

National Pharmaceutical Regulatory Agency Ministry of Health Malaysia

USER MANUAL

QUEST 3+ System

Module: **COMPLIANCE & LICENSING**

(Front-End)

Document No.: Q3+/User Manual/M5/1

Version 1.0

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1.0 INTRODUCTION

Compliance & Licensing module is to record information from user application such as:-

- i) License application, renewal and assessment
- ii) Certificate production and verification
- iii) Inspection application and assessment
- iv) Add supplementary user

Each application must meet the necessary procedures and documents. If there is insufficient information, the applicant must submit the information needed or else the incomplete applications will be rejected.

Reports on every application also can be generated from the system.

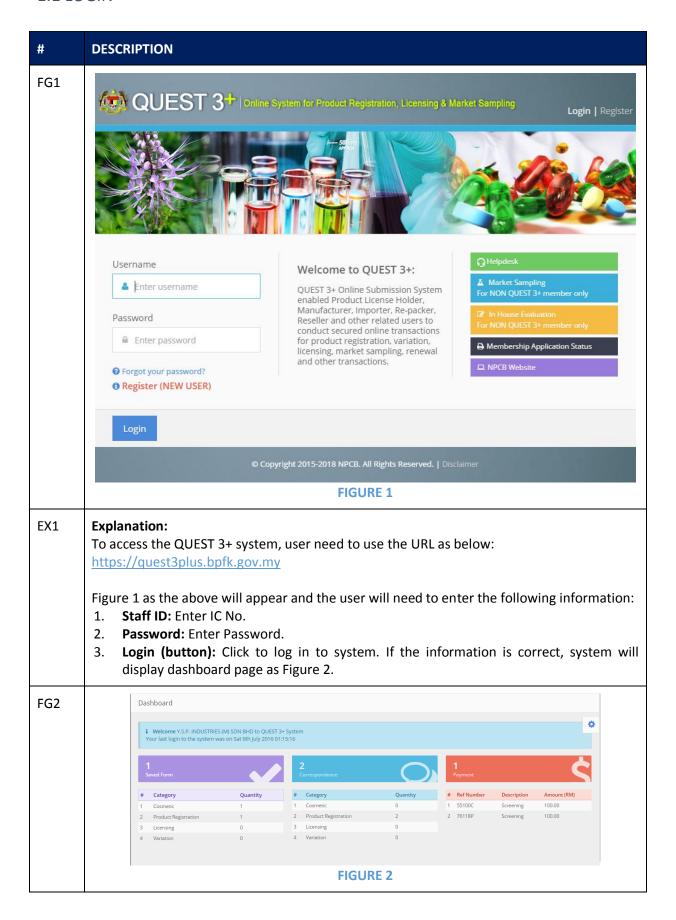
Pre-requisite:

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. Internet Explorer 9.0 and above
- 4. Valid Digital Certificate (USB Token) To be purchased online during Membership Application
- 5. Scanner
- 6. PDF Reader/Writer Software
- 7. Photo editor to edit (crop, resize or other editing functions) your attachments in jpg format
- 8. Valid email account for correspondences and system notifications
- 9. Online banking account (Personal or Business) or credit card to conduct payment transactions via FPX (Financial Process Exchange). FPX is a payment channel that allows you to make payment via online real-time through your current or savings account. All you need is an Internet banking account with any of FPX participating banks.



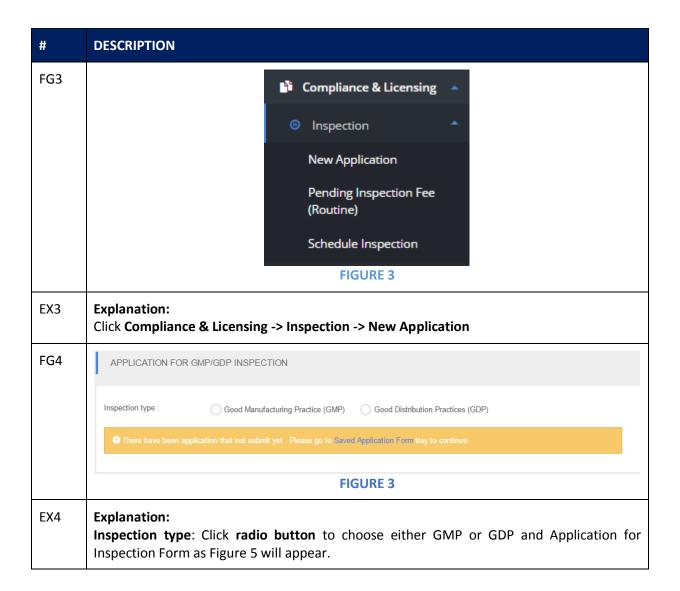
1.1 LOGIN



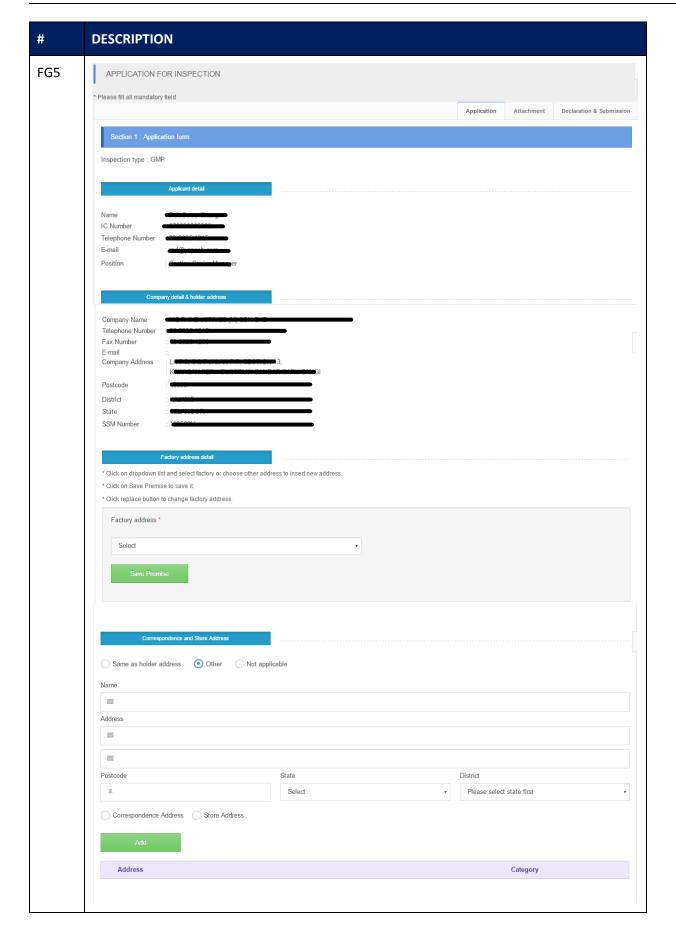


#	DESCRIPTION
EX2	Explanation: Figure 2 shows a summarize tables that contained the information of user applications and transactions such as: 1. Saved Form 2. Correspondence 3. Payment

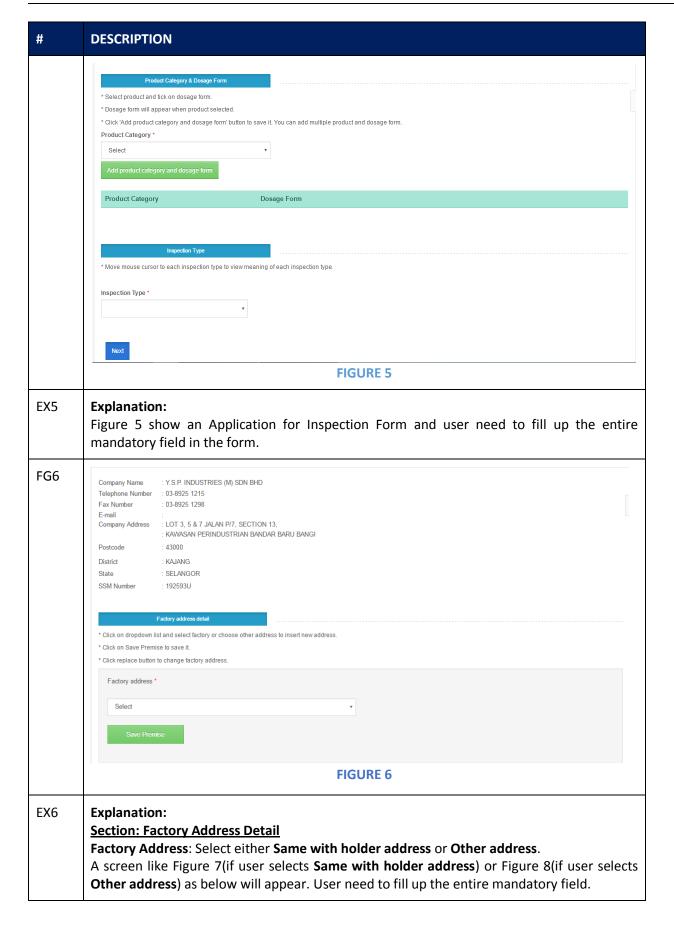
2.0 INSPECTION APPLICATION



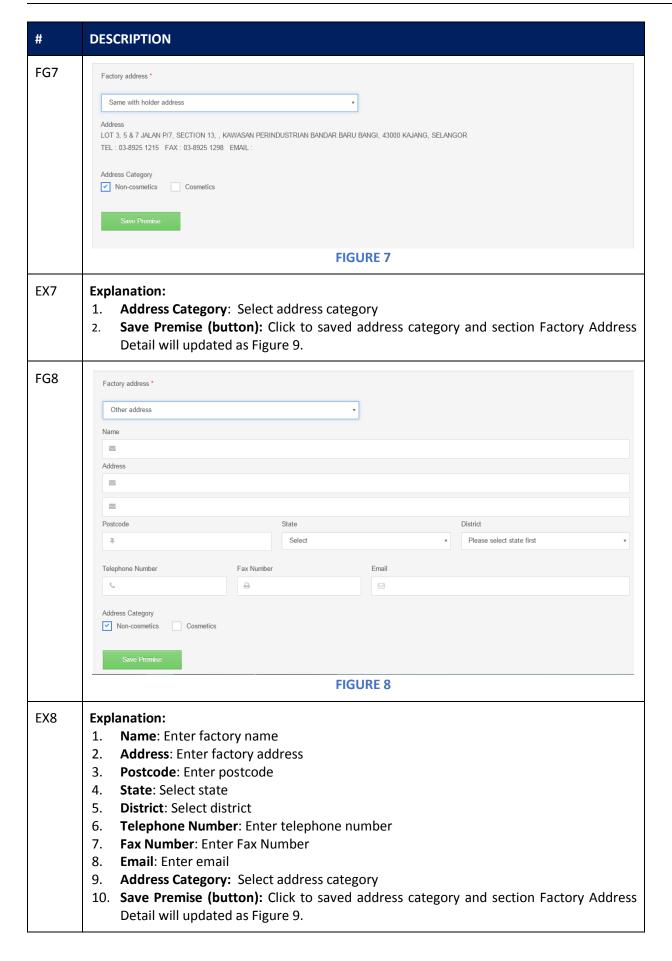




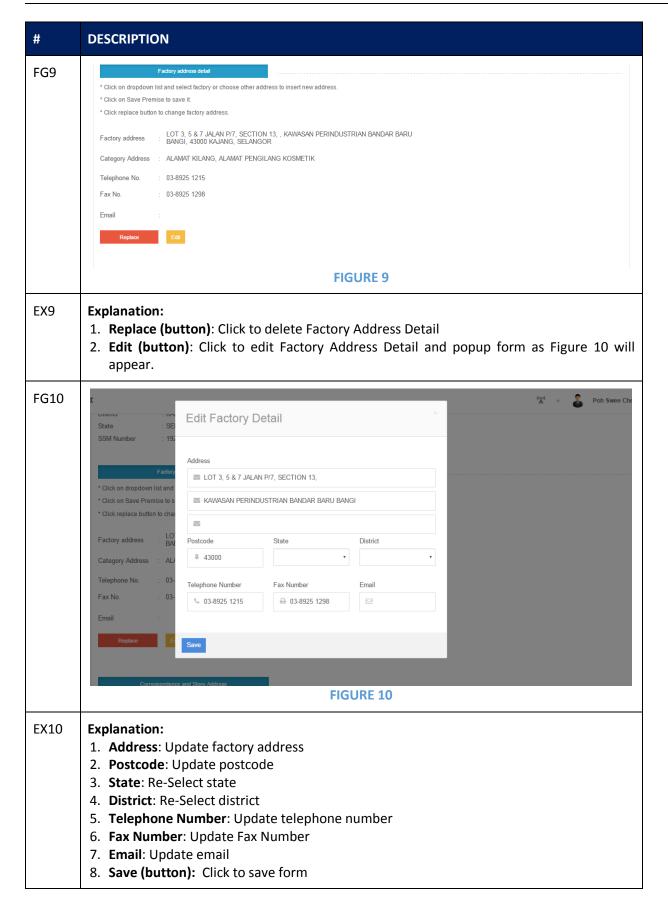




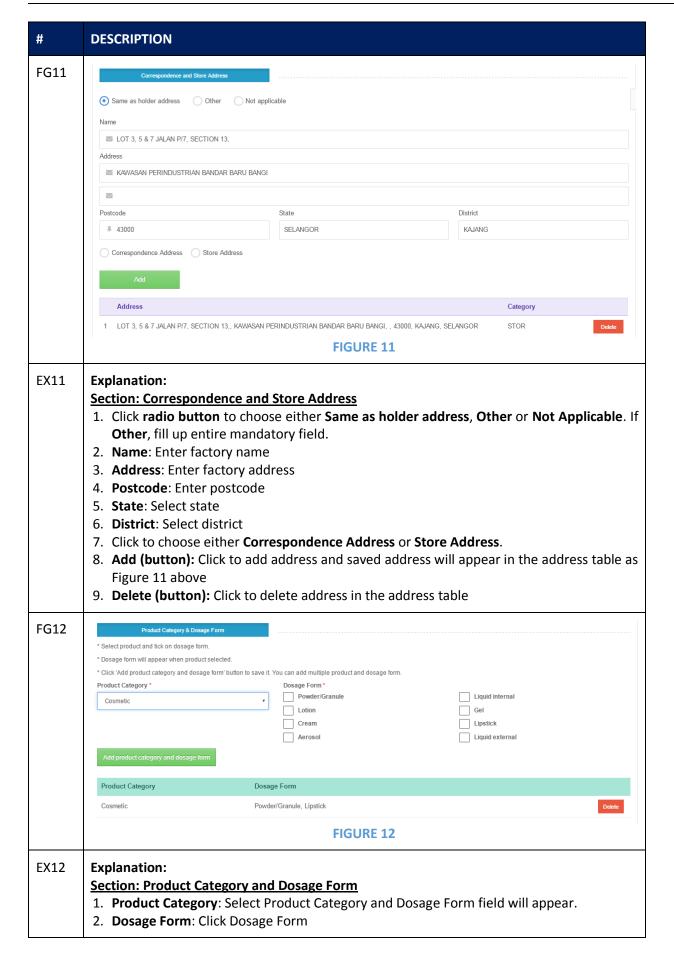




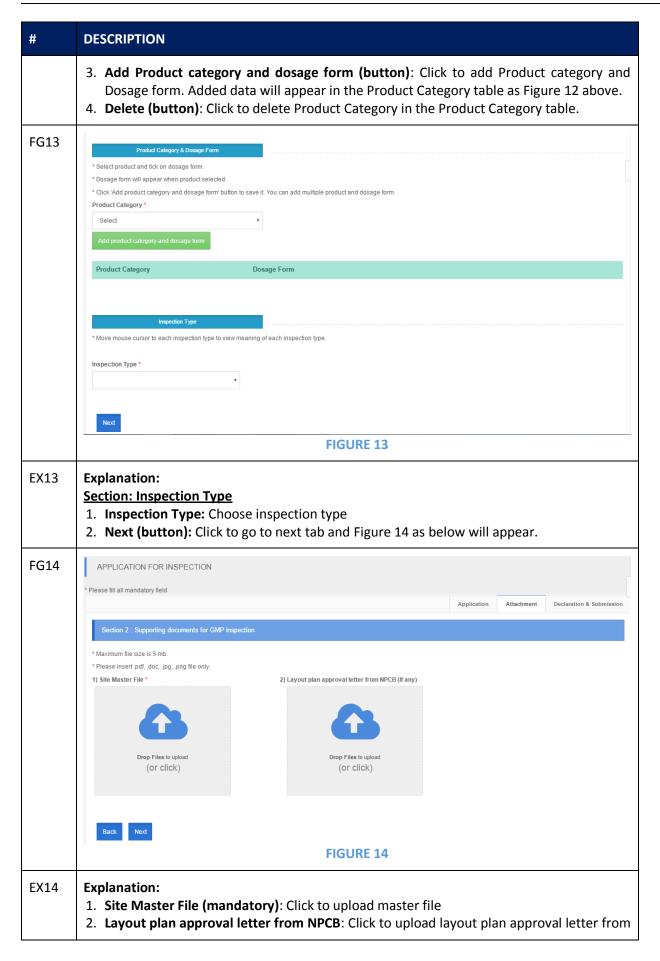








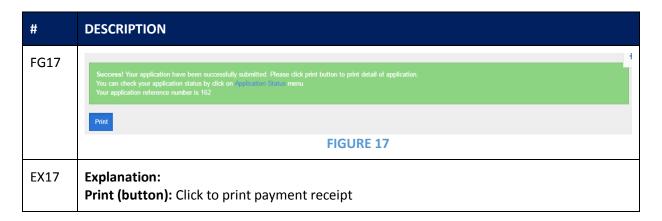




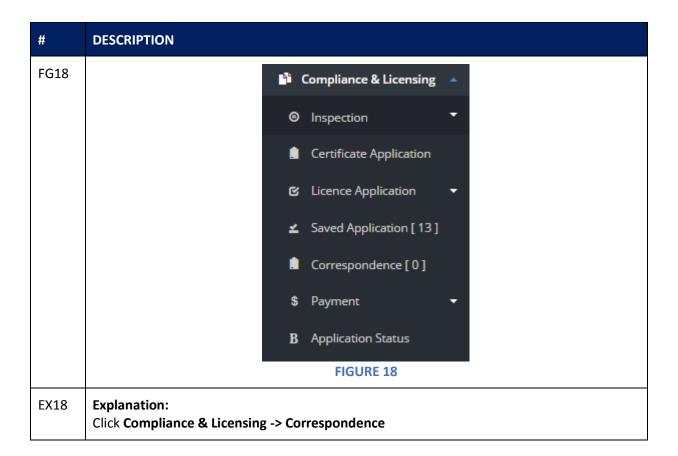




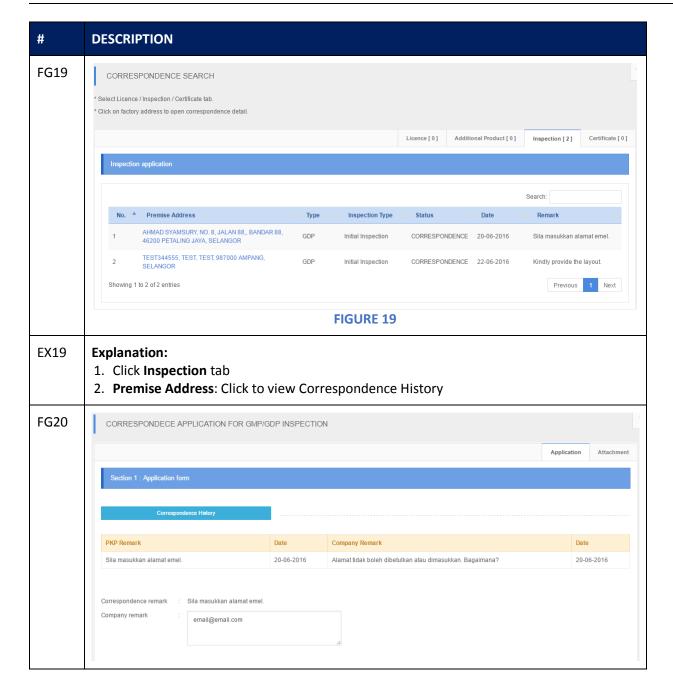




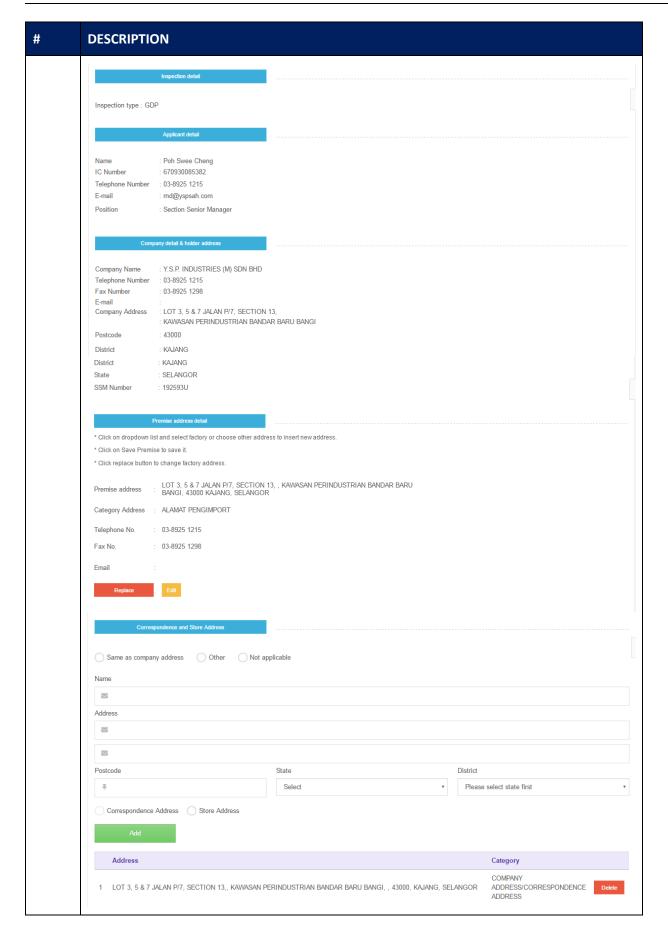
3.0 CORRESPONDENSE FOR INSPECTION APPLICATION



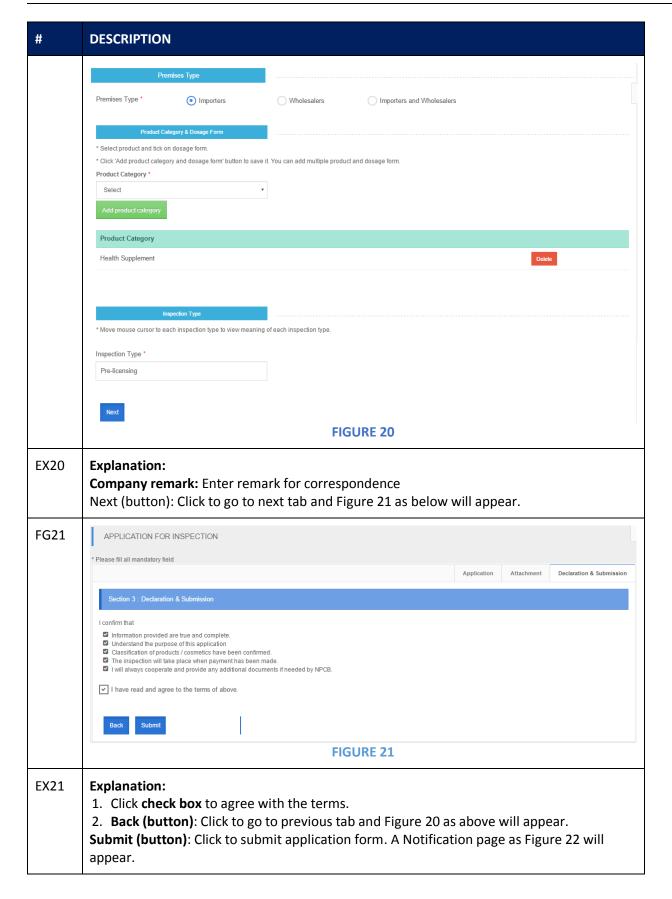








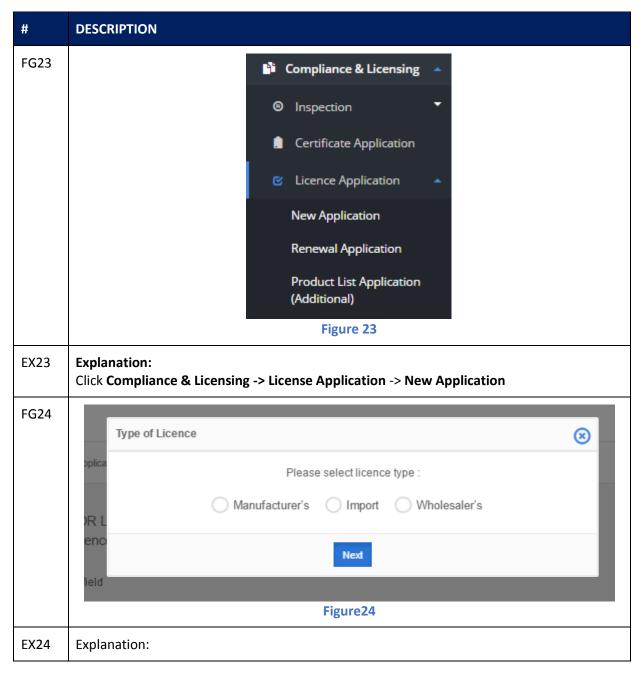




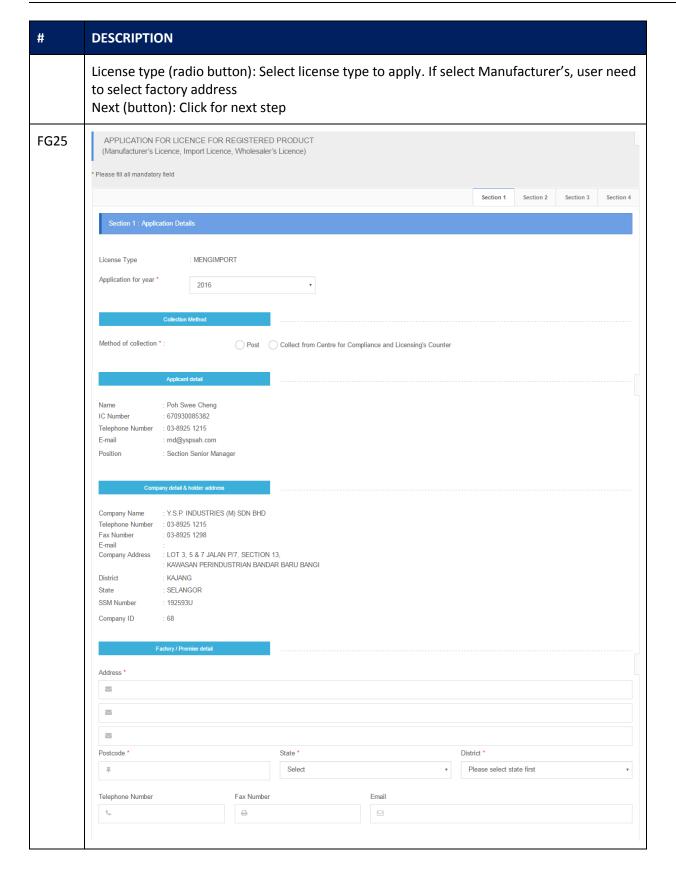


#	DESCRIPTION
FG22	Success! Your application have been successfully submitted. Please click print button to print detail of application. You can check your application status by click on Application Status menu. Your application reference number is 146
	Print
	FIGURE 22
EX22	Explanation: Print (button): Click to print payment receipt

4.0 LICENSE APPLICATION







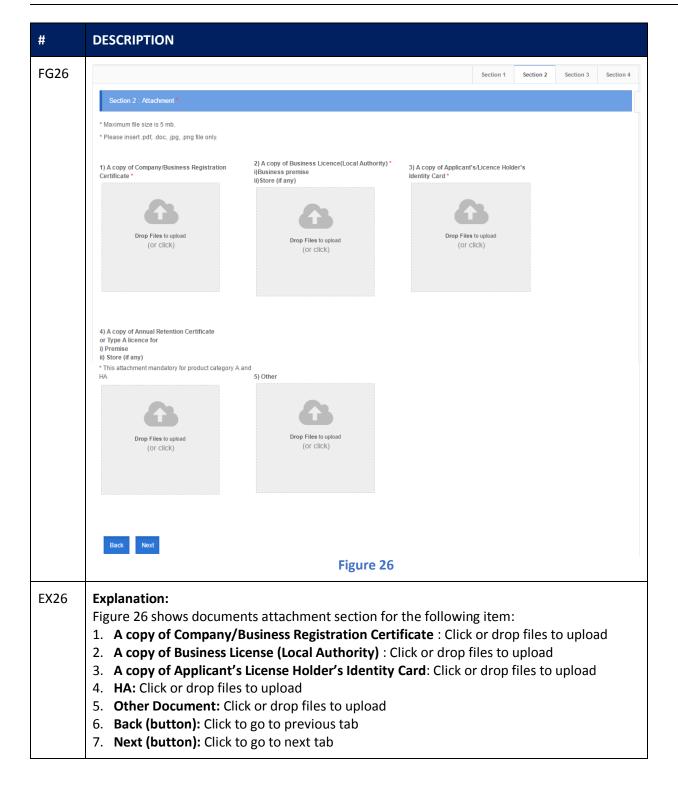


DESCRIPTION				
Corresponde	ence and Store Address			
Correspondence and Stor		Other Not Applicable		
Name and Address				
Postcode		State		District
#		Select	Ψ	Please select state first
ADD				
Address				Category
Res	oonsible Persons			
Details of Two Responsil	ble Persons (contactable 24 hours)	*:		
	Person 1		Person 2	
Name				
IC No.				
Position				
Telephone				
тегерпопе				
Handphone				
	Product Class			
Product Class * :		Mar Driver (V)		Tooditional (T)
Poison (A)		Non Poison (X)		Traditional (T)
Health Supplement	(N)	Poison Veterinary (HA)		Non Poison Veterinary (HX)
L	icense Holder			
Detail of Applicant (Licen	se Holder) *:	Ic No. or Passport No.		E-mail
Poh Swee Cheng		670930085382		rnd@yspsah.com
Gender				
Male Female Position				
Section Senior Manage	r			
* Annual Potentian Codific	rata's No. and Tyne A License's No. in	mandatory for product class A and HA		
Annual Retention Certific		Type A License's No.		
Annual Retention Certific				
Annual Retention Certific				
Annual Retention Certific				

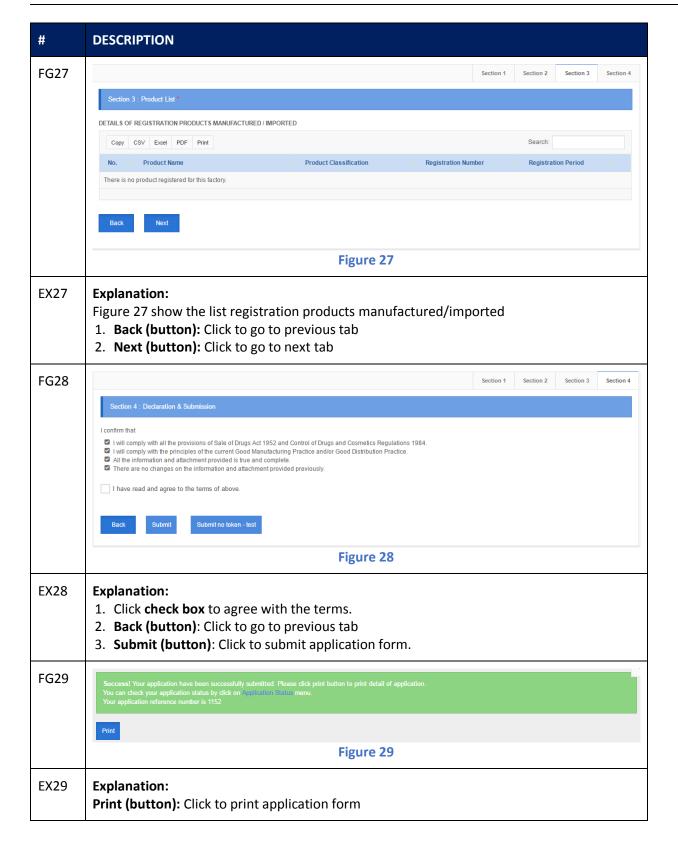


#	DESCRIPTION
EX25	Explanation:
	Figure 25 shows Application For License For Registered Product form and user need to fill
	up the field as following:
	Application for year: Select year to apply
	2. Method of collection (radio button): Select method of license collection
	3. Address: Enter factory/premise address
	4. Postcode : Enter factory/premise postcode
	5. State : Enter factory/premise state
	6. District : Enter factory/premise district
	7. Telephone Number : Enter factory/premise telephone number
	8. Fax Number: Enter factory/premise fax number
	9. Email : Enter contact person's email
	10.Correspondence and Store Address (radio button): select either Other or Not
	Applicable
	11. Radio button: select either Correspondence Address or Store Address
	12. Address: Enter Correspondence / Store address
	13. Postcode: Enter Correspondence / Store postcode
	14. State: Enter Correspondence / Store state
	15. District: Enter Correspondence / Store district
	16. Add (button): Click to add the address into the address table
	17. Name: Enter responsible person's name
	18. IC No : Enter responsible person's IC no
	19. Position : Enter responsible person's position
	20. Telephone : Enter responsible person's telephone number
	21. Handphone: Enter responsible person's handphone number
	22. Product Class (checkbox): Select product class
	23. Name: Enter license holder's name
	24. IC No or Passport No : Enter license holder's IC No or Passport No
	25. E-mail : Enter license holder's email
	26. Gender (radio button): Select license holder's gender
	27. Position : Enter license holder's position
	28. Annual Retention Certificate's No: Enter Annual Retention Certificate's No
	29. Type A License's No: Enter Type A License's No
	30. Repacker (radio button) : Select either Yes or No
	31. Next (button): Click to go to next tab



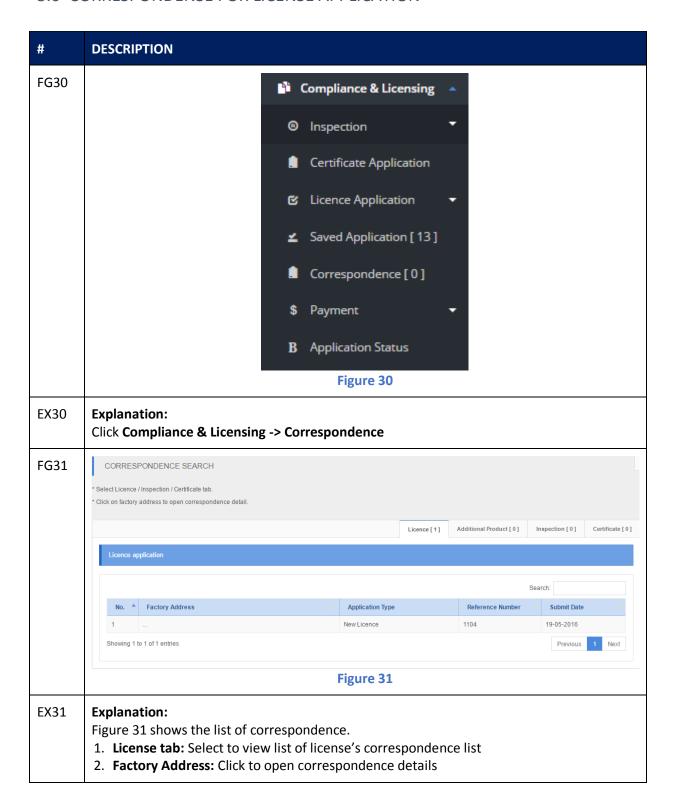




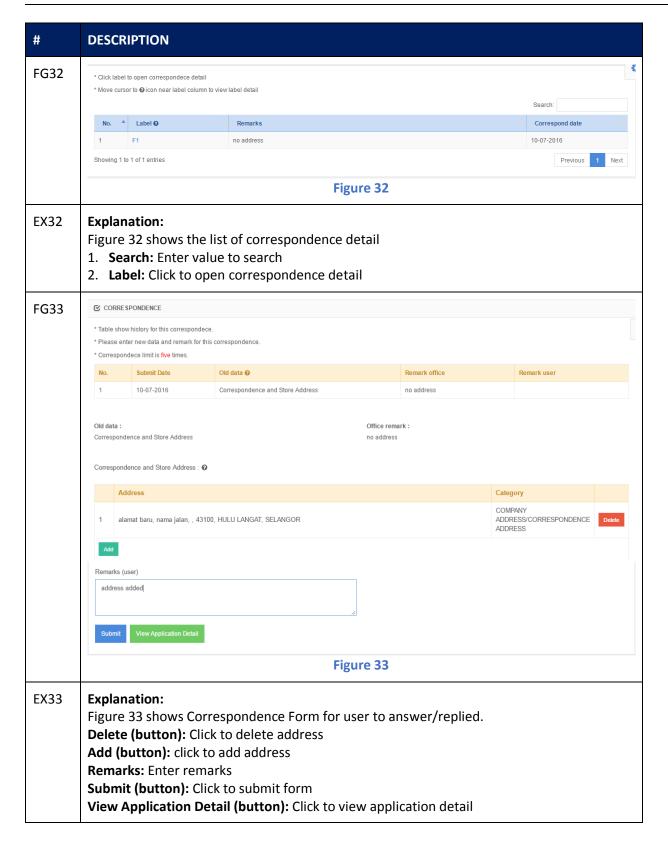




5.0 CORRESPONDENSE FOR LICENSE APPLICATION

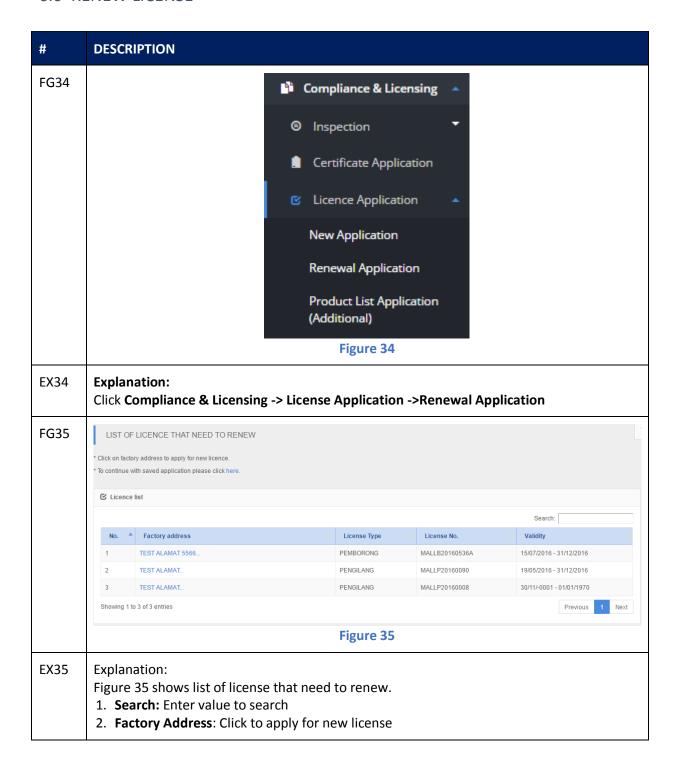




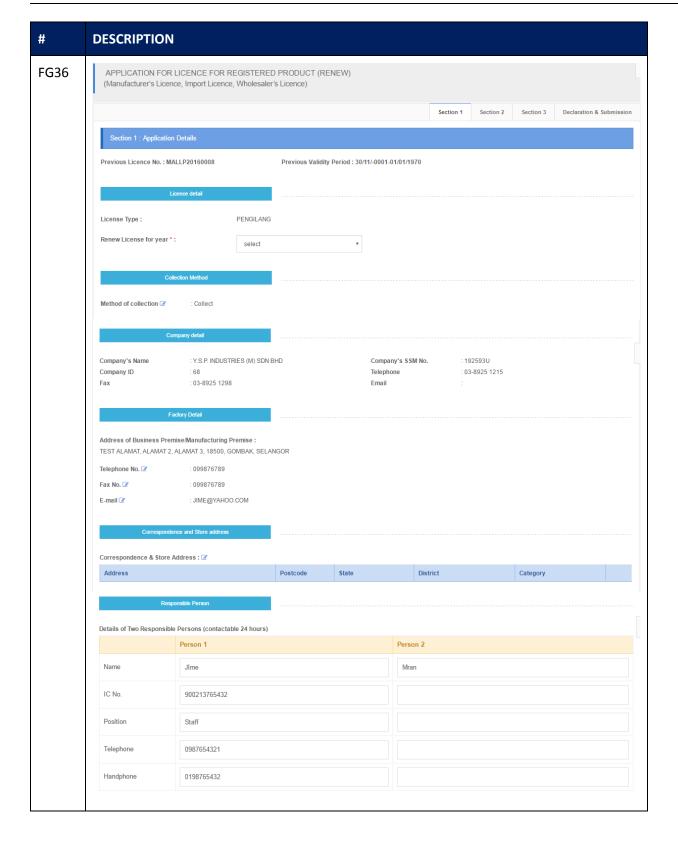




6.0 RENEW LICENSE





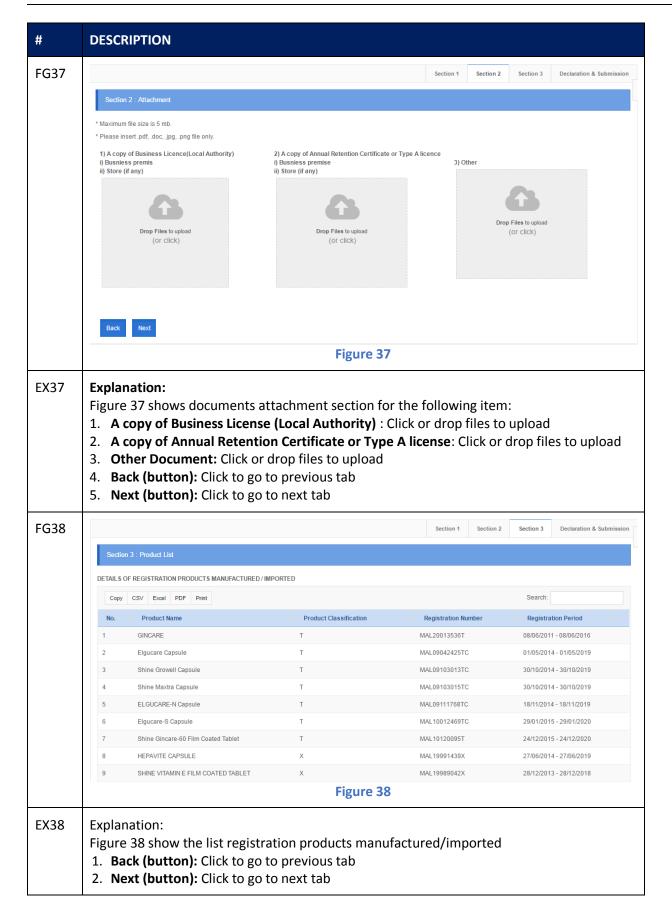




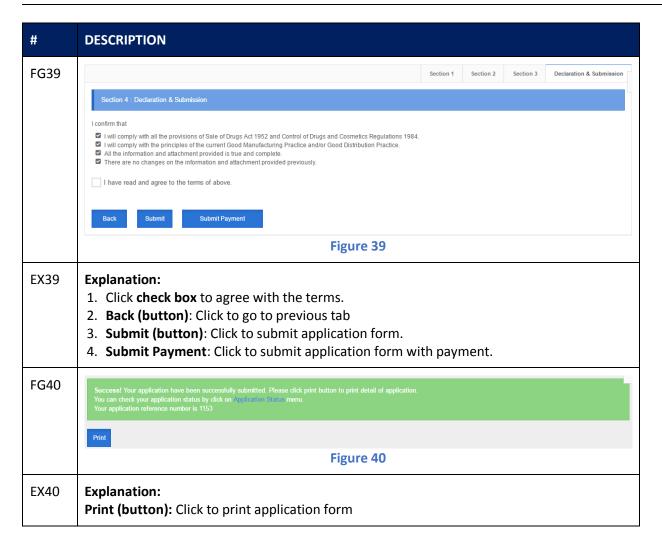
#	DESCRIPTION		
	Product Class Product Classification: Poison (A) Health Supplement (N)	Non Poison (X) Poison Veterinary (HA)	Traditional (T) Non Poison Veterinary (HX)
	Licence Holder Detail of Applicant (License Holder) *: Name Poh Swee Cheng Gender Male Female Position Section Senior Manager	Ic No. or Passport No. 670930085382 Annual Retention Certificate's No.	E-mail md@yspsah.com Type A License's No.
	Next	Figure 36	
EX36	Explanation: Figure 36 shows Application Forneed to fill up the field as follows. Renew License for year: Second to the field as follows. Method of collection: Click of the edit factors. Address: Click to edit factors. For Click to edit factors. Lick to edit factors. Telephone Number: Click to edit factors. Email: Click to edit factors. Email: Click to edit factors. Lick to edit factors. Email: Click to edit factors. Permail: Click to edit factors. Lick to edit factors. Email: Click to edit factors. Amme: Enter responsible postore. Lick to edit factors. Email: Click to edit factors. Amme: Enter responsible postore. Lick to edit factors. Email: Click to edit factors. Email: Email: Enter responsible potentions. Email: Click to edit factors. Email: Enter responsible potentions. Email: Enter responsible potentions. Email: Enter license holder. Email: Enter license holder.	wing: elect year to apply to edit method of license coll ry/premise address ory/premise postcode premise state y/premise district to edit factory/premise telepho actory/premise fax number person's email e Address: Click to edit Corresp erson's IC no e person's position tole person's telephone numbe ible person's handphone num Select product class of s name r license holder's IC No or Pass of s email ect license holder's gender der's position te's No: Enter Annual Retention	ection one number oondence and Store Address r ber

24. Next (button): Click to go to next tab

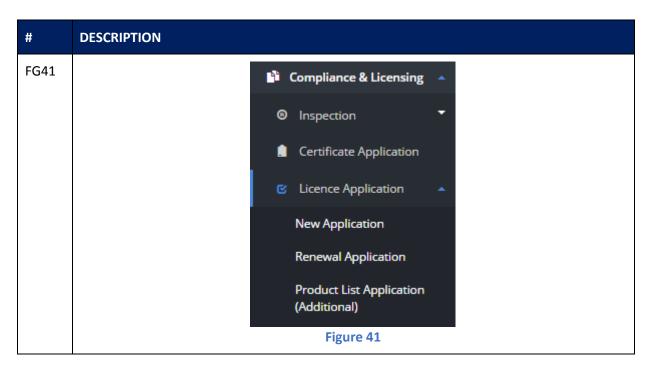




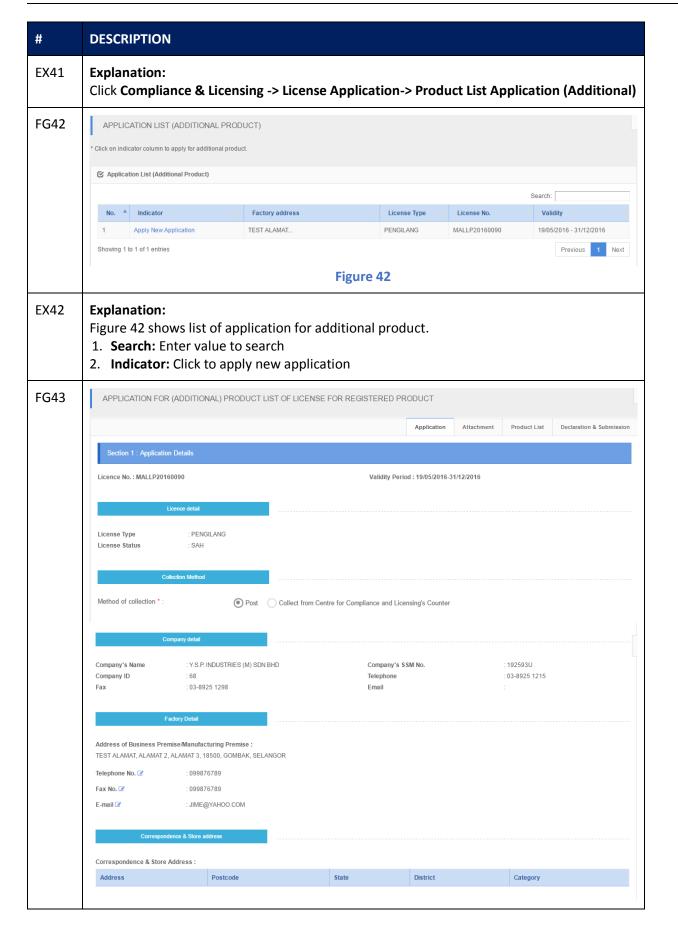




7.0 PRODUCT LIST APPLICATION



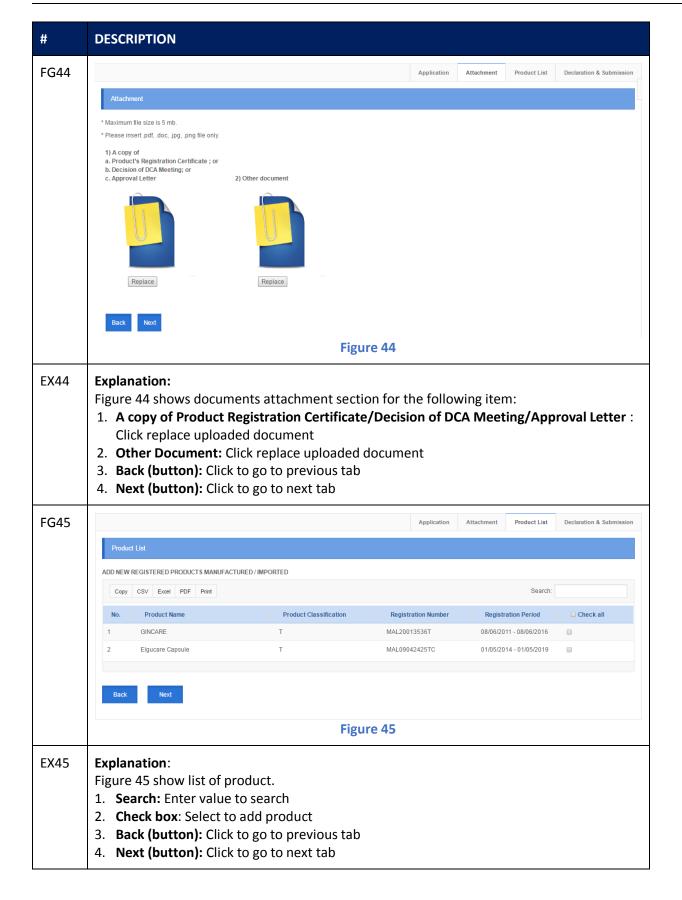




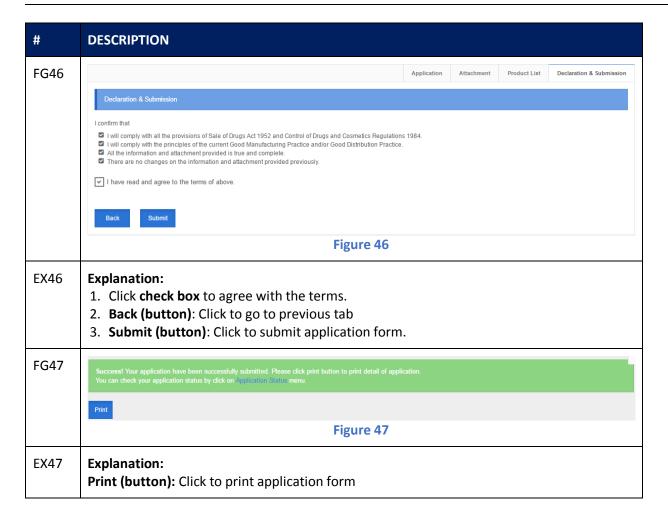


#	DESCRIPTION				
	Resp	onsible Person			
	Details of Two Responsible	Persons (contactable 24 hours)			
	Name	Person 1		Person 2	
	Name	a		asad	
	IC No.	12121		12213	
	Position	asas		ada	
	Telephone	12121		123123	
	Handphone	12121		12312321	
	Pr	oduct Class			
	Product Classification :				
	Poison (A)		✓ Non Poison (X)		Traditional (T)
	→ Health Supplement (N	1)	Poison Veterinary (HA)		Non Poison Veterinary (HX)
	Lice	ence Holder			
	Detail of Applicant (Licens Name	e Holder) *:	Ic No. or Passport No.		E-mail
	Poh Swee Cheng		670930085382		rnd@yspsah.com
	Gender Male Female				
	Position		Annual Retention Certificate's No.		Type A License's No.
	Section Senior Manager				
	Next		Figure 43	3	
EX43	form. User ne 1. Method o 2. Product Cl 3. Name: End 4. IC No or P 5. E-mail: End 6. Gender: E 7. Position: E 8. Annual Re 9. Type A Lic	ed to fill up the efficient (radillassification (cheter License Holdetssport No: Enter License Holdetset License Holdetster License Holdetset License Holdetse License Holdetset License Holdetset License Holdetset License L	entire field as follow io button): Select moder's Select production er's name er License Holder's IC er's email der's gender Ider's position ate's No: Enter Annu- Type A License's No	ing: ethod of lid uct classifid C No or Pas al Retentid	ssport No

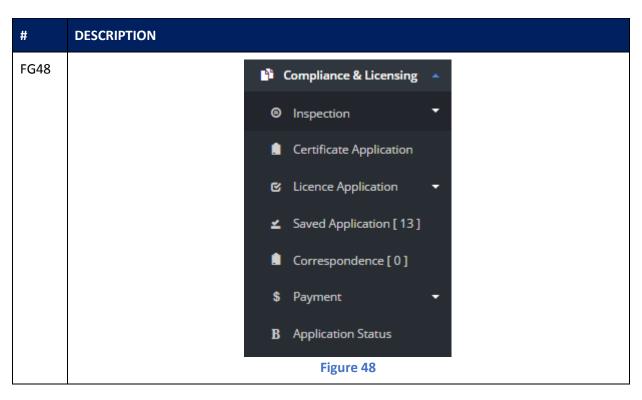




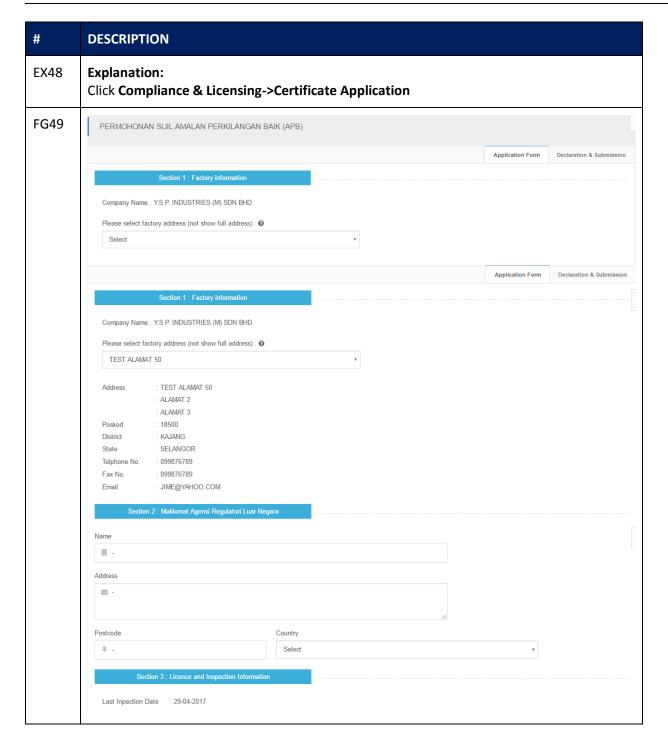




8.0 CERTIFICATE APPLICATION









#	DESCRIPTION
	Product Category * Pharmaceuticals (Active substances) Traditional and Health Supplements Cosmetics Health Supplements only Traditional Medicines only Veterinary Pharmaceuticals (Biological products) Pharmaceuticals (Medicinal products) Dosage Form * Tablet liquids for internal use Capsules, hard shell Liquids for external use Granules Granules Granules Semi solids Suppositories Granules G
	Next Figure 49
EX49	Explanation: Figure 49 show Permohonan Sijil Amalan Perkilangan Baik form and user need to fill up entire field as following: 1. Factory address: select factory address 2. Name: Enter name 3. Address: Enter address 4. Postcode: Enter postcode 5. Country: Select country 6. Product Category (radio button): Select product category 7. Dosage Form (checkbox): Select dosage form 8. Next (button): Click to go to next tab
FG50	Application Form Declaration & Submission
	Declaration & Submission Saya wakil syarikat yang memohon mengaku bahawa: Saya akan mematuhi semua peruntuka-peruntukan Akta Jualan Dadah 1952, Peraturan-Peraturan Kawalan Dadah dan Kosmetik (Pindaan) 2006 dan lain-lain akta yang berkaitan. Segala maklumat yang dinyatakan adalah benar. Jika tidak, Pengarah Perkhidmatan Farmasi berhak menolak dan membatalkan permohonan ini. I have read and agree to the terms of above. Back Submit Figure 50
EX50	 Explanation: Click check box to agree with the terms. Back (button): Click to go to previous tab Submit (button): Click to submit application form.



