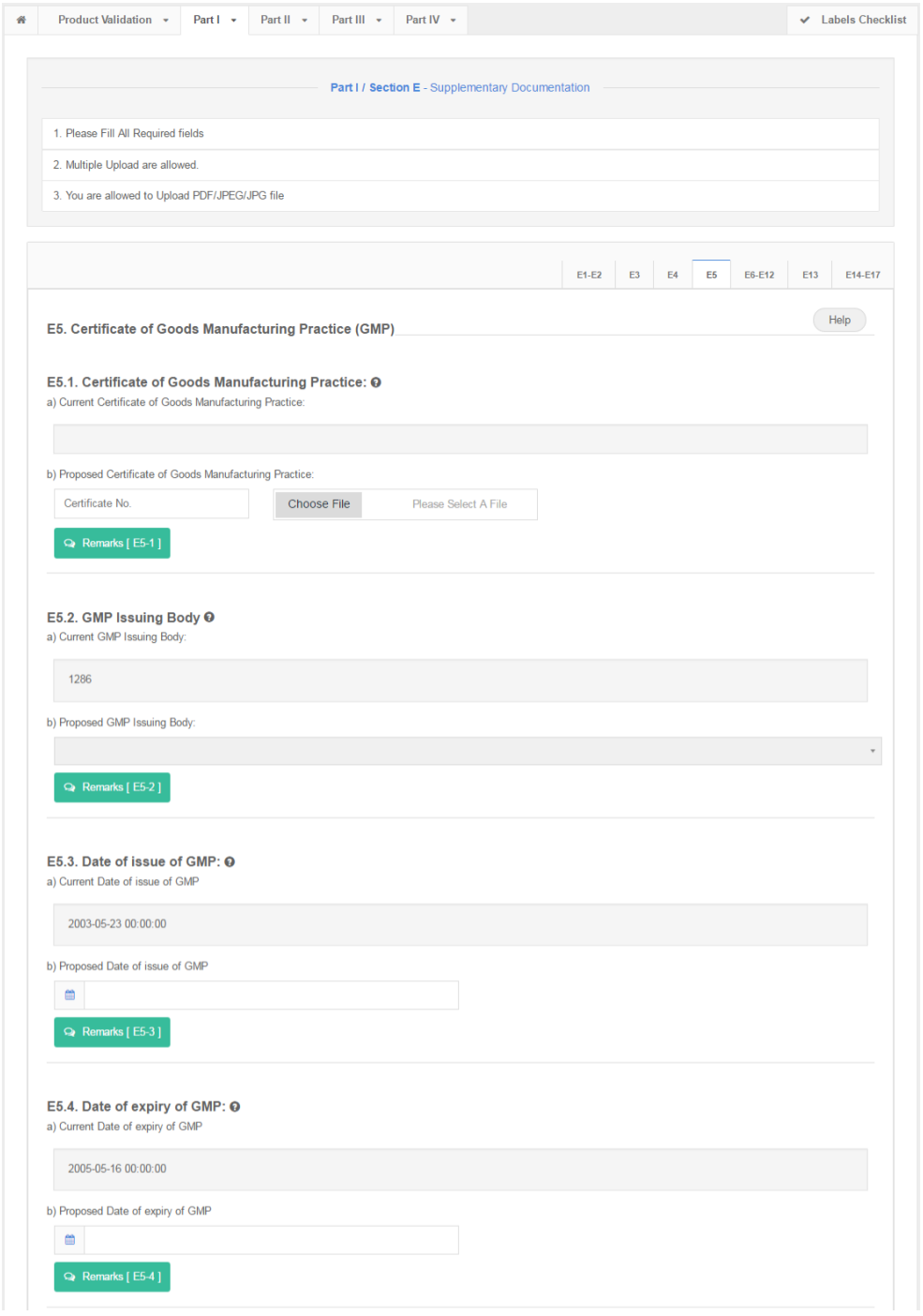
EX22	**Explanation:** Click on Part 1 / Section E / E1 – E2. Key-in the followings:- E1 upload attachment file E2 upload attachment file

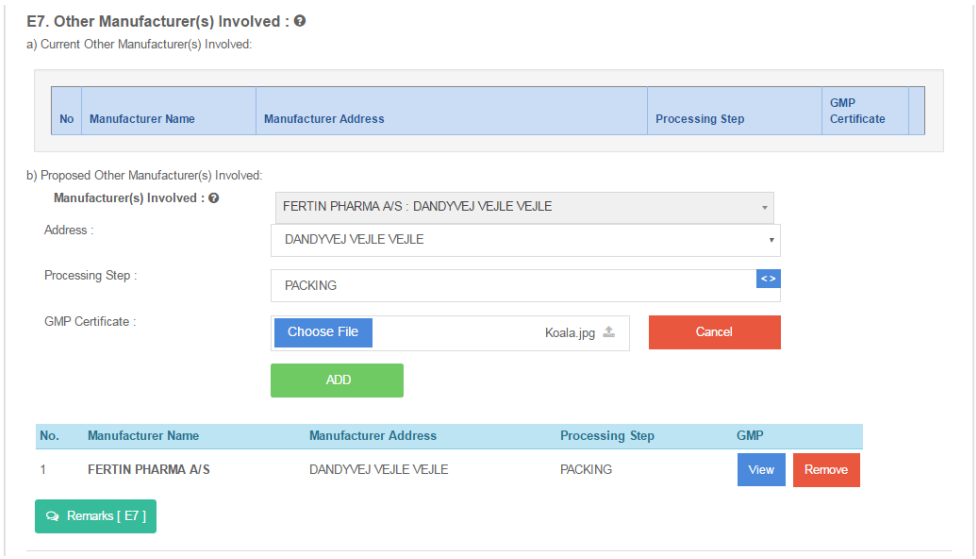
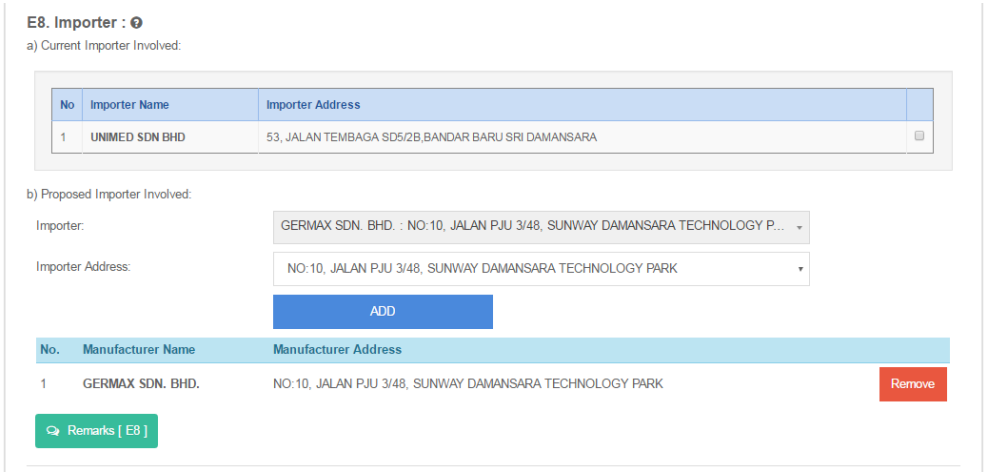
FG23

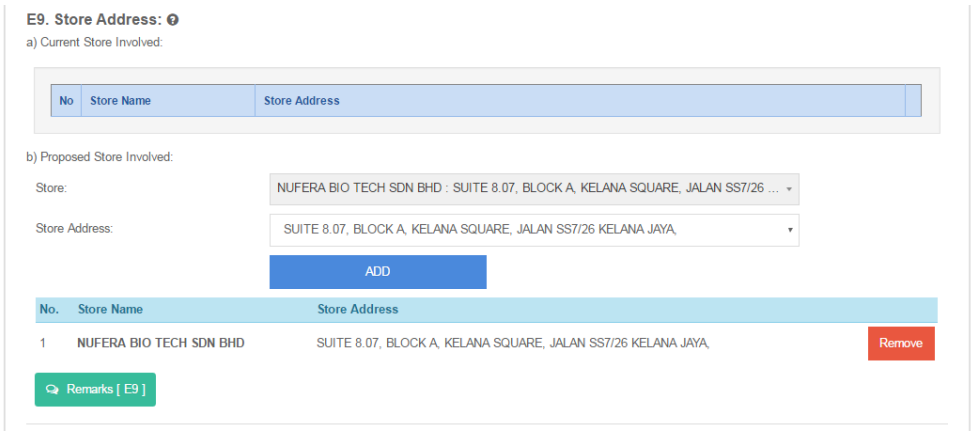
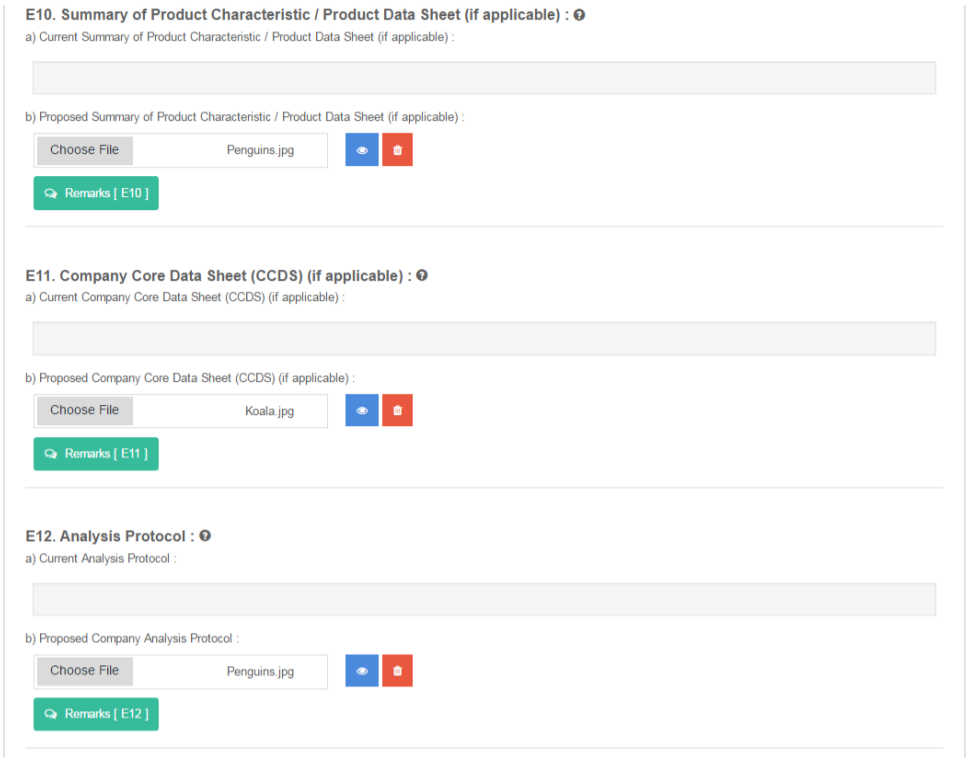

E1-E2
E3
E4
E5
E6-E12
E13
E14-E17
Help
E3. Certificate of Pharmaceutical Product (CPP)
E3.1. Certificate of Pharmaceutical:
a) Current Certificate of Pharmaceutical:
b) Proposed Certificate of Pharmaceutical:
Certificate No.
Choose File
Please Select A File
Remarks [E3-1]
E3.2. CPP Issuing Body
a) Current 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]

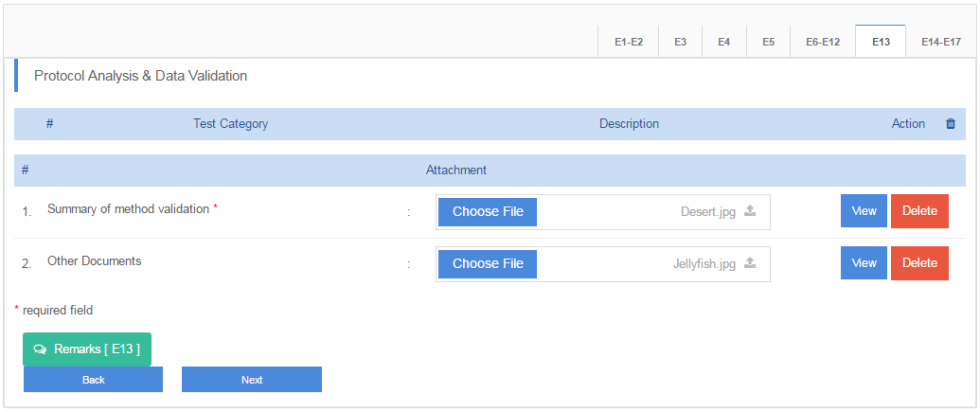
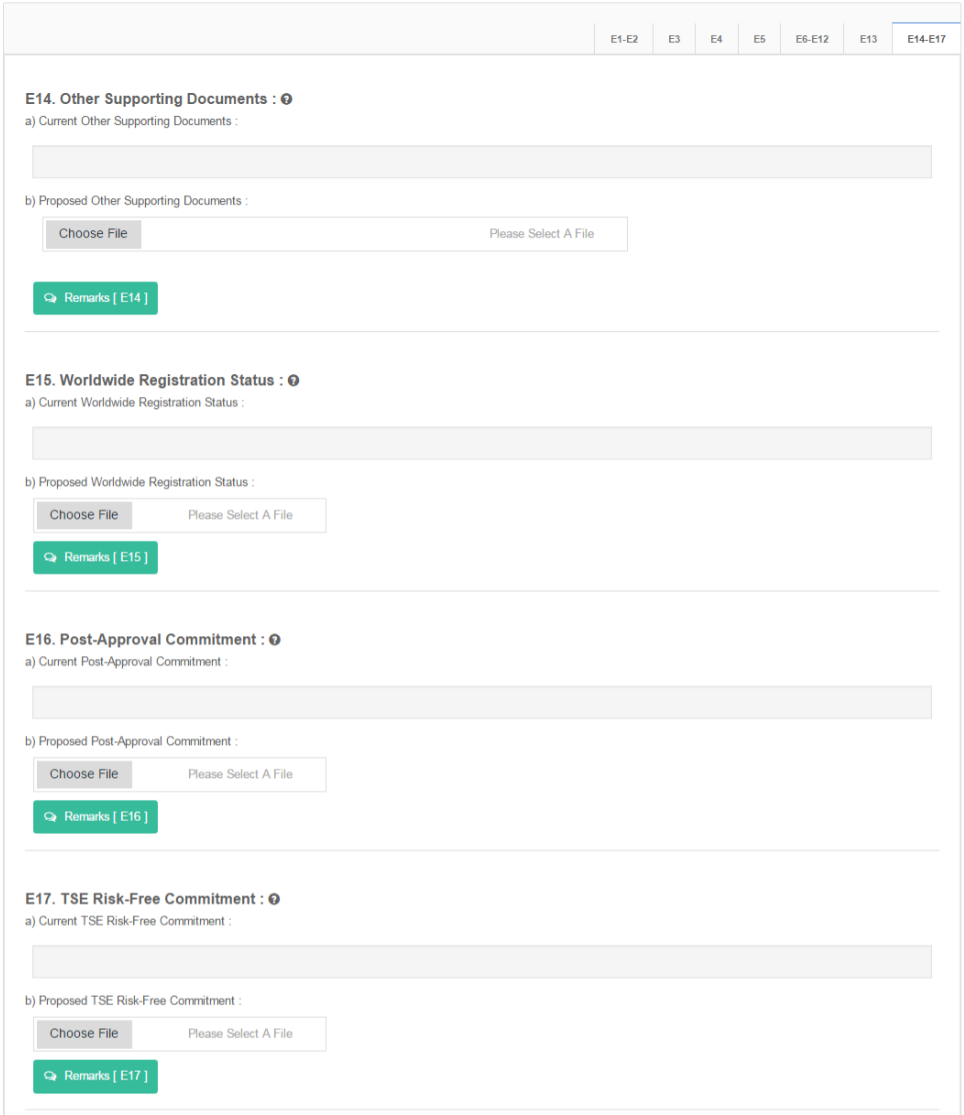
EX23	**Explanation:** Click on Part 1 / Section E / E3. Key-in the followings:- E3.1 upload attachment file E3.2 fill in issuing body - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list E3.3 fill in reason E3.4 fill in reason E3.5 fill in date E3.6 fill in date

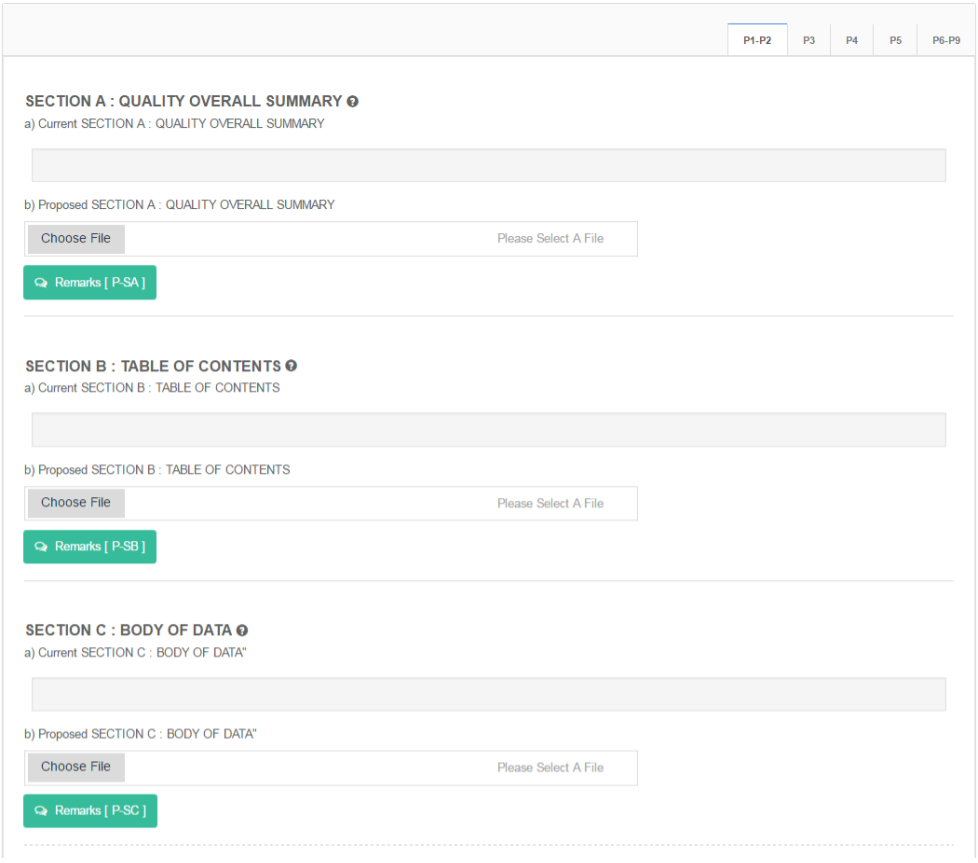
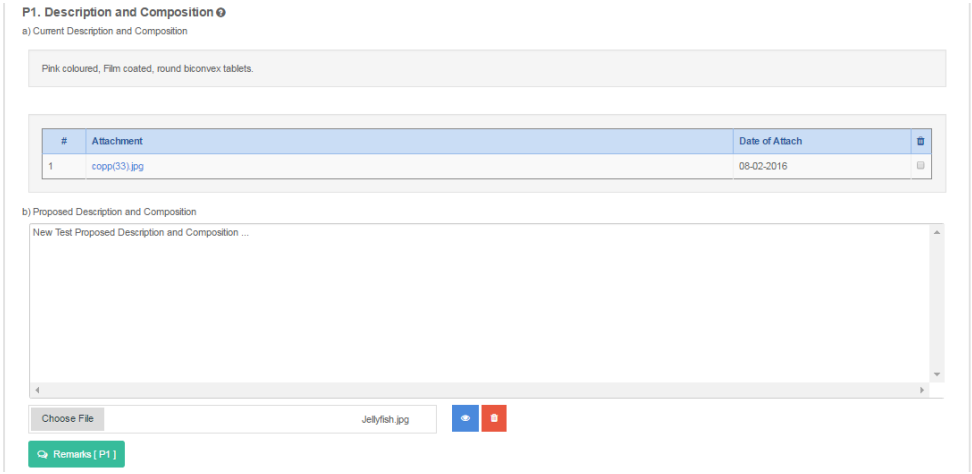
FG24	
EX24	**Explanation:** Click on Part 1 / Section E / E4. Key-in the followings:- E4.1 upload attachment file E4.2 fill in issuing body - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list E4.3 fill in date E4.4 fill in date

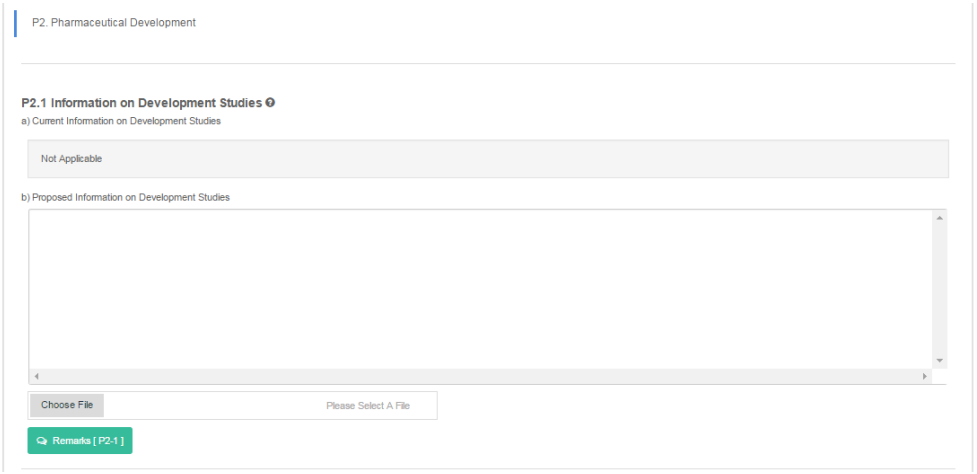
FG25	
EX25	**Explanation:** Click on Part 1 / Section E / E5. Key-in the followings:- E5.1 upload attachment file E5.2 fill in issuing body - Fill in issuing body by entering a minimum 3 character and choose from the dropdown list E5.3 fill in date E5.4 fill in date

FG26	
EX26	**Explanation:** Click on Manufacturer(s) Involved field to search for a manufacturer. Select Address and Processing Step. Upload GMP by clicking on the Choose File button Click on ADD button to add the selected manufacturer.
FG27	
EX27	**Explanation:** Click on Importer field to search. Select Importer Address. Click on ADD button to add the selected Importer.

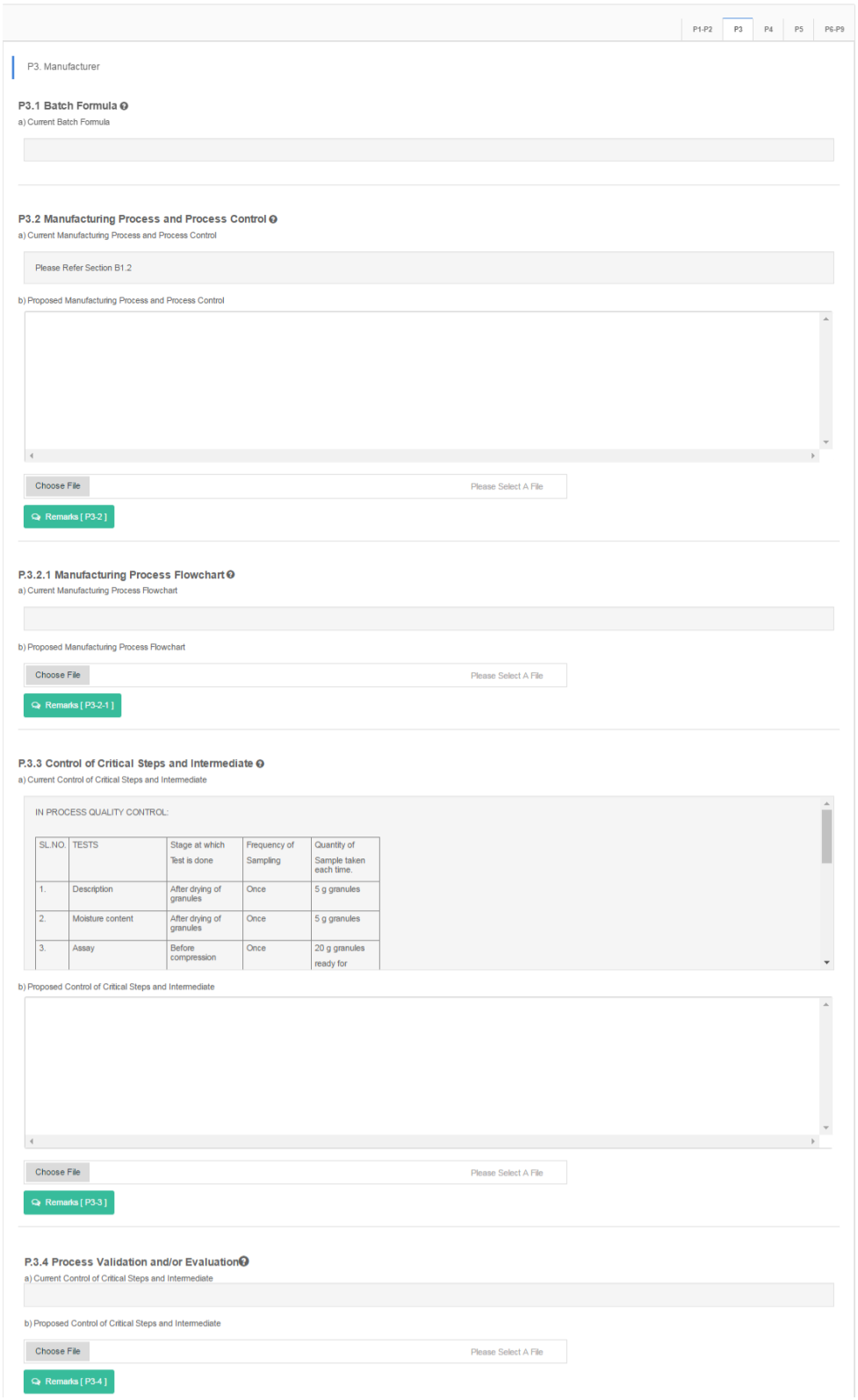
FG28	
EX28	**Explanation:** Click on Store field to search. Select Store Address. Click on ADD button to add the selected Store.
FG29	
EX29	**Explanation:** Click on Choose File button to select and upload attachment file for E10, E11, and E12.

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

EX31	**Explanation:** Click on Part 1 / Section E / E14 – E17. Click Choose File button to select and upload attachment.
FG32	
EX32	**Explanation:** Click Choose File button to select and upload attachment.
FG33	
EX33	**Explanation:** Type or paste text on the text area and click on Choose File Button to upload attachment.

FG34	
EX34	**Explanation:** Type or paste text on the text area and click on Choose File Button to upload attachment. Key-in for the following P2.2 – P2.7.

FG35

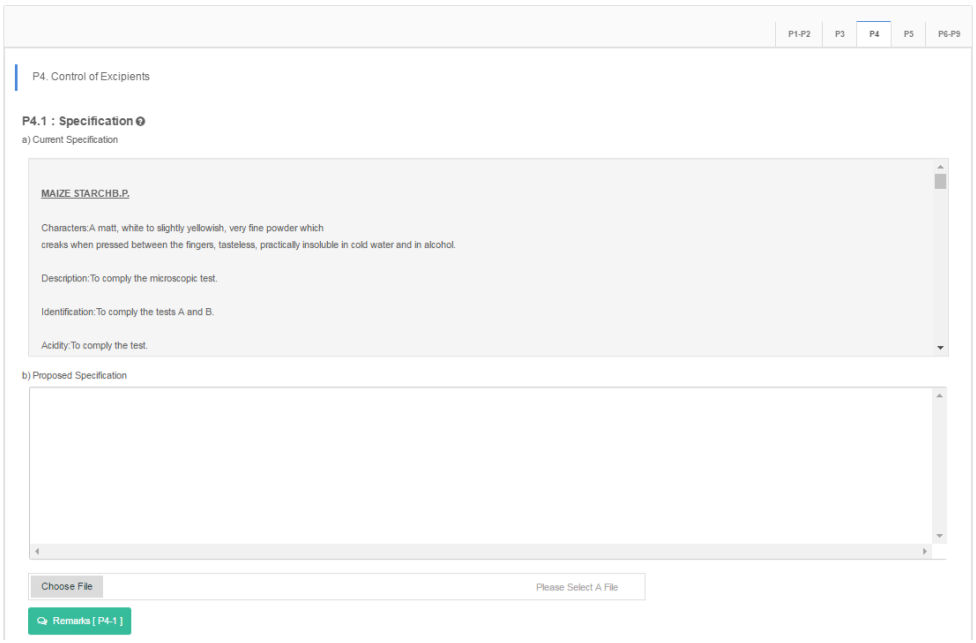
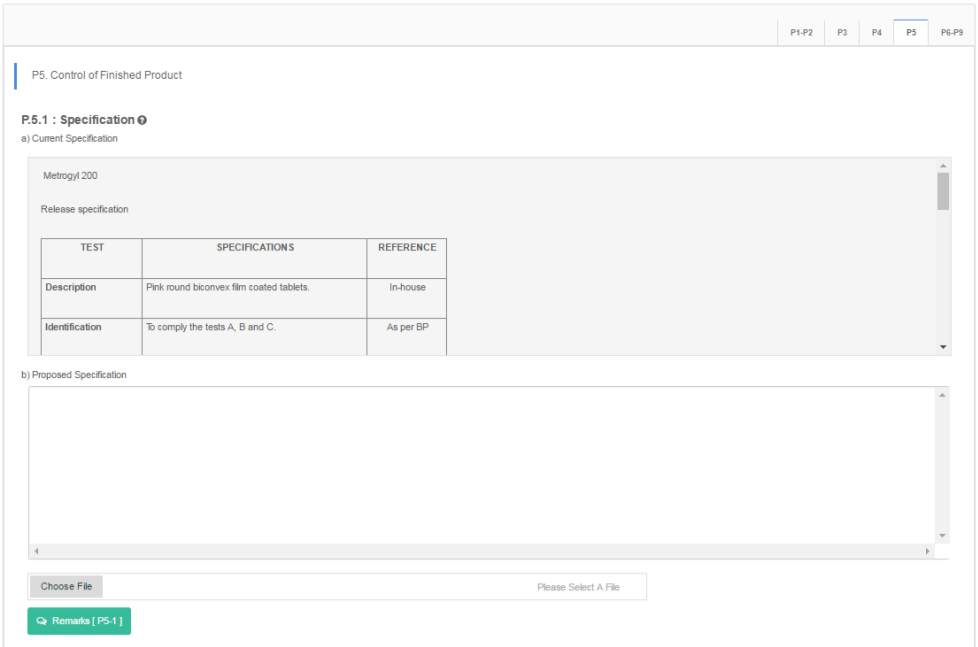


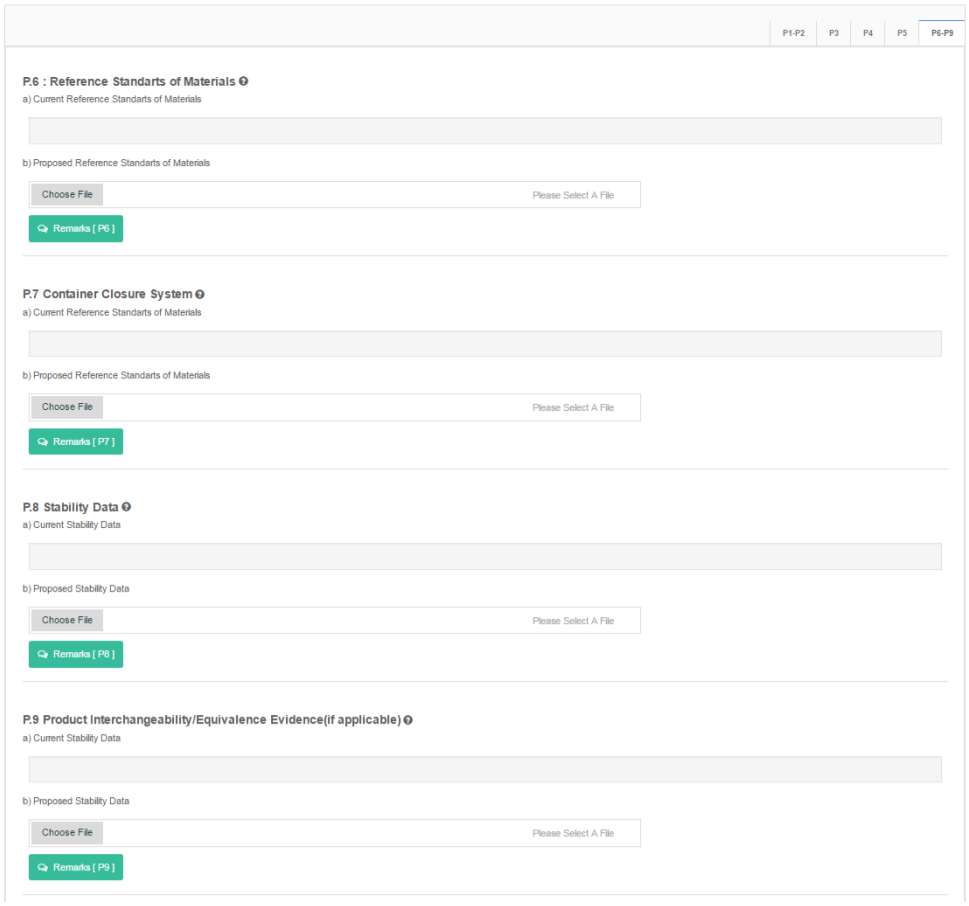
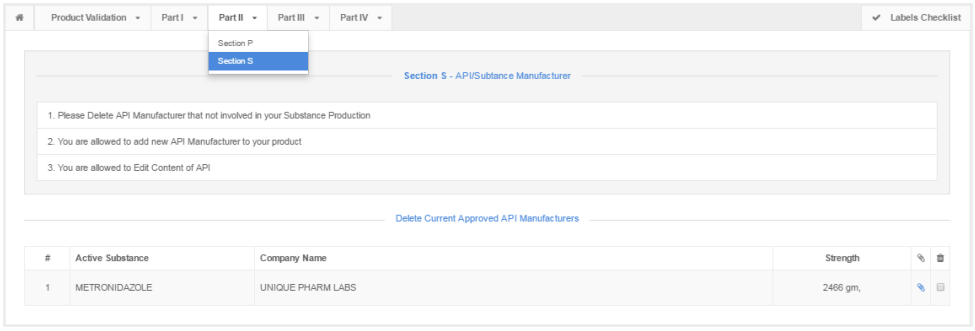
EX35

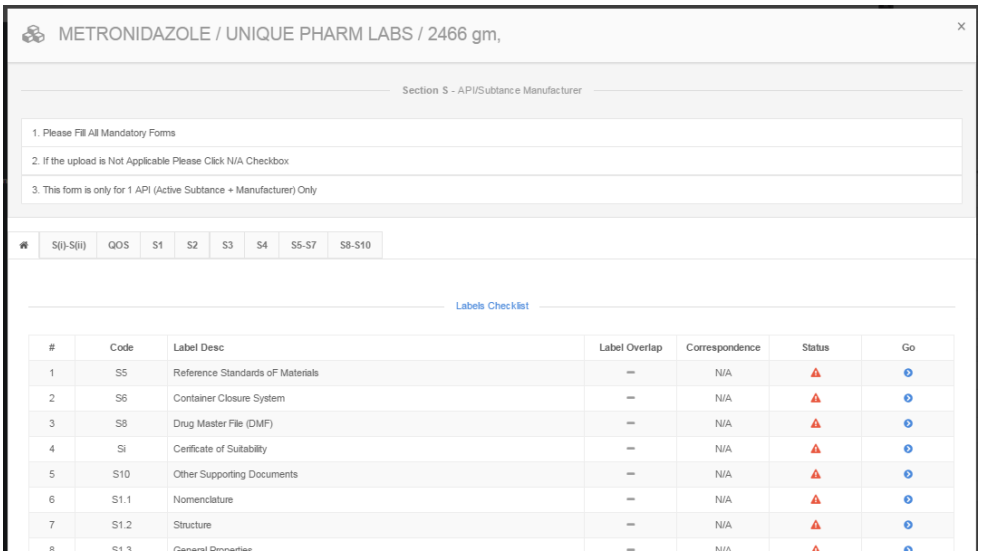
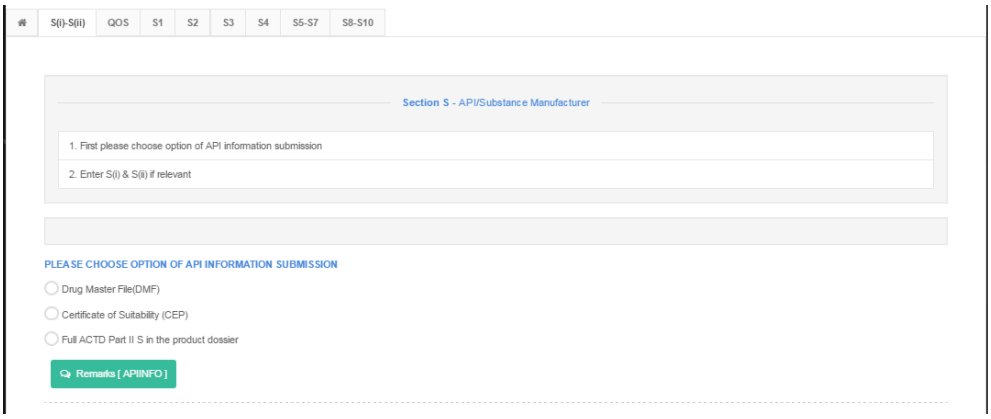
Explanation:

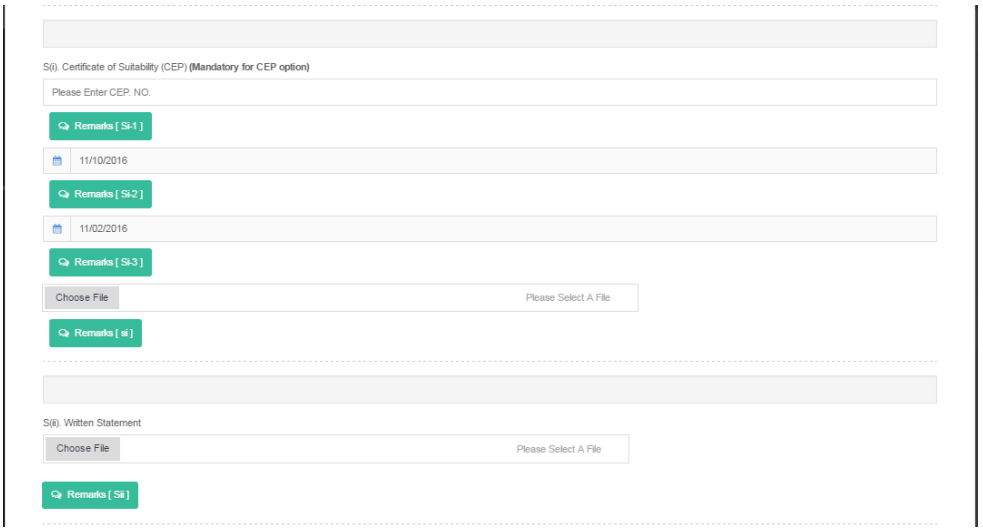
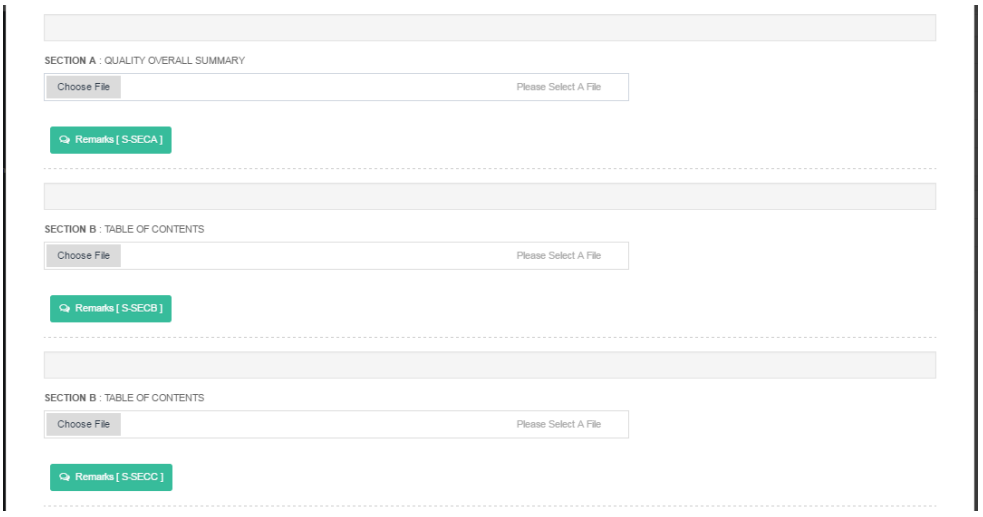
Type or paste text on the text area and click on Choose File Button to upload attachment.

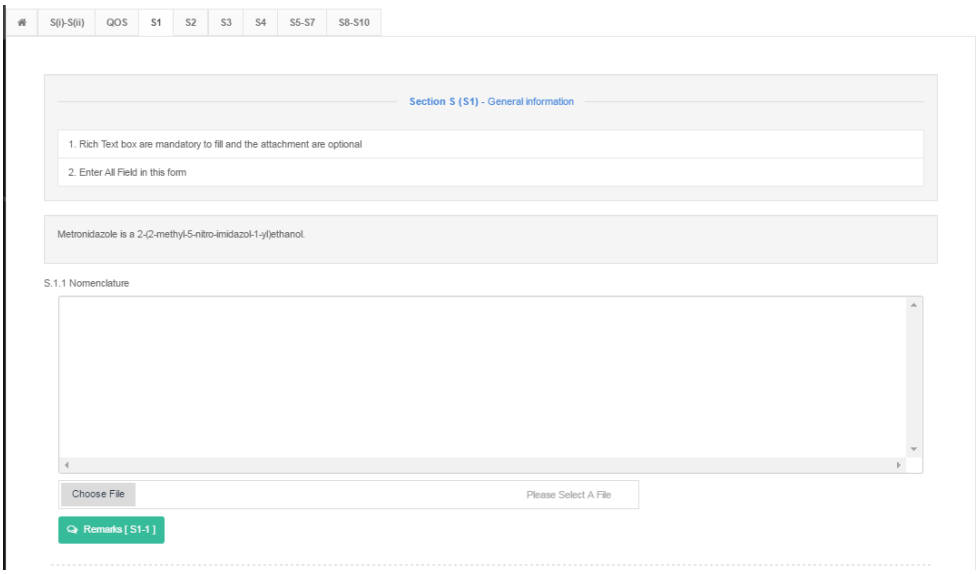
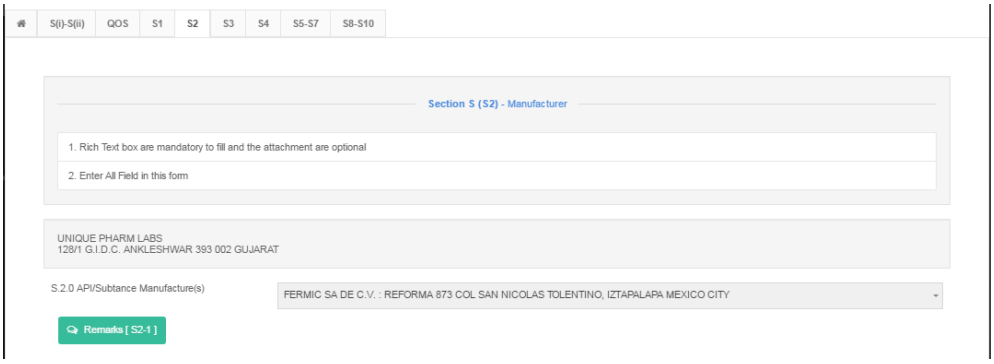
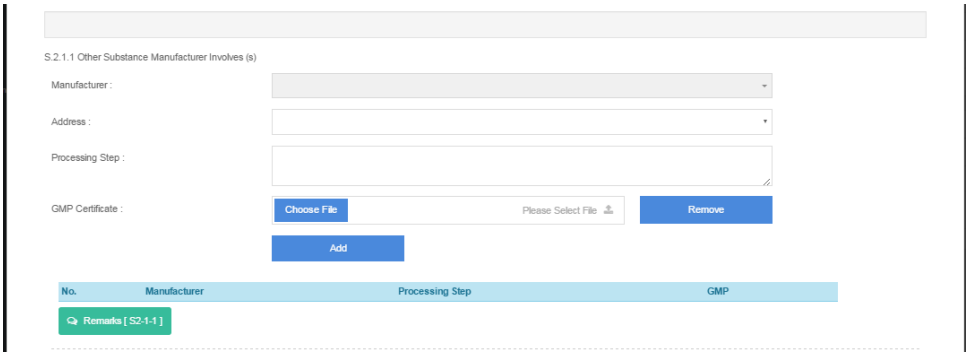
Key-in for the following P3.2 – P3.4.

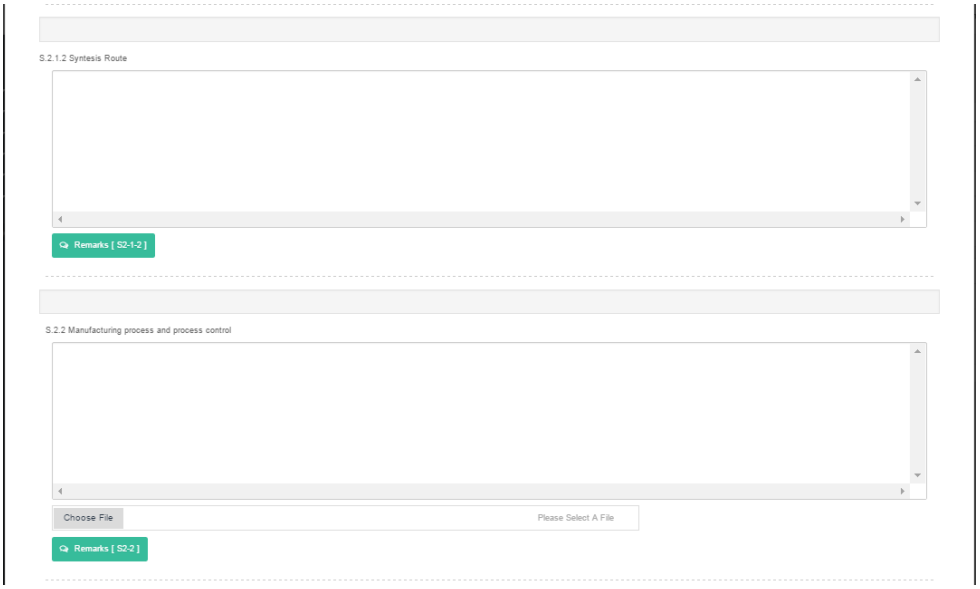
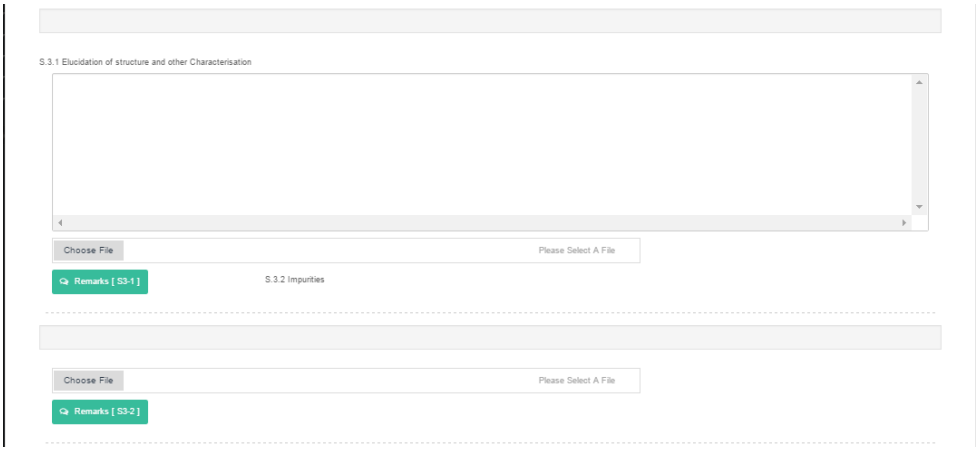
FG36	
EX36	**Explanation:** Type or paste text on the text area and click on Choose File Button to upload attachment. Key-in for the following P4.1 – P4.6.
FG37	
EX37	**Explanation:** Type or paste text on the text area and click on Choose File Button to upload attachment. Key-in for the following P5.1 – P5.11.

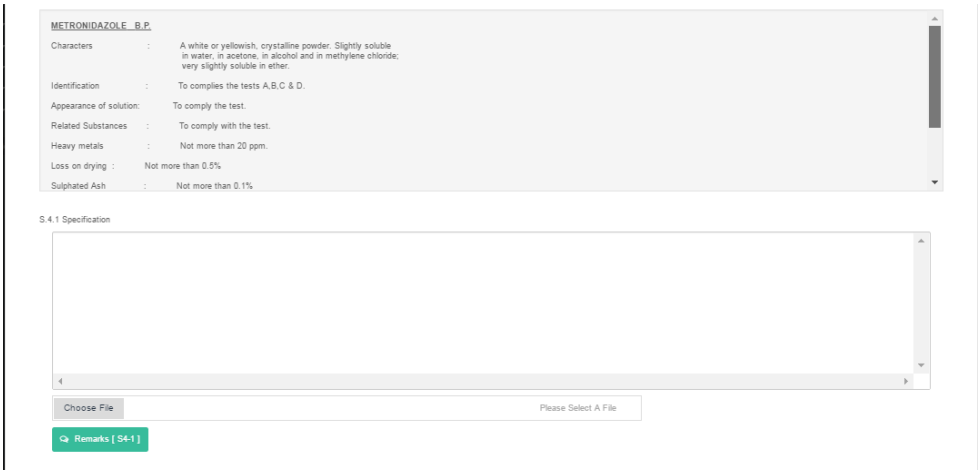
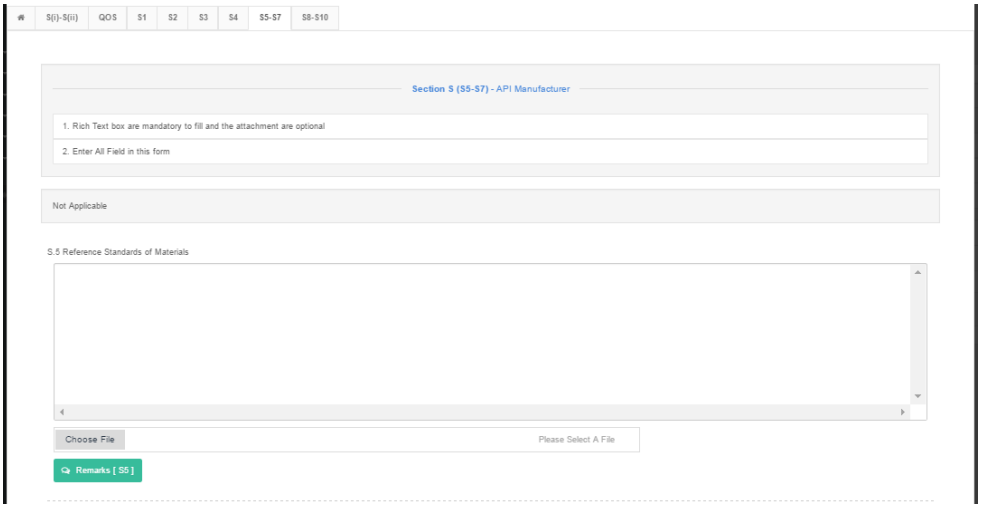
FG38	
EX38	**Explanation:** Click on Choose File button to upload attachment for P6 – P9.
FG39	
EX39	**Explanation:** Click on Part 2 / Section S Click on the clip-icon to open the popup form.

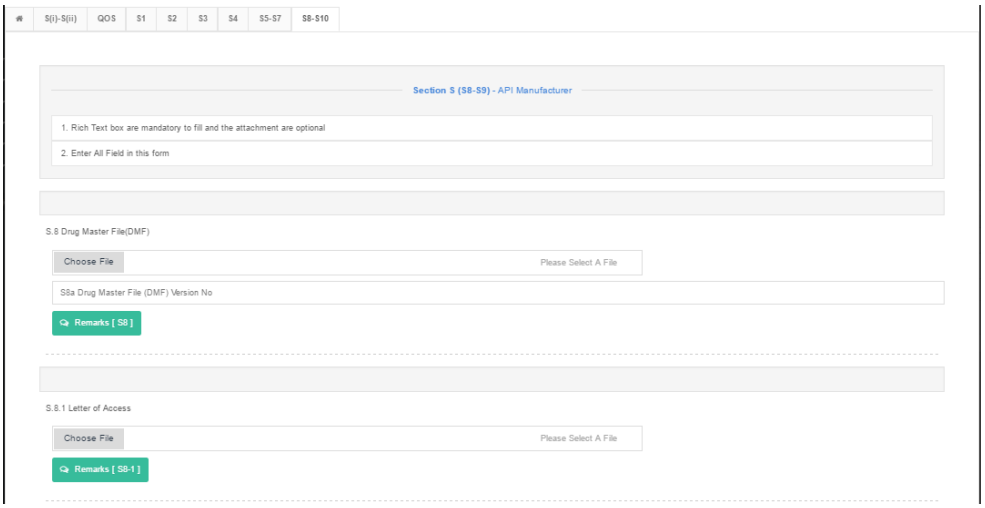
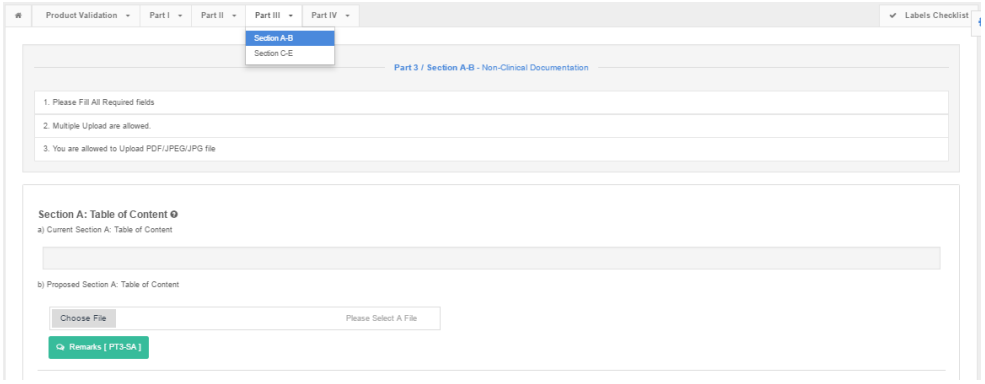
FG40	
EX40	**Explanation:** FG40 shows a popup form for Section S.
FG41	
EX41	**Explanation:** Click on S(i)-S(ii) Select API Information

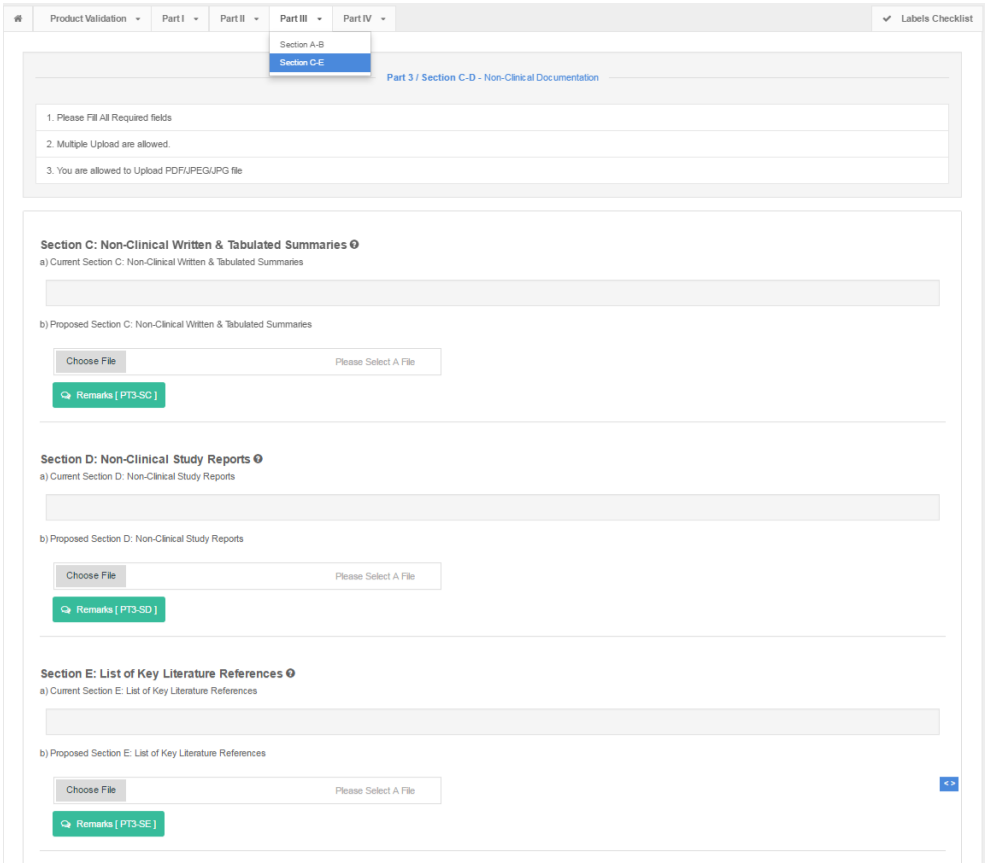
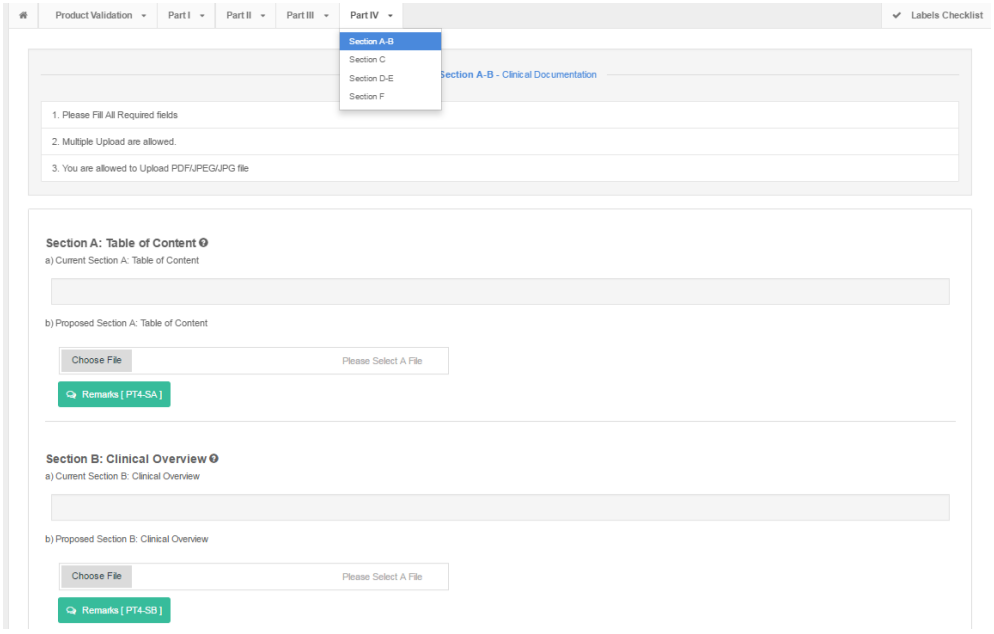
FG42	
EX42	**Explanation:** Select Date by clicking on the calendar-icon. Click on Choose File button to upload attachment
FG43	
EX43	**Explanation:** Click on QOS Click on Choose File button to upload attachment

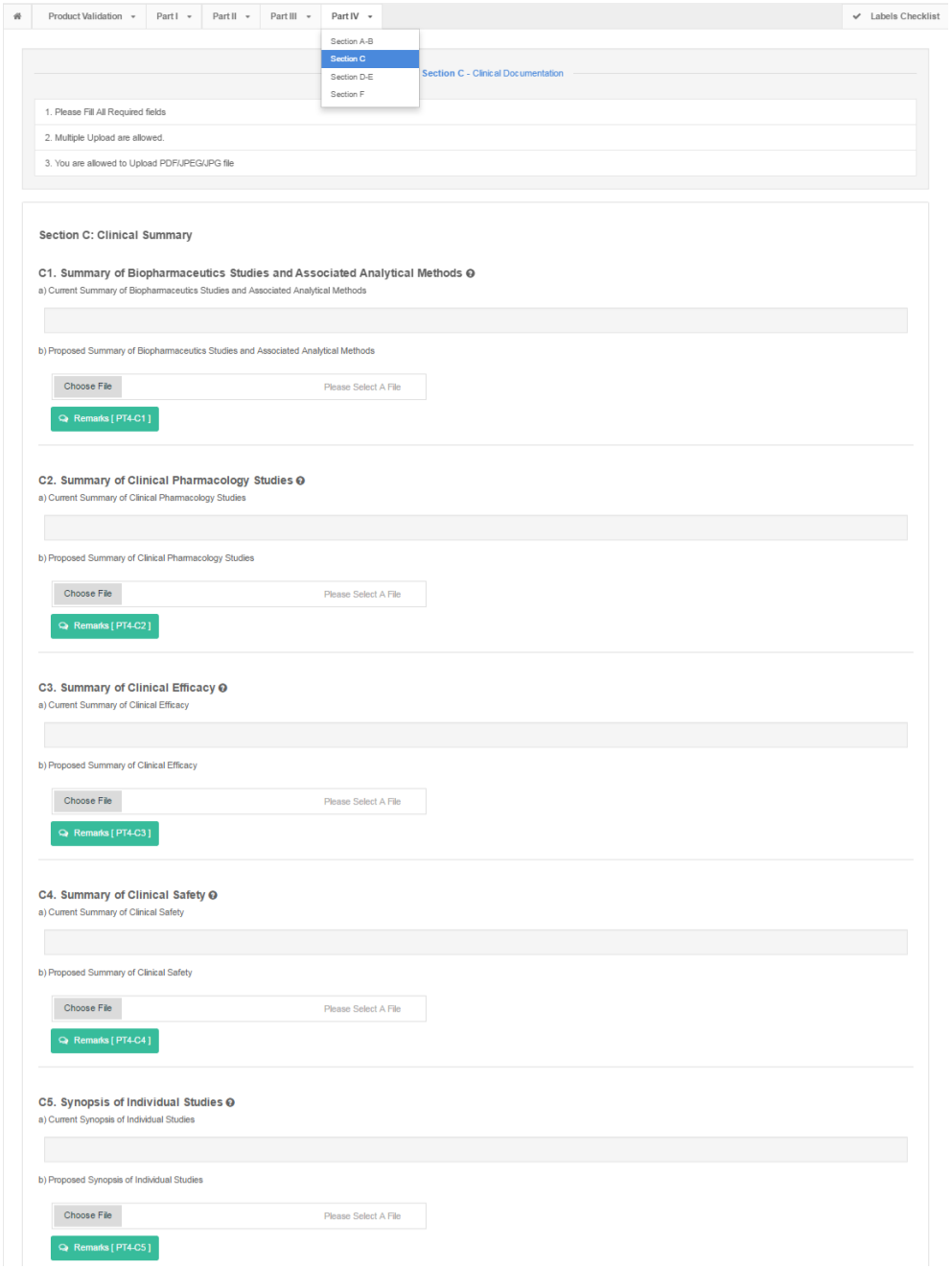
FG44	
EX44	**Explanation:** Click on S1 Type or paste text into the text area. Click on Choose File button to upload attachment. Key-in the following S.1.1 – S.1.3
FG45	
EX45	**Explanation:** Click on the dropdown option to search for API Substance Manufacturer.
FG46	
EX46	**Explanation:** Click on Manufacturer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

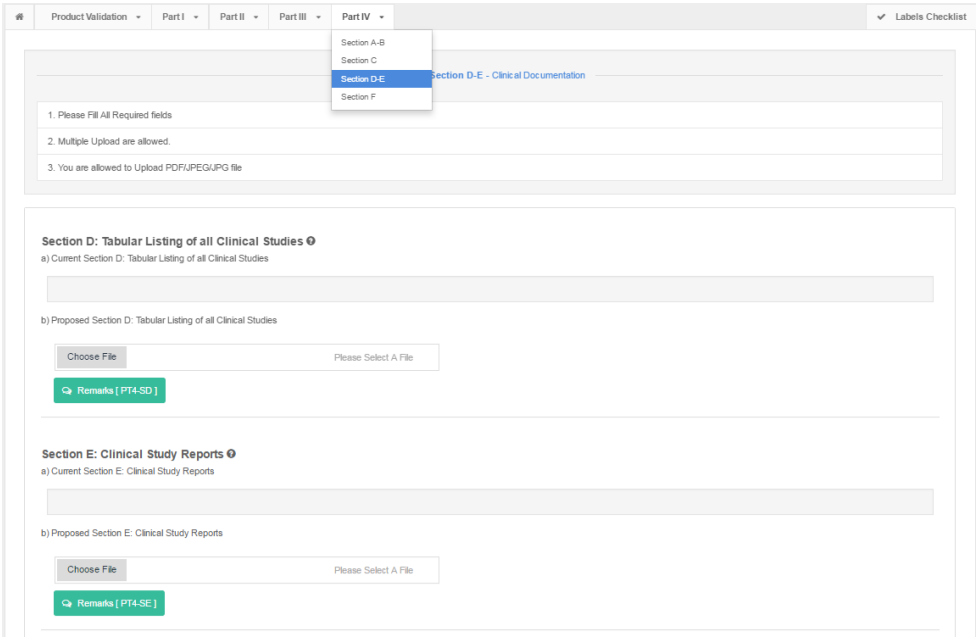
	Select Address and key-in Processing Step. Upload GMP by clicking on the Choose File button Click on ADD button to add the selected manufacturer.
FG47	
EX47	**Explanation:** Type or paste text into the text area. Click on Choose File button to upload attachment.
FG48	
EX48	**Explanation:** Click on S3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

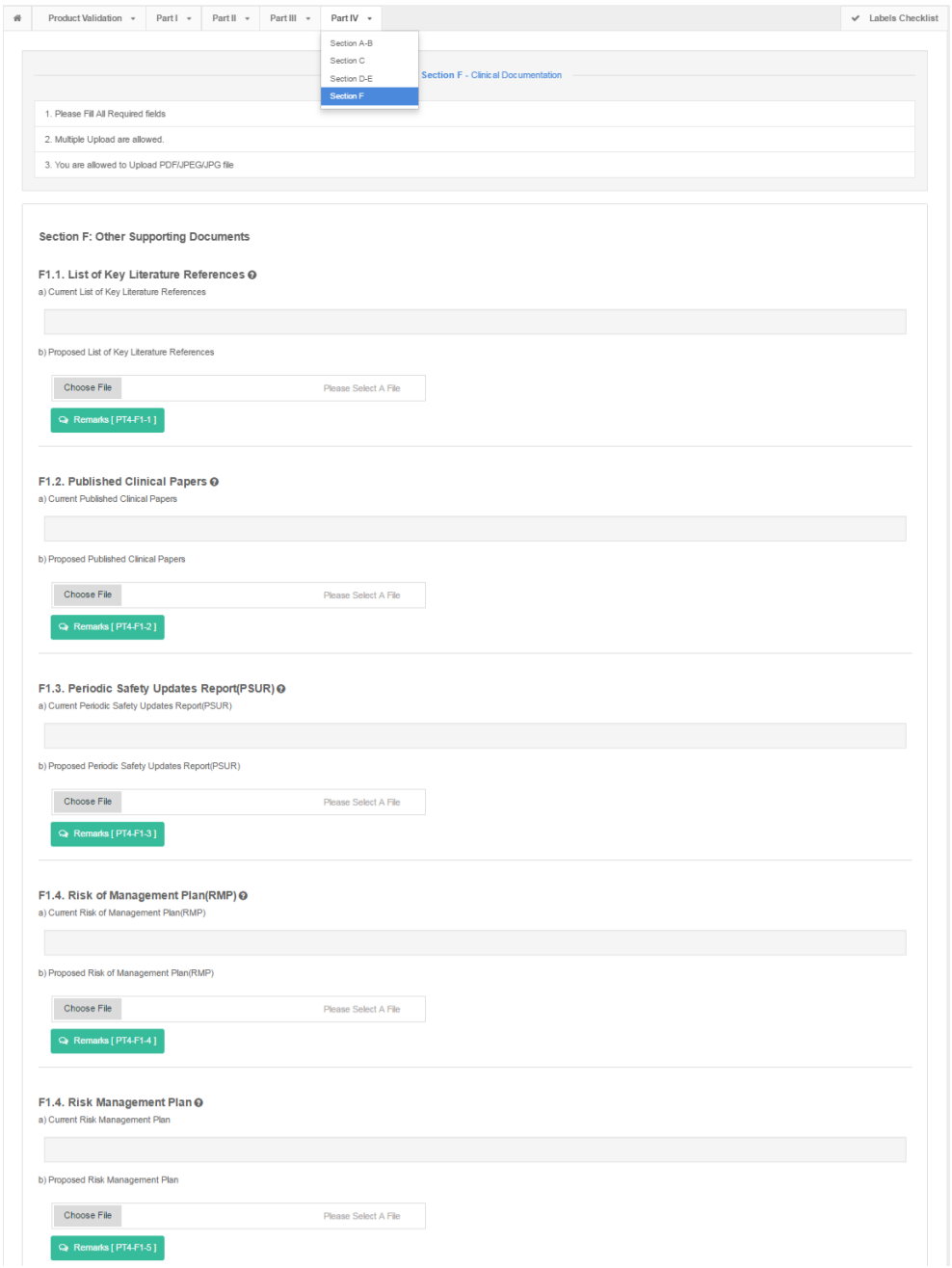
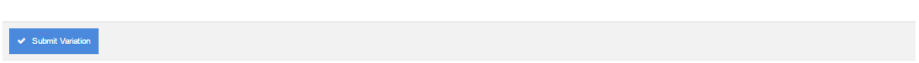
FG49	
EX49	**Explanation:** Click on S4 Type or paste text into the text area. Click on Choose File button to upload attachment. Key-in the following S.4.1 – S.4.5
FG50	
EX50	**Explanation:** Click on S5-S7 Type or paste text into the text area. Click on Choose File button to upload attachment. Key-in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

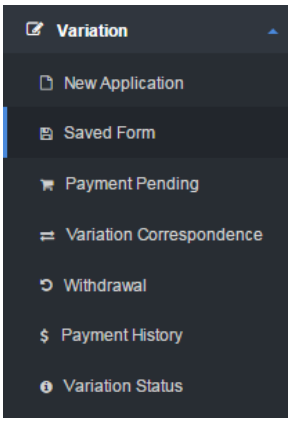
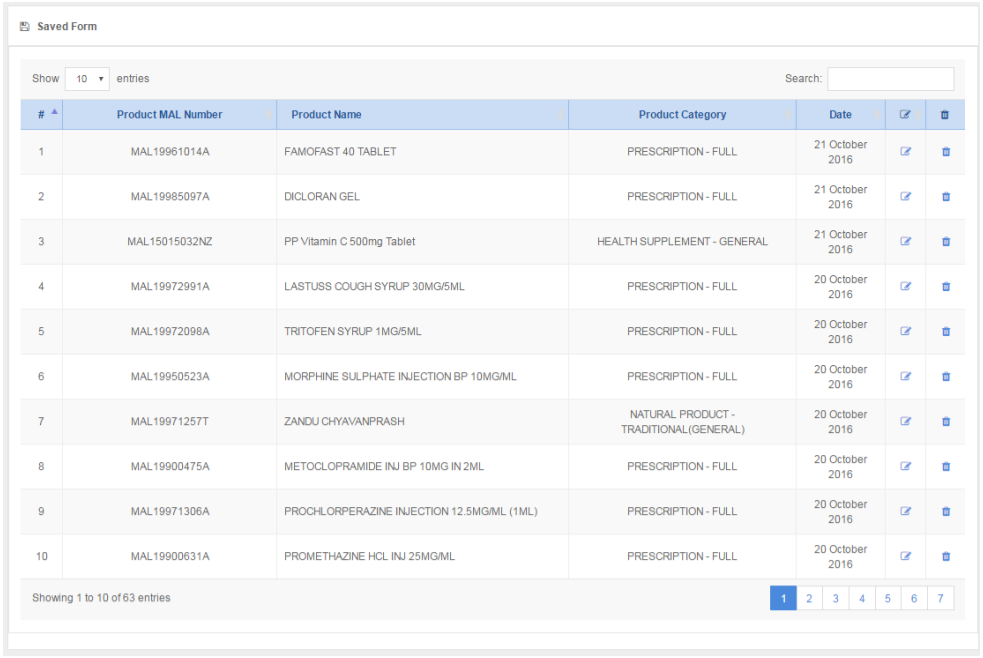
FG51	
EX51	**Explanation:** Click on S8-10 Type or paste text into the text area. Click on Choose File button to upload attachment. Click on calendar-icon to select date Key-in the following S8 – S10 Click anywhere outside the popup form to close.
FG52	
EX52	**Explanation:** Click on Part 3 / Section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

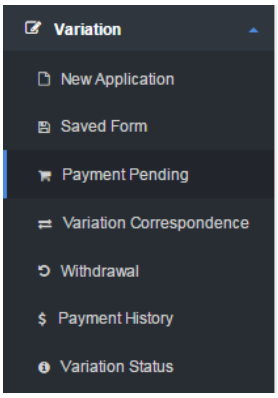
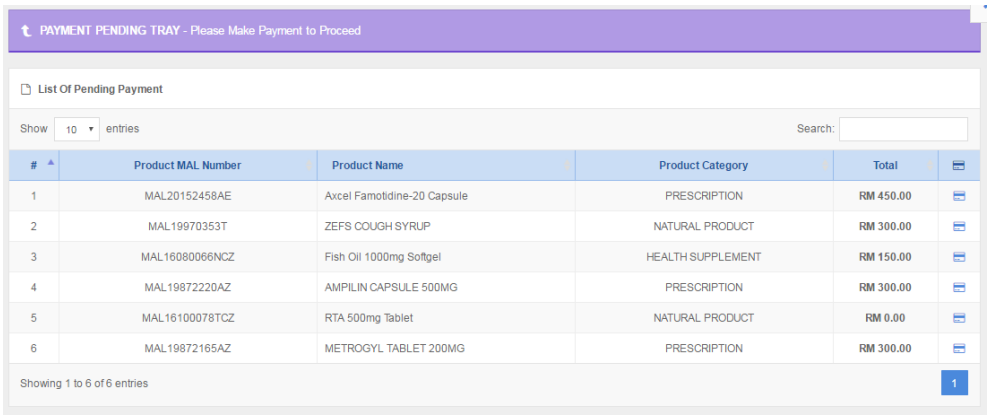
FG53	
EX53	**Explanation:** Click on Choose File button to select and upload attachment.
FG54	
EX54	**Explanation:** Click on Choose File button to select and upload attachment.

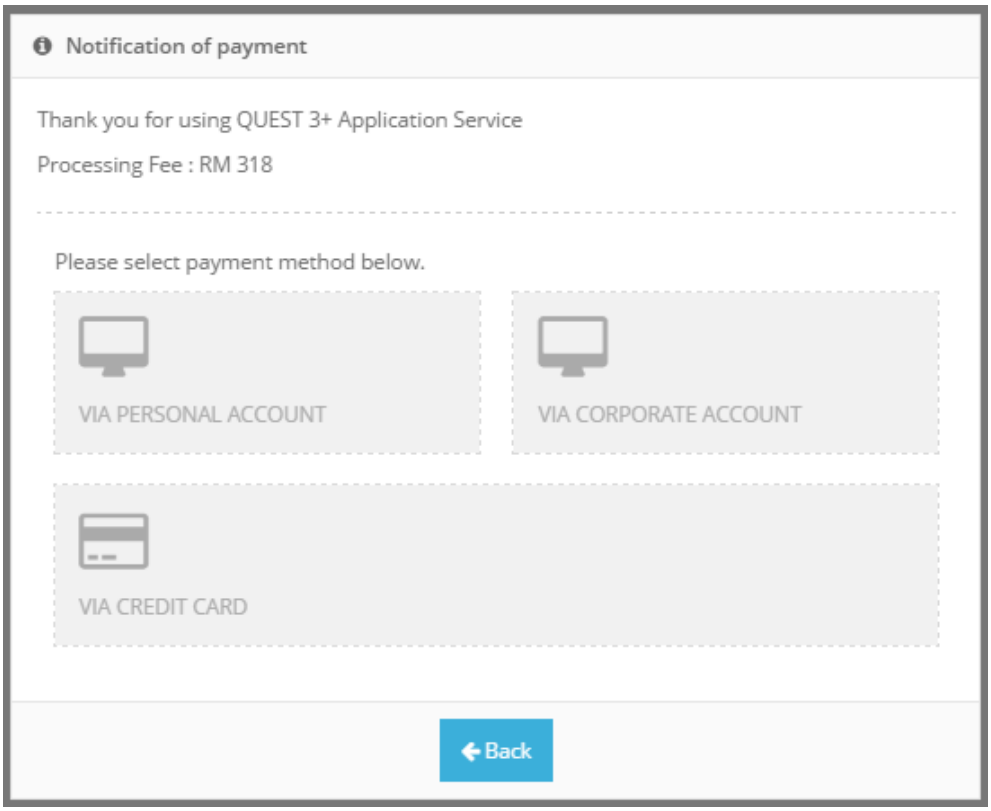
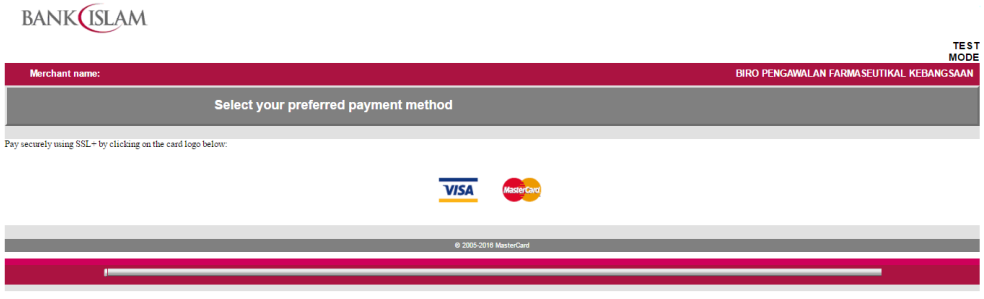
FG55	
EX55	**Explanation:** Click on Part 4 / Section C Click on Choose File button to select and upload attachment.

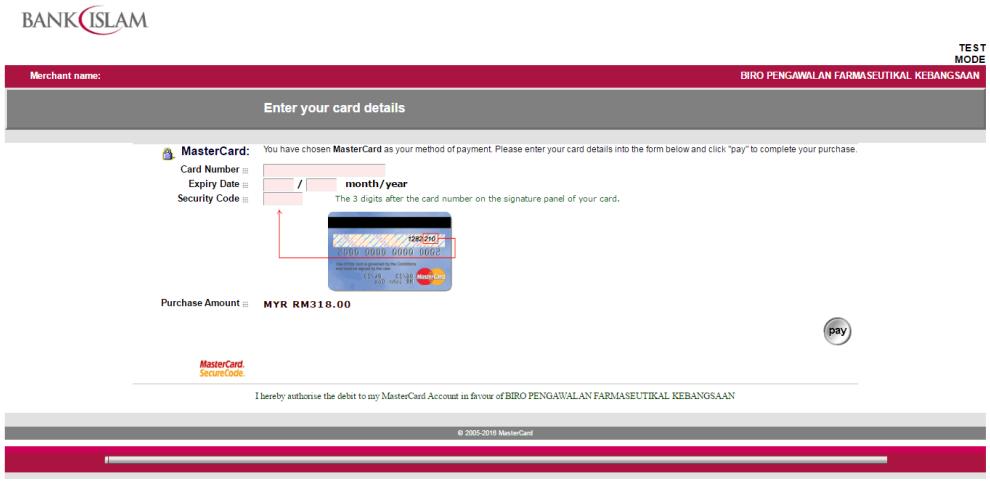
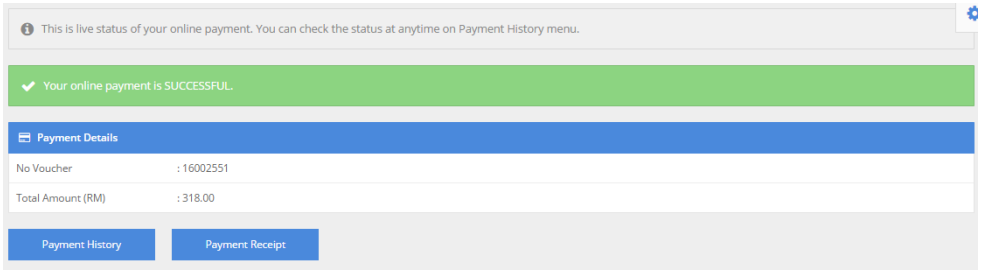
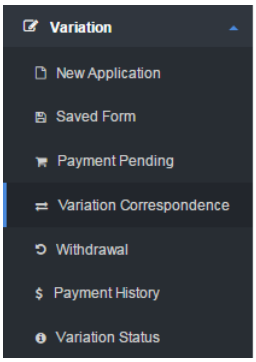
FG56	
EX56	**Explanation:** Click on Part 4 / Section D-E Click on Choose File button to select and upload attachment.

FG57	
EX57	**Explanation:** Click on Part 4 / Section F Click on Choose File button to select and upload attachment.
FG58	
EX58	**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 FG58

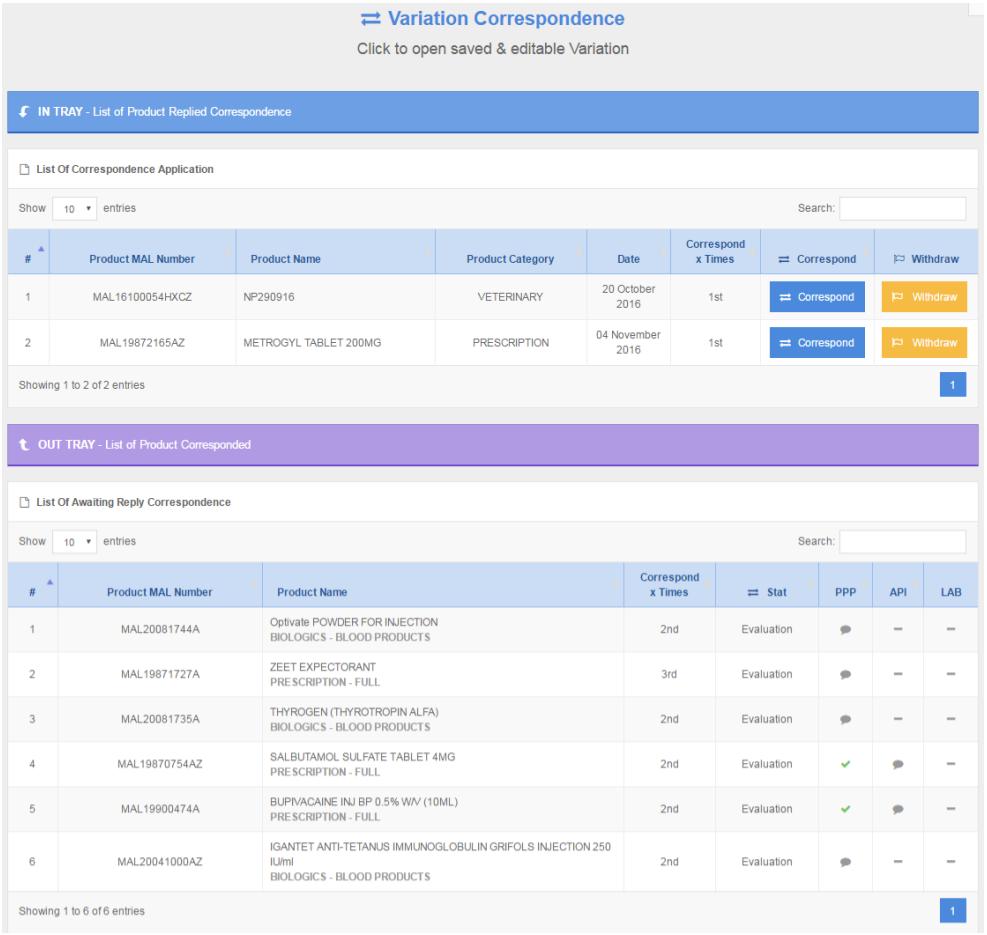
2.2	**Saved Form**
FG59	
EX59	**Explanation:** Click on Variation / Saved Form
FG60	
EX60	**Explanation:** FG60 show a list of saved form. Click on the edit-icon to open the saved form Click on the trash-icon to delete the saved form
2.3	**Payment Pending**

FG61	
EX61	**Explanation:** Click on Variation / Payment Pending
FG62	
EX62	**Explanation:** FG62 shows a list Variation Application with Pending payment status. Click on the credit card-icon to proceed with payment.

FG63	
EX63	**Explanation:** FG63 shows list of available payment method. Click on Payment Method icon to continue.
FG64	
EX64	**Explanation:** Select prefered payment method by clicking on the icon.

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

FG68



EX68

Explanation:

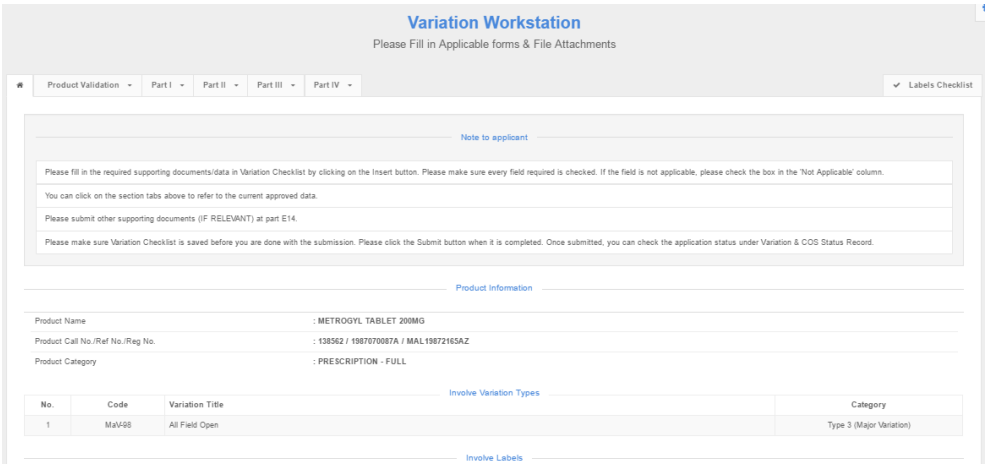
The IN TRAY table shows a list of Variation Application that needs to be correspond/replied by the user/applicant

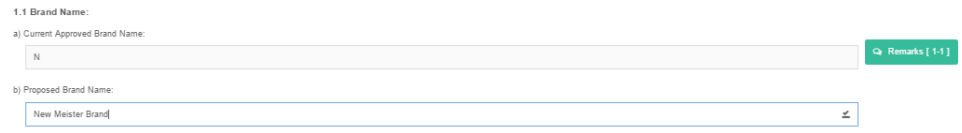
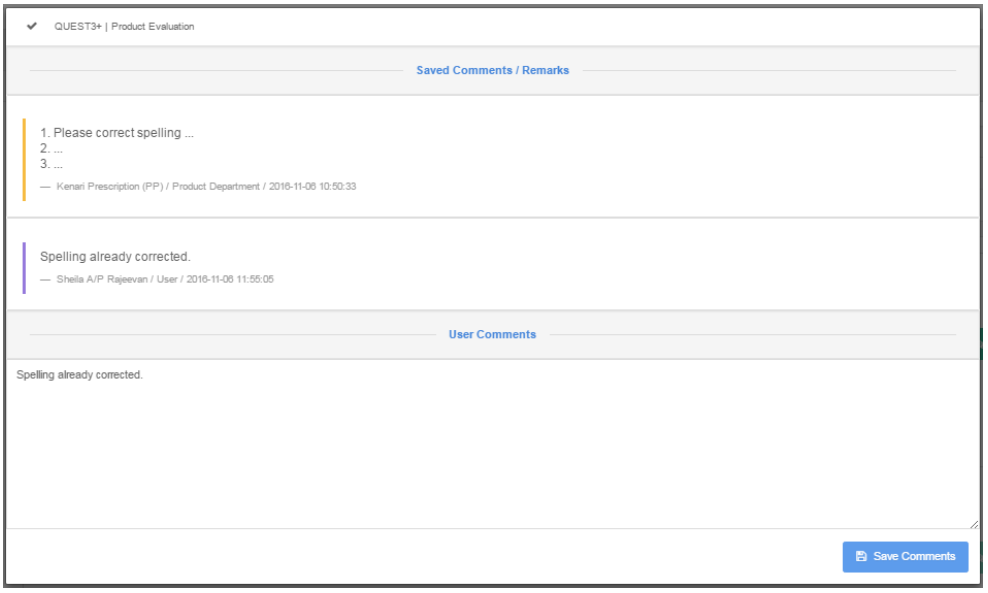
The OUT TRAY table shows a list of Variation Application that has been replied by user/applicants

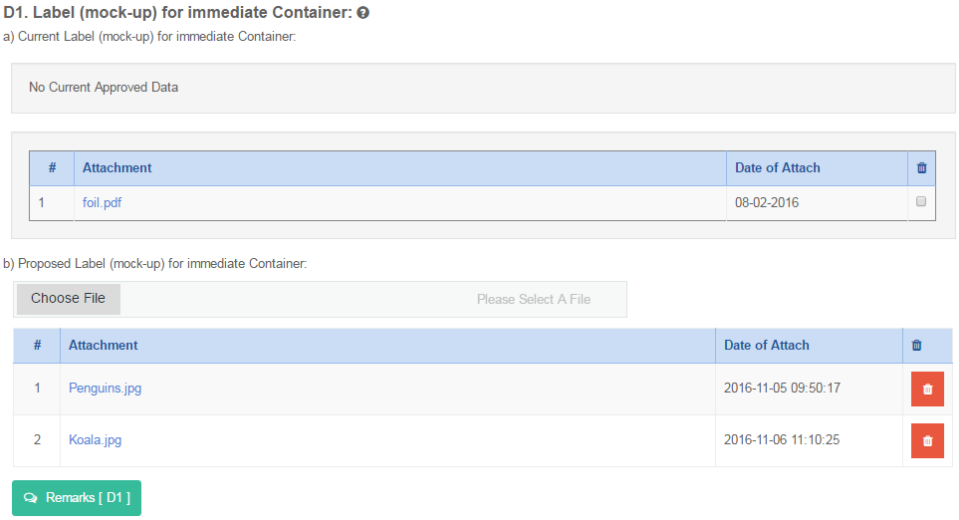
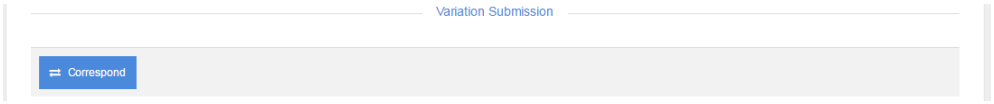
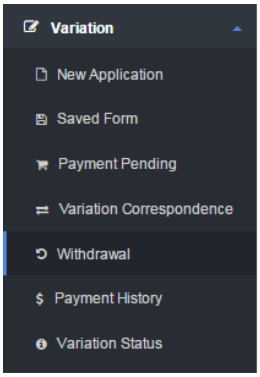
Click on the Correspond button to reply correspondence.

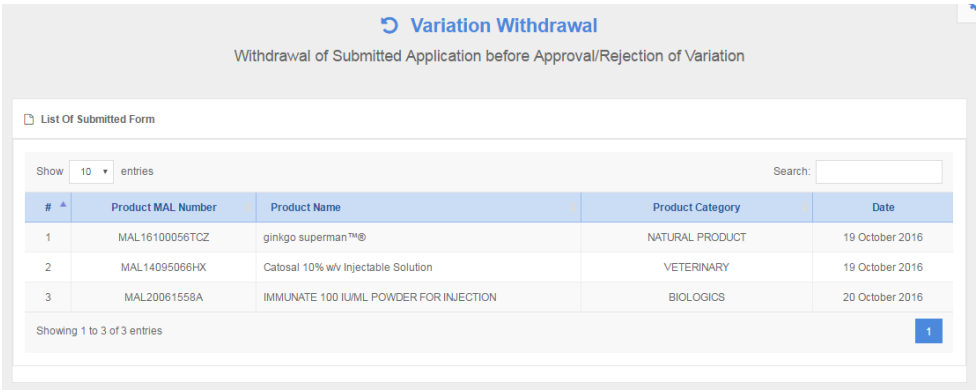
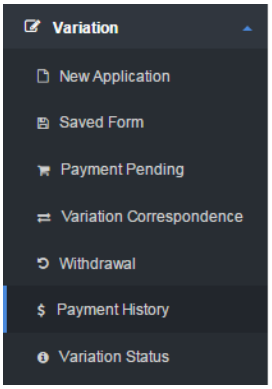
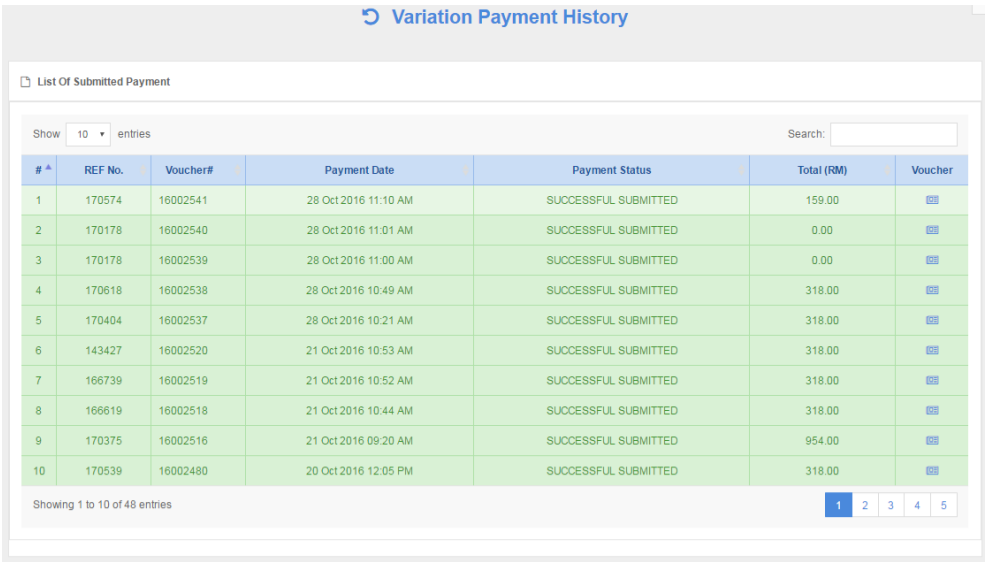
Click on the Withdraw button to withdraw/cancel the application. Refer (FG74 – FG75, EX74 – EX75)

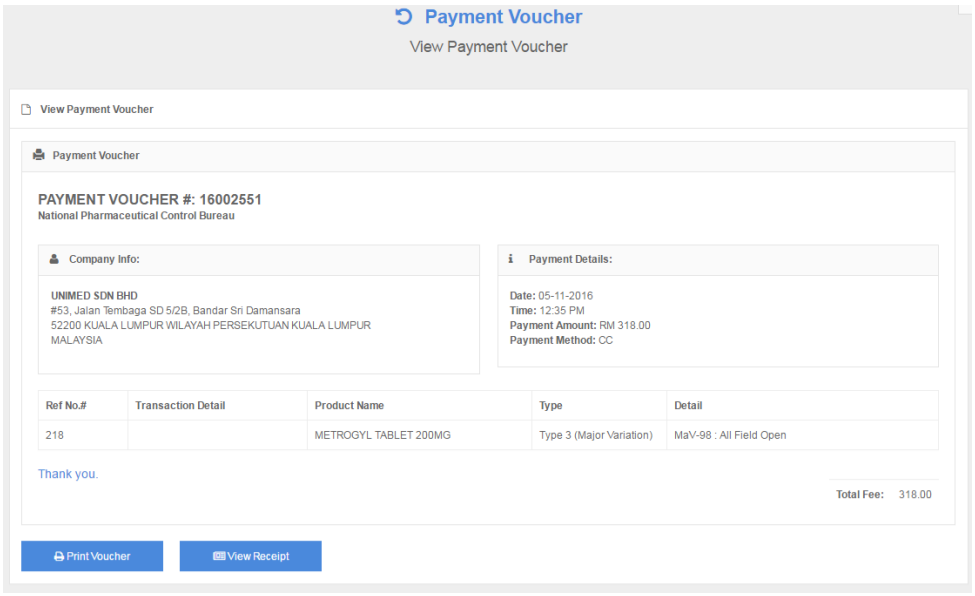
FG69

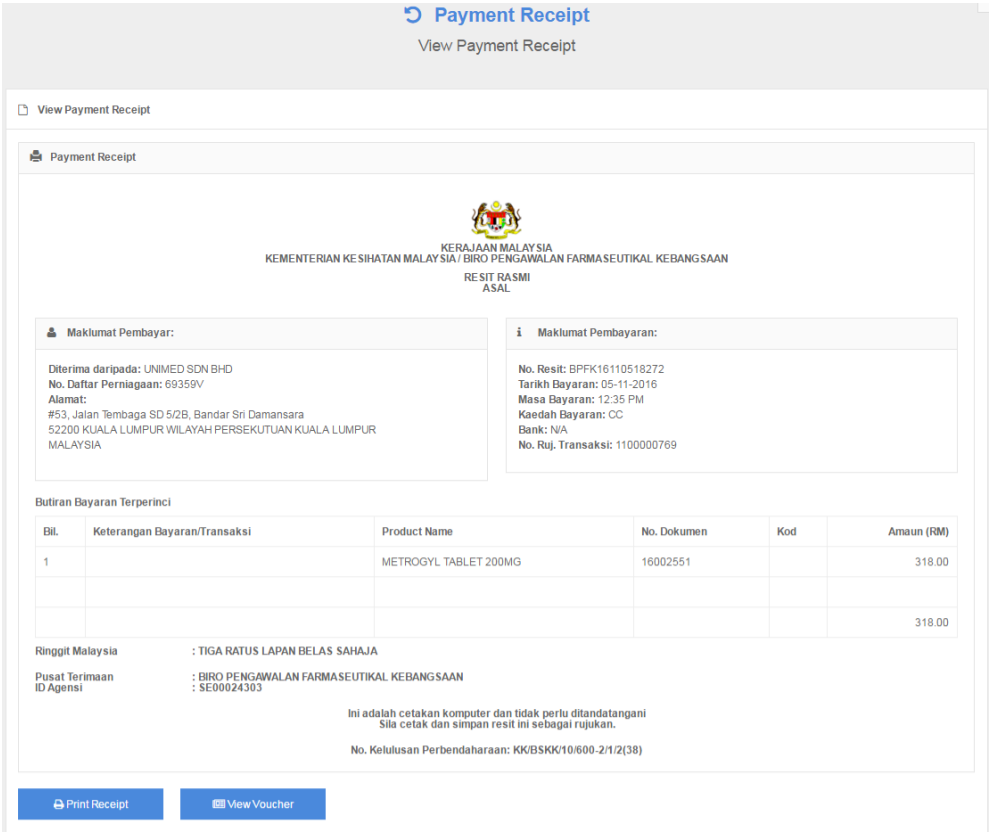
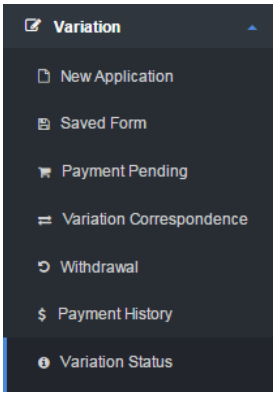


EX69	**Explanation:** FG69 shows a Variation Workstation Opened when user click on Correspond button in FG68.
FG70	
EX70	**Explanation:** User/applicants can only edit/ammends or make changes on label marked as reject by Evaluator. Click on the remarks button to view comments/remarks from the Evaluator.
FG71	
EX71	**Explanation:** FG71 shows a popup form appear when user click on Remarks button. User can see the remarks/comments from the evaluator User can reply to the comments by typing appropriate comments on the textarea provided and click on Save Comments button. Click anywhere outside the popup box to close.

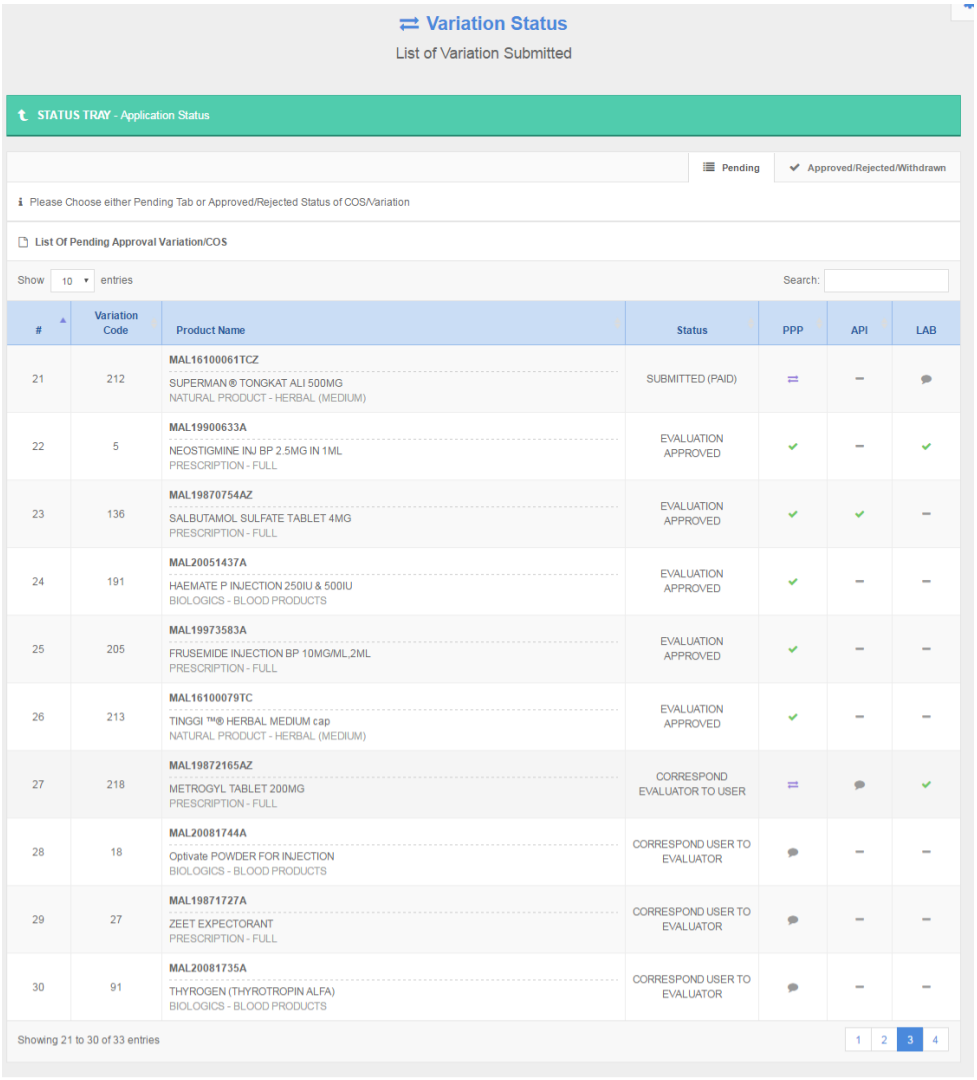
FG72	
EX72	**Explanation:** FG72 show a sample label with multiple attachments (D1) that requires the users to correspond. Click on Choose File button to select and upload new attachments. Click on the file name to view the uploaded files. Click on red trash-icon button to delete the uploaded files Click on Remarks button to open popup Remarks/Comments form.
FG73	
EX73	**Explanation:** Click on the Correspond button located at the bottom of home page in the Variation Workstation after finish completing the corresponded label.
	Variation Withdrawal
FG74	
EX74	**Explanation:** Click on Variation / Withdrawal

FG75	
EX75	**Explanation:** FG75 shows a list of withdrawn Variation Application.
	Payment History
FG76	
EX76	**Explanation:** Click on Variation / Payment History
FG77	

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

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

FG81



EX81

Explanation:

FG81 shows a list of variation application with their status.

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

FG82

EX82

Explanation:

	FG82 show the detail of a Variation application.