

USER MANUAL

QUEST 3+ System

Module: Variation

(Front-End)

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Pengemaskinian Dokumen

Versi	Tarikh	Dikemaskini oleh	Ringkasan Perubahan	Senarai Edaran
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Pengesahan Dokumen

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INTRODUCTION

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

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

Pre-requisite:

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

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



Contact Person

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

Administrative Enquiries:

Name:	Cik Nurulfajar Mohd Jamid
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1.0 QUEST3+ Front-end login

#	SCREENSHOTS / EXPLANATION	
1	Login	
FG1	QUEST 3 ⁺ Johns	System for Product Registration, Licensing & Market Sampling Login Register
	Username Enter username Password Enter password Forgot your password? Register (NEW USER)	Welcome to QUEST 3+: QUEST 3+ Online Submission System enabled Product License Holder, Manufacturer, Importer, Re-packer, Reseller and other related users to conduct secured online transactions for product registration, variation, licensing, market sampling, renewal and other transactions.
	Login	yright 2015-2018 NPCB. All Rights Reserved. Disclaimer
EX1	 User Name: User ID Password: Enter Password. 	
	1. User Name: User ID	



2.0 Variation

#	SCREENSHOTS / EXPI	LANATION			
2.1	Variation Applicatior	1			
2.1.1	New Application				
FG2	 Variation New Application Saved Form Payment Pending Variation Correspond Withdrawal Payment History Variation Status 				
EX2	Explanation: Click on side menu 'V	ariation / New Ap	plication'		
FG3			List of Product Qualify f Please Select product to creat		
	Approved Products			See 1	
	Show 10 • entries	Product Name		Search:	2
	1 MAL15045002NC	Vitamode CalciVit D3 Plus K	2 Tablet	HEALTH SUPPLEMENT - GENERAL	
	2 MAL15015025N	Ezzensa Evening Primrose (Dil with Royal Jelly & Vitamin E Softgel	HEALTH SUPPLEMENT - GENERAL	28
	3 MAL14125118NC	LAC Sheep Placenta + Soft		HEALTH SUPPLEMENT - GENERAL	8
	4 MAL15045051N 5 MAL15045174NCR	VIVA LIFE SCIENCE OQ O		HEALTH SUPPLEMENT - GENERAL	
	5 MAL15045174NCR 6 MAL15055020NCR	VitaHealth Asta-Glutathione PRISTIN MOPL OMEGA -	3 FISH OIL 650MG SOFTGEL	HEALTH SUPPLEMENT - GENERAL HEALTH SUPPLEMENT - GENERAL	
	7 MAL15045104NC	MEGA FIBER POWDER		HEALTH SUPPLEMENT - GENERAL	CR .
	8 MAL15055023N	SAMI Direct Calci D Zinc Ta		HEALTH SUPPLEMENT - GENERAL	C.
	9 MAL15045055N 10 MAL15045121NC		US VITAMIN E SOFTGELS	HEALTH SUPPLEMENT - GENERAL HEALTH SUPPLEMENT - GENERAL	
	Showing 1 to 10 of 259 entries	PowerLIFE Mecazin ALA PI	13 lablet	1 2 3 4 5	
EX3	Explanation: FG3 show a list of app	proved product in a	a company. Click on the	edit icon to proceed to Variation Worksta	tion.
FG4	■ New Variation	Batch Form		Confirm	Variation
			Product Information	1	
	Product Registration Number		138562		
	Product Name		METROGYL TABLET 200MG		
	Product Category		PRESCRIPTION - FULL		
	Variation Number		218		
EX4	Explanation:				



	FG4	shows the info	ormation about the	e product selected by user for Variation	n Process.	
	_			Please Select Variation Type		
FG5				May (4. Observe and (as additional indication data in a server)		
		Type 3 (Major Variation)	٣	MaV-1 - Change and/or additional indication/dosing regimen/	patient population/inclusion of clinical +	
EX5	Exp	lanation:				
	Use	r can select mo	ore than one (1) Va	ariation title by clicking the + button aft	er selecting an option from the dro	opdown list.
500	_			List of Variation		
FG6		lumber Code	Vestation Title		Coloren	
	P	Number Code	Variation Title	ndication/dosing regimen/patient population/inclusion of clinical inf	Category	
		1 MaV-1	extending the usage of the		Type 3 (Major Variation)	
		2 MaV-2	Change of content of produ	uct labeling	Type 3 (Major Variation)	
EX6	Exp	lanation:				
		shows a list of ation Title.	Variation Title add	ded by user for a Variation application.	User can click on the X button to r	emove the added
	Vari	ation fitte.				
FG7						
	Cli	ick Confirm Variation to Pr	roceed to Workstation		Confirm Variation	
EX7	Exp	lanation:				
	Click	c on Confirm Va	ariation Button to	proceed the application to Variation W	/orkstation.	
				Variation Workstation		
FG8				Please Fill in Applicable forms & File Attachments	S	
	*	Part I 👻				
				Note to applicant	^	
		not applicable, please	e check the box in the 'Not Appli		sure every field required is checked. If the field is	
				py and paste the existing data into proposed field.		
			supporting documents (IF RELE			
		Please make sure Var check the application	riation Checklist is saved before status under Variation & COS S	you are done with the submission. Please click the Submit button v Status Record.	when it is completed. Once submitted, you can	
				Product Information		
	-	Product Name		Sample Product Test 008		
		Product Call No./Ref No		239427 / 1234567890 / MAL20170003A		
		Product Category	:	NEW CHEMICAL ENTITY - NEW CHEMICAL ENTITY/RADIOPHA	RMACEUTICAL SUBSTANCE	
EX8	Exp	lanation:				



FG9	_		Involve Labels				
	#	Code	Label Desc	Label Overlap	Correspond	Status	Go
	1		Brand Name		N/A	A	0
	2		Generic Name	_	N/A		0
	3		Full Product Name	_	N/A	A	0
	4		Excipient	_	N/A	A	0
	5	5.1	Origin	-	N/A	A	0
	6	5	Ingredients of Human or Animal Origin (Active Ingredients, Excipients and Capsule Shell	d/or _	N/A	A	ø
	7	13	Does this Product Contains Any Premix ?	-	N/A	A	0
	8	13.3	Manufacturer Address	-	N/A	A	0
	9	13.2	Manufacturer Name	-	N/A	A	٥
	10) A1	Active Ingredient	-	N/A		Ð
FG10	*	Product Validation Product Validation Product Name Excipient Other Information 1. Please Fill All Rec 1. Brand Name:) Current Approved B N) Proposed Brand Na	Product Validation - Product V		×		✓ Labels Checklist
	a b	.2 Generic Name () Current Approved G N) Proposed Generic N .3 Full Product Na	ieneric Name (if applicable):		×		emarks [1-2]
	a) Current Full Produc METROGYL TAE) Proposed Full Produ	I Name: LET 200MG				emarks [1-3]
		Back	Noxt		~		
EX10	Click o Fill the	e required pa	alidation / Product Name. articular in the text box. narks for the Evaluator by clicking the Remarl	ks Button on the	right side o	f each f	field.



FG11	Γ.	Q	UEST3+ Product Evaluation						Nobe of
				Saved Comments /	Remarks				
			Remarks ohd Amiruddin Arumugam Bin Abdullah / Use	r/2016-11-04 15:00:40					
				User Comme	nts				
	Tes	st Rem	arks						
								🖺 Save Co	
EX11	Ехр	lanat	tion:						
	FG1	1 sho	ows User Remarks Popup wind	łow.					
	Fill ı	ema	rks in the field provided and c	lick on Save Comments	s button.				
	Clic	k any	where outside the popup win	dow to close the popu	p window.				
FG12	*	Prod Exci Othe	oduct Validation • Part I • Part II • uct Name • • • • • plent • • • • • r Information • • • • • Wease Fill All Excipient Information • • • • Ou are allowed to add more than one excipient • • •	Part III • Part IV • Product Validation - E	Excipients			♥ Labe	s Checklist
				List of Current Approve	d Excipient				
		#	Excipient	Function	Strength	Source	Part	Remarks	ŵ
		1	Sodium Methyl Hydroxy Benzoste		0.500;mg;;			None	0
		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	0
		5	OPADRY II Pink	COLOURING AGENT	7.875;mg;;			None	0
		6	PURIFIED WATER		;qs;;			None	0
EX12	Clic	< on	tion: Product Validation / Excipient						
			ow a list of current approved e click on checkbox on the tras			ent approv	ved exci	pient.	



FG13			Add new E	xcipient (Propose)					
1015		4.1 Excipient	Hydrochloric Acid					*		
		4.2 Strength of Excipient	12	Unit	ml		* IN			
		4.3 Function of Excipient	FLAVOURING AGENT					¥		
		4.4 Source of Excipient	Synthetic Plant Ani	mal 🔵 Other						
		4.5 Remarks(if any)	Test Remarks							
								h		
				Add Exc	ipient					
			List of Pr	oposed Excipient						
		# Excipient	Function	Strength	Source	Part	Remarks	Ē		
		1 Hydrochloric Acid	FLAVOURING AGENT	12 ml	Synthetic	NONE	Test Remarks	ŵ		
		Qr Remarks [4-1]								
EX13		planation:								
		the following field:								
		Excipient								
		Strength of Excipient								
		Function of Excipient								
	4.4	Source of Excipient								
	4.5	Remarks(if any)								
	The	en click on the Add Excipier	nt Button.							
	Clic	k on the trash-icon located	d on each row to delete a	added propo	sed excipien	t.				
FG14	ñ	Product Validation • Part I •	Part II 👻 Part III 👻 Part IV	1 -				 Labels Checklis 	st	
FG14		Product Name								
		Excipient Other Information	Product Vali	idation - Other Infor	m ———					
		1. Please Fill All Required fields								
		5 Ingredients of Human or Animal O	rigin(Active Ingredient, Excipient and /	or Cansule	O Yes C	No	Remarks [5]			
		Shell)		or capouro	- 100 -		inemarks [5]			
		5.1 Origin				• 9	Remarks [5-1]			
		13. Does this product contain any pro	emix?		O Yes	No 오	Remarks [13]			
		13.2 Manufacturer Name	: Type Here				Remarks [13-2]			
		13.3 Manufacturer Address					Remarks [13-3]			
		13.5 Manufacturer Audress				-h	Remarks [15-5]			
	Exp	planation:								
EX14		k on Product Validation / 0	Other Information.							
		the required field.								



FG15	A4. Product Descriptic a) Current Product Description	
	Pink round, biconvex film	coated tablets.
	b) Proposed Product Description	'n
	< <p>Remarks [A4]</p>	* *
EX15	Explanation:	
	FG15 shows one of t	he field available in the Variation Title.
	User can view the cu	rrent data on part a)
	User can fill the new	data on the text area on part b)
	Click on Remarks but	ton to leave a remark to Evaluator.
	Fill the following field	9
	A4 – A20	
FG16	A21. ATC Code a) Current ATC Code J01XD01	
	b) Proposed ATC Code	
	Level 1	CARDIOVASCULAR SYSTEM *
	Level 2 Level 3	BETA BLOCKING AGENTS +
	Level 4	BETA BLOCKING AGENTS, NON-SELECTIVE, THIAZIDES AND OTHER DIURETICS +
	Level 5	TIMOLOL, THIAZIDES AND OTHER DIURETICS
	Generated ATC Code	
	C07DA06	
	Q Remarks [A21]	
EX16	Explanation: To fill label A21. ATC	Code, user need to select the ATC code starting from Level. Click to select ATC Code.





FG17 Image: Product valuation in a part	
Section C Part I / Section B - Product Formula Section D Section D Section E . 2. You are allowed to edit overage value of Active Ingredient & Excipient . 3. You are allowed to Upload PDF/JPEG/JPG file . B1. Batch Size I . a) Current Batch Size . 8,00,000 Tablets . b) Proposed Batch Size . c: Remarks [B1-1] . EX17 Explanation:	
1. Please Enter All Product Section E 2. You are allowed to edit overage value of Active Ingredient & Excipient 3. You are allowed to Upload PDF/JPEG/JPG file B1. Batch Size • a) Current Batch Size • b) Proposed Batch Size b) Proposed Batch Size c: remarks [B1-1] EX17	
3. You are allowed to Upload PDF/JPEG/JPG file B1. Batch Size • a) Current Batch Size 8,00,000 Tablets b) Proposed Batch Size •	
B1. Batch Size • a) Current Batch Size 8,00,000 Tablets b) Proposed Batch Size •	
a) Current Batch Size 8,00,000 Tablets b) Proposed Batch Size	
a) Current Batch Size 8,00,000 Tablets b) Proposed Batch Size	
EX17 Explanation:	
EX17	
EX17	
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 dr	opdown option.
	· · ·
FG18 B1.2 Batch Formula	
List of Active Ingredients	
Current	
# Active Ingredient Overage Proposed Overage Source S	itrength
1 METRONIDAZOLE X NA X 12 24	466 gm,
List of Current Approved Excipients (Edit Overage)	
# Excipients Current Overage Proposed Overage Source S	trength
1 Sodium Methyl Hydroxy Benzoate 🗙 N/A [©] ✔ N/A 0.500,r	mg;;
2 Magnesium Stearate BP x N/A x N/A 1.00;m	g;;
3 COLLOIDAL ANHYDROUS SILICA 🗙 NA S X NA	mg;;
4 Maize Starch, B.P. 🗙 🗙 N/A 👶 🗙 1 57.5;m	g;;
5 OPADRY II Pink x NA	mg;;
6 PURIFIED WATER x NA x NA x NA x (NA	
List of Proposed Excipients (Overage)	
# Excipients Proposed Overage Source Streng	jth
1 Hydrochloric Acid \ref{acid} 3 Synthetic 12 m	nl
Q. Remarks [B1-2]	
sa remans [0-2]	
EX18 Explanation:	
User is require to fill all the Proposed Overage column in the table shown in FG18	



			n Manufacturin atch Manufacturing		θ						
	b) l	Proposed	Batch Manufacturi	ing Formula							
		Choos	se File			Chrysanthemum.jpg	۲	•			
		Sa Rei	marks [B2]								
.9	Expla	anatio	n:								
	Click	on th	e Choose Fi	ile button	to select	a file to be uploaded	d in the s	ystem.			
	User	can V	iew the upl	oaded file	e by clicki	ng on the blue eye-i	con butto	n.			
					-	emove the uploaded					
	CIICK	on th					inc.				
20	#	Produ	ct Validation 👻	Part I 👻	Part II 🝷	Part III 👻 Part IV 👻				✓ La	bels Checklist
				Section A Section B							
				Section C		Part I / Section C - Particu	lars of packing				
		1. Click	: "ADD" button after	Section D Section E	peat th	hese steps if there is more than on	e(1) pack size.				
						utton. For editing, click on the "ED					
		3. Thos	e field with symbol	* is a compulsor	y fields. If those	e fields are not filled, submission of	application is n	ot permitted.			
		a) Cu	rrent Particular of Pa	acking							
		#	C1. Pack Size			Field			Data		D
						C2. Immediate Container Type			PLASTIC		
						C3. Container Type Description			HDPE PLASTIC container		
		1	1000Tablet GRA	MS [WEIGHT]		C4. Barcode / Serial No.			300200201507		•
						C5. Recommended Distributor's	Price		RM 30.00		
						C6. Recommended Retail Price			RM 40.00		
		b) Pro	posed Particular of	Packing							
			C1	1. Pack Size* :	12		Unit	KILOGR/	AMS	•	
			C2. Immediate Con	ntainer Type* :	PAPER		٠	If Other:	please specify		
		(C3. Container Type	Description* :	Desc						
										11	
		C4. Ba	rcode / Serial No. (i	if applicable) :	123456789						
		C5. R	ecommended Distrib	butor's Price* :	80						
			CG. Decommended	Datail Drivet -							
			C6. Recommended		90						
				st of Pack Size		Add Pack Size					
		Su	ccess! Packing Part	ticular has been	Added						
		#	C1. Pack Size			Field			Data	Action	
						C2. Immediate Container Type			PAPER []		
						C3. Container Type Description			Desc		
		1	12 KILOGRAMS	[Weight]		C4. Barcode / Serial No.	Dire		123456789	Û	
						C5. Recommended Distributor's F C6. Recommended Retail Price	тсе		RM 80.00		
						SS. Recommended Ketall Mice			N/I 90.00		
20	Expla	anatio	on:								
20	-		n: rt 1/ Sectio	n C							



	Us	er cai	click on checkbox on the trash-icon column to pr	opose delete current a	pproved pack size.				
	Clie	ck on	the trash-icon located on the action column on e	ach row to delete adde	d proposed pack size.				
FG21			el (mock-up) for immediate Container: 🚱 Label (mock-up) for immediate Container:						
		No C	rrent Approved Data						
		# Attachment Date of Attachment D							
		1	Lignopad_Inner label new(1).pdf		16-04-2016				
	b)	Propose	d Label (mock-up) for immediate Container:						
		Cho	se File	Desert.jpg					
		Succ	ss! The file V_252_20161121_031426_D1.jpg has been uploaded						
		#	Attachment		Date of Attach	Ŵ			
		1	Chrysanthemum.jpg		21 Nov 2016 - 11:17 AM	â			
		2	Desert.jpg		21 Nov 2016 - 11:17 AM	Ö			
		Q Re	marks [D1]						
EX21	Exp	olana	tion:						
	Clie	Click on Part 1 / Section D							
	FG	FG21 show a part of Section D. User can view current attachment files by clicking on the filename in the Current label table.							
	Clie	Click on the Choose file Button to upload new files for Variation.							
	Use	er cai	click on checkbox on the trash-icon column to pr	opose delete current a	pproved attachments.				
	Clie	ck on	the red trash-icon button to remove uploaded att	achments.					
	Μι	ultiple	file attachment are available in some Field/Label						
	Fill	the r	equired field D1-D5						





	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							•	
Generatis [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 Owne a) Current Letter of Appointment of the Contract Manufacturer from the Product Owner:	r: O							
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								
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 Choose File Koala.jpg								
Q Remarks [E24]								



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



	E1-E2 E3 E4 E5 E6-E12 E1:	3 E14-E17	
E3. Certificate of Pharmaceutical Product (CPP)		Help	
E3.1. Certificate of Pharmaceutical: O Unrent Certificate of Pharmaceuticat:			
b) Proposed Certificate of Pharmaceuticat: 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:			
Q Remarks [E3-2]			
E3.3. Is this product licensed to be placed on the market for use in the exporting) Current Answer and Remark:	country? O		
Y Yes			
o) Proposed Answer and Remark: ©Yes ©NO			
		*	
G Remarks [E3-3]		v F	
E3.4. Is this product on the market in the exporting country? a) Current Answer and Remark:			
Yes			
i) Proposed Answer and Remark: ◎Yes ◎NO			
		Â	
		÷	
Q Remarks [E34]		,	
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 [E36]			



EX23	Explanation:
LALO	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



Ar Product Validation → Part II → Part III → Part III → Part III → Part IV →	✓ Labels Checklist
Part I / Section E - Supplementary Documentation	
1. Please Fill All Required fields	
2. Multiple Upload are allowed.	
3. You are allowed to Upload PDF/JPEG/JPG file	
E1-E2 E3 E4 E5	E6-E12 E13 E14-E17
E4. Certificate of Free Sales (CFS) (if applicable)	Help
E4.1. Certificate of Free Sales: a) Current Certificate of Free Sales:	
b) Proposed Certificate of Free Sales:	
Certificate No. Choose File Please Select A File Remarks [E4-1]	
E4.2. CFS Issuing Body a) Current CFS Issuing Body:	
1255	
b) Proposed CFS Issuing Body.	
	Ŧ
Qr Remarks [E4-2]	
E4.3. Date of Issue of CFS a) Current Date of Issue of CFS:	
2003-05-23 00:00:00	
b) Proposed Date of Issue of CFS	
Q Remarks [E4-3]	
E4.4. Date of expiry of CFS (a) a) Current Date of expiry of CFS:	
2005-05-16 00:00:00	
b) Proposed Date of expiry of CFS	
m	
Q Remarks [E44]	
xplanation:	
ick on Part 1 / Section E / E4. ey-in the followings:-	
4.1 upload attachment file	
4.2 fill in issuing body	
- Fill in issuing body by entering a minimum 3 character and choose from the drop	down list
4.3 fill in date	
4.4 fill in date	



Product Validation • Part I • Part II • Part III • Part IV •	✓ Labels Checklist
Part I / Section E - Supplementary Documentation	
1. Please Fill All Required fields	
2. Multiple Upload are allowed.	
3. You are allowed to Upload PDF/JPEG/JPG file	
E1-E2 E3 E4 E5 E6-E12	E13 E14-E17
E5. Certificate of Goods Manufacturing Practice (GMP)	Help
E5.1. Certificate of Goods Manufacturing Practice: a) Current Certificate of Goods Manufacturing Practice:	
b) Proposed Certificate of Goods Manufacturing Practice:	
Certificate No. Choose File Please Select A File Remarks [E5-1]	
E5.2. GMP Issuing Body a) Current GMP Issuing Body:	
1286	
b) Proposed GMP Issuing Body:	v
😋 Remarks [E5-2]	
E5.3. Date of issue of GMP: a) Current Date of issue of GMP	
2003-05-23 00:00:00	
b) Proposed Date of issue of GMP	
🔾 Remarks (E5-3)	
E5.4. Date of expiry of GMP: a) Current Date of expiry of GMP	
2005-05-16 00:00:00	
b) Proposed Date of expiry of GMP	
Q Remarks [E5-4]	
lanation:	
k on Part 1 / Section E / E5.	
-in the followings:-	
1 upload attachment file	
2 fill in issuing body	n list
 Fill in issuing body Fill in issuing body by entering a minimum 3 character and choose from the dropdown 	n list
2 fill in issuing body	ı list



FG26	E7. Other Manufacturer(s) Involve					
	No Manufacturer Name	Manufacturer Address	Proc	essing Step	GMP Certificate	
	b) Proposed Other Manufacturer(s) Invol Manufacturer(s) Involved : @ Address :	FERTIN PHARMA A/S : DANDYVEJ VEJ DANDYVEJ VEJLE VEJLE	JLE VEJLE	•		
	Processing Step :	PACKING		<>		
	GMP Certificate :	Choose File	Koala.jpg 🚢	Cancel		
		ADD				
	No. Manufacturer Name	Manufacturer Address	Processing Step	GMP		
	1 FERTIN PHARMA A/S	DANDYVEJ VEJLE VEJLE	PACKING	View	Remove	
	Q Remarks [E7]					
EX26	Explanation: Click on Manufacturer(s) Inv	volved field to search for a ma	nufacturer.			
	Select Address and Processi	ng Step.				
	Upload GMP by clicking on t	he Choose File button				
	Click on ADD button to add	the selected manufacturer.				
FG27	E8. Importer : a) Current Importer Involved:					
	No Importer Name	Importer Address				
	1 UNIMED SDN BHD	53, JALAN TEMBAGA SD5/2B,BANDAR BAR	U SRI DAMANSARA			
	b) Proposed Importer Involved:			TECHNOLOGY D		
	Importer:	GERMAX SDN. BHD. : NO:10, JALAN F	JU 3/48, SUNWAY DAMANSARA	TECHNOLOGY P +		
	Importer Address:	NO:10, JALAN PJU 3/48, SUNWAY DA	WANSARA TECHNOLOGY PARK	*		
		ADD				
	No. Manufacturer Name	Manufacturer Address			_	
	1 GERMAX SDN. BHD.	NO:10, JALAN PJU 3/48, SUNWAY DAM	ANSARA TECHNOLOGY PARK		Remove	
	Qr Remarks [E8]					
EX27	Explanation:					
E771	Click on Importer field to se	arch.				
	Select Importer Address.					
		the colocted increases.				
	Click on ADD button to add	the selected Importer.				



FG28	E9. Store Address: O a) Current Store Involved:		
	No Store Name	Store Address	
	b) Proposed Store Involved:		
	Store:	NUFERA BIO TECH SDN BHD : SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 \star	
	Store Address:	SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA,	
		ADD	
	No. Store Name	Store Address	
	1 NUFERA BIO TECH SDN BHD	SUITE 8.07, BLOCK A, KELANA SQUARE, JALAN SS7/26 KELANA JAYA, Remove	
	Explanation:		
EX28	Click on Store field to search.		
	Select Store Address.		
	Click on ADD button to add the	e selected Store.	
FG29	E10. Summary of Product Characteristic	cteristic / Product Data Sheet (if applicable) : Product Data Sheet (if applicable) :	
	b) Proposed Summary of Product Characteris	tic / Product Data Sheet (if applicable) :	
	Choose File Penge	ins.jpg 🔹 🛍	
	E11. Company Core Data Sheet (a) Current Company Core Data Sheet (CCDS		
	b) Proposed Company Core Data Sheet (CCI Choose File Kc	DS) (if applicable) : ala.jpg	
	Q Remarks [E11]		
	E12. Analysis Protocol : a) Current Analysis Protocol :		
	b) Proposed Company Analysis Protocol :		
		ins jpg	
	😡 Remarks [E12]		
			1
EX29	Explanation: Click on Choose File button to	select and upload attachment file for E10, E11, and E12.	
		······································	





FG30	E1-E2 E3 E4 E5 E6-E12 E13 E14-E17
	Protocol Analysis & Data Validation
	# Test Category Description Action
	# Attachment
	1. Summary of method validation * : Choose File Desert.jpg 🟝 View Delete
	2. Other Documents : Choose File Jellyfish.jpg 초 View Delete
	* required field
	Qx Remarks [E13] Back Next
	Explanation:
EX30	Click on Part 1/ Section E / E13.
	Click Choose File button to select and upload attachment.
FG31	E1-E2 E3 E4 E5 E6-E12 E13 E14-E17
	E14. Other Supporting Documents : @
	a) Current Other Supporting Documents :
	b) Proposed Other Supporting Documents :
	Choose File Please Select A File
	Sa Remarks [E14]
	E15. Worldwide Registration Status : a) Current Worldwide Registration Status :
	b) Proposed Worldwide Registration Status :
	b) Proposed workwore Registration status . Choose File Please Select A File
	Qr Remarks [E15]
	E16. Post-Approval Commitment : a) Current Post-Approval Commitment :
	b) Proposed Post-Approval Commitment : Choose File Please Select A File
	🔉 Remarks [E16]
	E17. TSE Risk-Free Commitment : a) Current TSE Risk-Free Commitment :
	b) Demagned TOE Dick Even Commitment -
	b) Proposed TSE Risk-Free Commitment : Choose File Please Select A File
	Q Remarks [E17]
1	



EX31	Explanation:
_	Click on Part 1 / Section E / E14 – E17.
	Click Choose File button to select and upload attachment.
FG32	P1-P2 P3 P4 P5 P6-P9
	SECTION A : QUALITY OVERALL SUMMARY a) Current SECTION A : QUALITY OVERALL SUMMARY b) Proposed SECTION A : QUALITY OVERALL SUMMARY Choose File Please Select A File a) Current SECTION B : TABLE OF CONTENTS a) Current SECTION B : TABLE OF CONTENTS b) Proposed SECTION B : TABLE OF CONTENTS b) Proposed SECTION B : TABLE OF CONTENTS Choose File Please Select A File a) Current SECTION B : TABLE OF CONTENTS SECTION C : BODY OF DATA O a) Current SECTION C : BODY OF DATA O b) Proposed SECTION C : BODY OF DATA'
	Choose File Please Select A File Remarks [PSC]
EX32	Explanation: Click Choose File button to select and upload attachment.
FG33	P1. Description and Composition • • Oursent Description and Composition • In coope(3) pg • Description and Composition • • Description and Composition • • Opposed Description and Composition • • Choose File • Option File
EX33	Explanation: Type or paste text on the text area and click on Choose File Button to upload attachment.



FG34	P2. Pharmaceutical Development
	P2.1 Information on Development Studies a) Current Information on Development Studies
	Not Applicable
	b) Proposed Information on Development Studies
	Choose File Please Select A File
	Q Remarks [P2-1]
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.



							P1-P2	P3 P4 P5 P6-P9
P3. Manu	ufacturer							
P3.1 Batc	ch Formula 😡							
	atch Formula							
	ufacturing Process and P		ontrol 🛛					
Please F	Refer Section B1.2							
) Proposed '	Manufacturing Process and	Process Control						
								*
4								• •
Choose	File				Please Select A File			
Q Rema	arks [P3-2]							
	anufacturing Proces anufacturing Process Flower							
	Manufacturing Process Flow	wchart						
Choose	_				Please Select A File			
🗣 Rema	arks [P3-2-1]							
IN PRO	ontrol of Critical Steps and In CESS QUALITY CONTROL		Frequency of	Quantity of				*
		Test is done	Sampling	Sample taken each time.				
1.	Description Moisture content	After drying of granules	Once	5 g granules 5 g granules				
3.	Assay	After drying of granules Before	Once	20 g granules				
		compression		ready for				*
) Proposed	Control of Critical Steps and	d Intermediate						
4								
Choose	File				Please Select A File			
Q Rema	anks [P3-3]							
	ocess Validation and Control of Critical Steps and		1 0					
		nd Intermediate						
a) Current (d Control of Critical Steps a				Please Select A File			
a) Current (
a) Current (b) Proposed Choose								
a) Current (b) Proposed Choose	File arks [P3-4]							
a) Current (b) Proposed Choose	File arks [P3-4]							
a) Current (b) Proposed Choose Q Reme planat	rFie antis [P3-4] tion:	the text a	area and c	lick on C	oose File Button to upl	oad atta	chment.	



FG36	P1-P2 P3 P4 P5 P6-P3	
	P4. Control of Excipients	
	P4.1 : Specification a) Current Specification	
	MAIZE STARCHB.P.	
	Characters: A matt, white to slightly yellowish, very fine powder which creatils when pressed between the fingers, tastletess, practically insoluble in cold water and in alcohol.	
	Description To comply the microscopic test.	
	Identification: To comply the tests A and B. Acidity: To comply the test.	
	b) Proposed Specification	
	*	
	Choose File Please Select A File	
	Q Remains (P4-1)	
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	P1-P2 P3 P4 P5 P6-P9	
	P5. Control of Finished Product	
	P.5.1 : Specification ●	
	P.5.1 : Specification a) Current Specification Metrogyl 200	
	a) Current Specification	
	a) Current Specification Metrog/l 200 Image: Control of the specification TEST SPECIFICATIONS REFERENCE Image: Control of the specification	
	a) Current Specification Metrogyl 200 Release specification	
	e) Current Specification Metrogyl 200 Release specification TEST SPECIFICATIONS REFERENCE Description Pink round biconvex film coated tablets. In-house	
	e) Current Specification Metrogyl 200 Release specification Image: Complexity of the set	
	e) Current Specification Metrogyl 200 Release specification Image: Comparison of the specification Description Pink round biconvex tilm coated tablets. In-house Identification b) Proposed Specification	
	e) Current Specification Metrogyl 200 Release specification Image: Comparison of the specification Description Pink round biconvex tilm coated tablets. In-house Identification b) Proposed Specification	
	e) Current Specification Release specification Image: Test specification Description Pink round biconver film coated tablets. Identification To comply the tests A, B and C. As per BP	
	e) Current Specification Release specification Image: Test specification Description Pink round biconvex film coated tablets. Identification To comply the tests A, B and C. As per BP	
	a) Current Specification Activate Specification TEST SPECIFICATIONS REFERENCE Description Pink round biconvers film coated tablets. In-house Identification To comply the tests A, B and C. As per BP Description Proposed Specification I Cocoe File Pisses Select A File Pisses Select A File	
EX37	e)Current Specification Release specification TEST SPECIFICATIONS Description Pink round bicorves film coated tablets. Identification To comply the tests A, B and C. As per BP	



FG38	P142 P3 P4 P5 P6499
	P6 : Reference Standarts of Materials ♥ a) Current Reference Standarts of Materials
	b) Proposed Reference Standarts of Matarials
	Choose File Please Select A File
	G Rematis [P6]
	P.7 Container Closure System a) Current Reference Standarts of Materials
	b) Proposed Reference Standarts of Materials Choose File Please Select A File
	Q Remarks [77]
	P8 Stability Data • a) Current Stability Data
	b) Proposed Stability Data
	Choose File Please Select A File Qr Remarks [P6]
	P.9 Product Interchangeability/Equivalence Evidence(if applicable) O a) Current Stability Data
	b) Proposed Stability Data Choose File Please Select A File
	Q Remarks [P9]
EX38	Explanation: Click on Choose File button to upload attachment for P6 – P9.
FG39	Image: Product Validation Part II Part III Part IIII Part IIII Part IIII Part III
	Section S - APUSubtance Manufacturer 1. Please Delete API Manufacturer that not involved in your Substance Production 2. You are allowed to add new API Manufacturer to your product
	3. You are allowed to Edit Content of API
	# Active Substance Company Name Strength % It
	1 METRONIDAZOLE UNIQUE PHARM LABS 2466 gm, %
EX39	Explanation:
	Click on Part 2 / Section S
	Click on the clip-icon to open the popup form.



88 N	METRONID.	AZOLE / UNIQUE PHARM LABS / 246	i6 gm,				× .
		Section 6	API/Subtance Manufacturer				
		360001.3 -	Ar // Sublance Manufacturer				
1. Pleas	se Fill All Mandatory F	īoms					
2. If the	upload is Not Applica	able Please Click N/A Checkbox					
3. This f	form is only for 1 API	(Active Subtance + Manufacturer) Only					
₩ S(i)	-S(ii) QOS	S1 S2 S3 S4 S5-S7 S8-S10					
			Labels Checklist				
#	Code	Label Desc	Label Overlap	Correspondence	Status	Go	
1	S5	Reference Standards oF Materials	-	N/A	A	Ø	
2	S6	Container Closure System	-	N/A	A	Ð	
3	S8	Drug Master File (DMF)	-	N/A	A	Ð	
4	Si	Cerificate of Suitability	-	N/A	A	Ð	
5	S10	Other Supporting Documents	-	N/A	A	Θ	
6	S1.1	Nomenclature	-	N/A	A	Ð	
7	S1.2	Structure General Dronartiae	-	N/A	▲ ▲	0	
-	hows a poj	pup form for Section S.					
FG40 sl	hows a poj	S1 S2 S3 S4 S5-S7 S8-S10	AP/Substance Manufacturer				
FG40 sł	hows a pop	St S2 S3 S4 S5-S7 S8-S10 Section S -	AP//Substance Manufacturer				
FG40 sł	hows a pop	St S2 S3 S4 S5-S7 S8-S10 Section of API Information submission	AP//Substance Manufacturer				
FG40 sł	hows a pop	St S2 S3 S4 S5-S7 S8-S10 Section of API Information submission	AP//Substance Manufacturer				
FG40 sł	hows a pop	St S2 S3 S4 S5-S7 S8-S10 Section of API Information submission	APUSubstance Manufacturer				
FG40 sł	hows a pop -s(ii) QOS : 1. First please choor 2. Enter S(i) & S(ii) if	S1 S2 S3 S4 S5-S7 S8-S10 Section S ae option of API information submission relevant	AP//Substance Manufacturer				
FG40 sł	hows a pop -s(ii) QOS : 1. First please choor 2. Enter S(i) & S(ii) if	S1 S2 S3 S4 S5-S7 S8-S10 Section S ae option of API Information submission relevant ON OF API INFORMATION SUBMISSION	AP//Substance Manufacturer				
FG40 sl	hows a pop +s(ii) QOS 1. First please choor 2. Enter S(i) & S(i) if ASE CHOOSE OPTIM	St S2 S3 S4 S5-S7 S8-S10 Section of API Information submission relevant ON OF API INFORMATION SUBMISSION 7) 7	APV/Substance Manufacturer				
FG40 sl	hows a pop +S(ii) QOS 1. First please choor 2. Enter S(i) & S(i) if ASE CHOOSE OPTI Drug Master File(DMF	S1 S2 S3 S4 S5-S7 S8-S10 Section of API Information submission relevant ON OF API INFORMATION SUBMISSION 7) y (OEP)	AP//Substance Manufacturer				
FG40 sl	hows a pop +S(ii) QOS 1. First please choor 2. Enter S(i) & S(i) # ASE CHOOSE OPTI Drug Master File(DMF Certificate of Suitabilit	S1 S2 S3 S4 S6-S7 S8-S10 Section S ac option of API information submission frelevant ON OF API INFORMATION SUBMISSION f) y (CEP) the product dossier	API/Substance Manufacturer				
FG40 sl	hows a pop +s(ii) QOS 1. First please choor 2. Enter S(i) & S(i) if ASE CHOOSE OPTD Drug Master File(DMF Certificate of Suitabilit Full ACTD Part II S in	S1 S2 S3 S4 S6-S7 S8-S10 Section S ac option of API information submission frelevant ON OF API INFORMATION SUBMISSION f) y (CEP) the product dossier	API/Substance Manufacturer				
FG40 sl	hows a pop -s(ii) QOS : 1. First please choor : 2. Enter S(i) & S(i) if ASE CHOOSE OPTION ASE CHOOSE OPTION Sug Master File(DMF Certificate of Suitabilit Full ACTD Part II S in P Remarks [APHINF	S1 S2 S3 S4 S6-S7 S8-S10 Section S ac option of API information submission frelevant ON OF API INFORMATION SUBMISSION f) y (CEP) the product dossier	AP//Substance Manufacturer				
FG40 sl	hows a pop -s(ii) QOS : 1. Fint please choo 2. Enter S(i) & S(i) # ASE CHOOSE OPTD Drug Master File(DMF Certificate of Subabili Full ACTD Part II S in P Remarks [APIINF ation:	S1 S2 S3 S4 S6-S7 S8-S10 Section S ac option of API information submission frelevant ON OF API INFORMATION SUBMISSION f) y (CEP) the product dossier	APVSubstance Manufacturer				
FG40 sl	hows a pop -s(ii) QOS : 1. First please choor : 2. Enter S(i) & S(i) if ASE CHOOSE OPTION ASE CHOOSE OPTION Sug Master File(DMF Certificate of Suitabilit Full ACTD Part II S in P Remarks [APHINF	S1 S2 S3 S4 S6-S7 S8-S10 Section S ac option of API information submission frelevant ON OF API INFORMATION SUBMISSION f) y (CEP) the product dossier	AP//Substance Manufacturer				



FG42			
	S(i). Certificate of Suitability (CEP) (Mandatory for CEP option)		
	Please Enter CEP. NO.		
	Q Remarks [Si-1]		
	m 11/10/2016		
	Q Remarks [Si-2]		
	11/02/2016		
	Q Remarks [Si-3]		
	Choose File	Please Select A File	
	Qr Remarks[si]		
	S(ii). Written Statement		
	Choose File	Please Select A File	
	Q Remarks [Si]		
			I
	Explanation:		
EX42			
	Select Date by clicking on the calendar-icon.		
	Click on Choose File button to upload attachment		
			1
FG43			
FG43	SECTION A - QUALITY OVERALL SUMMARY Choose File	Please Select A File	
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose File	Please Select A File	
FG43	SECTION A : QUALITY OVERALL SUMMARY	Please Select A File	
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose File	Please Select A File	
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose File Q Remarka [S:SECA]	Please Select A File	
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose File	Please Select A File	
FG43	SECTION B : TABLE OF CONTENTS		
FG43	SECTION B : TABLE OF CONTENTS		
FG43	SECTION B : TABLE OF CONTENTS Choose File SECTION B : TABLE OF CONTENTS Choose File		
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose Fie Q Remarks (SSECA) SECTION B : TABLE OF CONTENTS Choose Fie Q Remarks [SSECB]		
FG43	SECTION B : TABLE OF CONTENTS Choose File SECTION B : TABLE OF CONTENTS Choose File		
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose Fie	Please Select A File	
FG43	SECTION B : TABLE OF CONTENTS	Please Select A File	
FG43	SECTION A : QUALITY OVERALL SUMMARY Choose Fie	Please Select A File	
	SECTION A : QUALITY OVERALL SUMMARY Choose File SECTION B : TABLE OF CONTENTS Choose File SECTION B : TABLE OF CONTENTS Choose File FixelEanation:	Please Select A File	
FG43 EX43	SECTION A : QUALITY OVERALL SUMMARY Choose File SECTION B : TABLE OF CONTENTS Choose File SECTION B : TABLE OF CONTENTS Choose File SECTION B : TABLE OF CONTENTS Choose File Explanation:	Please Select A File	
	SECTION A : QUALITY OVERALL SUMMARY Choose File SECTION B : TABLE OF CONTENTS Choose File SECTION B : TABLE OF CONTENTS Choose File FixelEanation:	Please Select A File	



FG44	# S(I)-S(III) QOS S1 S2 S3 S4 S6-S7 S8-S10
	Section S (S1) - General information
	1. Rich Text box are mandatory to fill and the attachment are optional
	2. Enter All Field in this form
	Metronidazole is a 2-(2-metry/-5-ntro-imidazol-1-y/lethanol.
	S.1.1 Nomenclature
	A
	×
	Choose File Please Select A File
	Q Remarks [S1-1]
EX44	Explanation:
2744	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
	W S(I)-S(II) QOS S1 S2 S3 S4 S5-S7 S8-S10
FG45	
	Section S (S2) - Manufacturer
	1. Rich Text box are mandatory to fill and the attachment are optional
	2. Enter All Field in this form
	UNIQUE PHARM LABS
	128/1 G.I.D.C. ANKLESHWAR 383 002 GUJARAT S.2.0 APJ/Subtance Manufacture(s) EEEMIC SAIDE C.V.: REFORMA 873 COL SAIN NICOLAS TOLENTINO 1272841 489, MEYLOD CITY
	FERMIC SA DE C.V.: REFORMA 873 COL SAN NICOLAS TOLENTINO, IZTAPALAPA MEXICO CITY FERMIC SA DE C.V.: REFORMA 873 COL SAN NICOLAS TOLENTINO, IZTAPALAPA MEXICO CITY
EX45	Explanation:
2743	Click on the dropdown option to search for API Substance Manufacturer.
FG46	S 2.1.1 Other Substance Manufacturer Involves (s)
	Manufacturer : •
	Address : •
	Processing Step :
	GMP Cettificate : Choose File Piesse Select File 🏝 Remove
	Add
	No. Manufacturer Processing Step GMP
	Q Rematis [52.1-1]
	Explanation:
EX46	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	S.1.2 Syntesis Roote
	<pre></pre>
EX47	Type or paste text into the text area. Click on Choose File button to upload attachment.
FG48	S.1 Excision of structure and other Characterisation
	Choose File Plass Select A File Q Remarks [53-2]
EX48	Explanation: Click on S3 Type or paste text into the text area. Click on Choose File button to upload attachment.



FG49	METRONIDAZOLE B.P. Characters A white or yellowish, crystalline poorder. Slightly soluble medine: Detacters Identification To comply the test. Appearance of solution Have metals Appearance of solution
EX49	Explanation:
2,45	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
	# \$(i)-\$(i) QOS \$1 \$2 \$3 \$4 \$5-57 \$8-310
FG50	
	Section S (SS-57) - API Manufacturer
	Rich Text box are mandatory to fill and the attachment are optional Enter All Field in this form
	2. Enter All Field in this form
	Not Applicable
	S.5. Reference Standards of Materials
	4
	Choose File Please Select A File Q. Remarks [52]
EX50	Explanation:
LY20	Click on S5-S7
	Type or paste text into the text area. Click on Choose File button to upload attachment.



FG51	# \$(i)-\$(ii) QOS \$1 \$2 \$3 \$4 \$5-\$7 \$8-\$10	
FG51		
	Section S (S8-S9) - API Manufacturer	
	1. Rich Text box are mandatory to fill and the attachment are optional	
	2. Enter All Field in this form	
	S 8 Drug Master File(DMF)	
	Choose File Please Select A File	
	S8a Drug Master File (DMF) Version No	
	Q. Remarks [S8]	
	S & 1 Letter of Access	
	Choose File Please Select A File	
	Q Remarks [S8-1]	
	Explanation:	
EX51		
	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	
	Key-in the following S8 – S10	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. # Product Validation + Part II + Part I	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part I + Part II + P	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part II +	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part I + Part II + P	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part II + Part II	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part I + Part II + Part	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part I + Part II + Part	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Product Validation + Part I + Part II + Part	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the popup form to close. Image: Click anywhere outside the population of	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. ************************************	
FG52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Image: Product Validation = Part	
	Key-in the following S8 – S10 Click anywhere outside the popup form to close.	
FG52 EX52	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Image: Part I Part II Part III Part III Part II Part II Part II Part II Part II Part	
	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Image: Part I mark of the part of the part I mark of the part of t	
	Key-in the following S8 – S10 Click anywhere outside the popup form to close. Image: Part I Part II Part III Part III Part II Part II Part II Part II Part II Part	



	*	Product Validation • Part I • Part II • Part III •	Part IV 👻		✓ Labels Checklist
FG53		Section A-B			
		Section C-E	Part 3 / Section C-D - Non-Cl	ic al Documentation	
		1. Please Fill All Required fields			
		2. Multiple Upload are allowed.			
		3. You are allowed to Upload PDF/JPEG/JPG file			
		Section C: Non-Clinical Written & Tabulated Summar a) Current Section C: Non-Clinical Written & Tabulated Summaries	es 0		
		b) Proposed Section C: Non-Clinical Written & Tabulated Summaries			
		Choose File	Please Select A File		
			Hoase Select A File		
		Q Remarks [PT3-SC]			
		a) Current Section D: Non-Clinical Study Reports @			
		a) Guirent Section D. Non-Giinical Study Reports			
		b) Proposed Section D: Non-Clinical Study Reports			
		Choose File	Please Select A File		
		🗣 Remarks [PT3-SD]			
		section E: List of Key Literature References a) Current Section E: List of Key Literature References			
		b) Proposed Section E: List of Key Literature References			
		Choose File	Please Select A File		•
		🗣 Remarks [PT3-SE]			
X53		planation: ck on Choose File button to select a	nd upload attachmer	t.	
X53		planation: ck on Choose File button to select a	nd upload attachmer	t.	
		ck on Choose File button to select a	nd upload attachmer	t.	✓ Labels Checklist
	Clic	ck on Choose File button to select a	Part IV Section A-B	t.	✓ Labels Checklist
	Clic	ck on Choose File button to select a	Part IV + Section A-8 Section C	t. kal Documentation	✓ Labels Checklist
	Clic	ck on Choose File button to select a	Part IV Section A-B Section C		✓ Labels Checklist
	Clic	Product Validation Part I Part II Part II Part III 1. Please Fill All Required fields	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	Product Validation Part I Part II Part II Part III Part III 1. Please Fill All Required fields 2. Multiple Upload are allowed.	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	Product Validation Part I Part II Part II Part III 1. Please Fill All Required fields	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	Product Validation Part I Part II Part II Part III Part III 1. Please Fill All Required fields 2. Multiple Upload are allowed.	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	k on Choose File button to select a Product Validation Part P	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	Product Validation Part I Part II Part II Part III Part III 1. Please Fill All Required fields 2. Multiple Upload are allowed.	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	Product Validation Parti Partii Partiii Partiii Product Validation Partii Partiii Partiiii Partiiii 1. Please Fil All Required fields	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	ex on Choose File button to select a Product Validation • Part II • Part III • I. Please Fil All Required fields Image: Compare the second secon	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	Product Validation Parti Partii Partiii Partiii Product Validation Partii Partiii Partiiii Partiiii 1. Please Fil All Required fields	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	ex on Choose File button to select a Product Validation • Part II • Part III • I. Please Fil All Required fields Image: Compare the second secon	Part IV • Section A-B Section D-E Section A-B - Cli		✓ Labels Checklist
	Clic	ck on Choose File button to select a Product Validation + Part I + Part II + Part III + 1. Please Fill All Required fields 2. Multiple Upbad are allowed. 3. You are allowed to Upbad PDF/APEGJAPG file Section A: Table of Content ● a) Current Section A. Table of Content b) Proposed Section A: Table of Content	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	ck on Choose File button to select a Product Validation • Partl • Partl • Partl • 1. Please Fil All Required fields . . 2. Multiple Upbad are allowed. . . 3. You are allowed to Upload PDF/JPEG/JPG file . Section A: Table of Content • a) Current Section A: Table of Content . b) Proposed Section A: Table of Content .	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	ck on Choose File button to select a Product Validation Part Part Part Part Part Part Part Part	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	ck on Choose File button to select a Product Validation • Partl • Partl • Partl • 1. Please Fil All Required fields . . 2. Multiple Upbad are allowed. . . 3. You are allowed to Upload PDF/JPEG/JPG file . Section A: Table of Content • a) Current Section A: Table of Content . b) Proposed Section A: Table of Content .	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	eck on Choose File button to select a Product Validation • Parti • Partii • Partiii • 1. Please Fil All Required fields 2. Multiple Upload are allowed. 3. You are allowed to Upload PDF/JPEG/JPG file Section A: Table of Content a) Current Section A: Table of Content b) Proposed Section A: Table of Content Choose File Choose File Section B: Clinical Overview Image: Sect	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	ex on Choose File button to select a Product Validation + Part II + Part II + Part III + 1. Please Fil All Required fields 1 1 2. Multiple Upload are allowed. 3. 1 3. You are allowed to Upload PDF/UPEG/UPG file 1 Section A: Table of Content ● a) Current Section A: Table of Content (Choose File) 1 Choose File 1 a) Current Section B: Clinical Overview ● a) Current Section B: Clinical Overview	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	eck on Choose File button to select a Product Validation • Parti • Partii • Partiii • 1. Please Fil All Required fields 2. Multiple Upload are allowed. 3. You are allowed to Upload PDF/JPEG/JPG file Section A: Table of Content a) Current Section A: Table of Content b) Proposed Section A: Table of Content Choose File Choose File Section B: Clinical Overview Image: Sect	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
FG54	Clic	ex on Choose File button to select a Product Validation + Part II + Part II + Part III + 1. Please Fil All Required fields 1 1 2. Multiple Upload are allowed. 3. 1 3. You are allowed to Upload PDF/UPEG/UPG file 1 Section A: Table of Content ● a) Current Section A: Table of Content (Choose File) 1 Choose File 1 a) Current Section B: Clinical Overview ● a) Current Section B: Clinical Overview	Part IV - Section A-B Section C Section P-E Section F		✓ Labels Checklist
	Clic	ex on Choose File button to select a Product Validation Part I Part II Part II Part III 1. Please Fill All Required fields 1 1 1 2. Multiple Upbad are allowed. 3 1 1 3. You are allowed to Upbad PDFJ.PEGJ.PEG III 0 0 a) Current Section A: Table of Content 0 0 a) Current Section A: Table of Content 0 0 b) Proposed Section A: Table of Content 0 0 a) Current Section B: Clinical Overview 0 0 0 a) Current Section B: Clinical Overview 0 0 b) Proposed Section B: Clinical Overview 0 0	Part IV - Section A 8 Section C Section A 9 Section C Section A 9 Section F		✓ Labels Checklist
	Clic	ex on Choose File button to select a Product Validation • Part I • Part II • Part III • Part III • Part III • 1. Please Fil All Required fields 1 2. Multiple Upload are allowed. 1 3. You are allowed to Upload PDF/APEG/APG file 1 Section A: Table of Content O a) Current Section A: Table of Content b) Proposed Section A: Table of Content Choose File Choose File a) Current Section B: Clinical Overview O a) Current Section B: Clinical Overview b) Proposed Section B: Clinical Overview	Part IV - Section A 8 Section C Section A 9 Section C Section A 9 Section F		✓ Labels Checklist
	Clic	ek on Choose File button to select a Product Validation • Parti • Partii • Partiii • 1. Please Fil All Required fields 2. Multiple Upbad are allowed. 3. You are allowed to Upbad PDF/JPEG/JPG file Section A: Table of Content ● a) Current Section A: Table of Content b) Proposed Section A: Table of Content Choose File • Current Section B: Clinical Overview ● a) Current Section B: Clinical Overview b) Proposed Section B: Clinical Overview • Dipposed Section B: Clinical Overview	Part IV - Section A 8 Section C Section A 9 Section C Section A 9 Section F		✓ Labels Checklist
	Clic	ex on Choose File button to select a Product Validation Part I Part II Part II Part III 1. Please Fill All Required fields 1 1 1 2. Multiple Upbad are allowed. 3 1 1 3. You are allowed to Upbad PDFJ.PEGJ.PEG III 0 0 a) Current Section A: Table of Content 0 0 a) Current Section A: Table of Content 0 0 b) Proposed Section A: Table of Content 0 0 a) Current Section B: Clinical Overview 0 0 0 a) Current Section B: Clinical Overview 0 0 b) Proposed Section B: Clinical Overview 0 0	Part IV - Section A 8 Section C Section A 9 Section C Section A 9 Section F		✓ Labels Checklist
554	Exp	ek on Choose File button to select a Product Validation • Parti • Partii • Partiii • 1. Please Fil All Required fields 2. Multiple Upbad are allowed. 3. You are allowed to Upbad PDF/JPEG/JPG file Section A: Table of Content ● a) Current Section A: Table of Content b) Proposed Section A: Table of Content Choose File • Current Section B: Clinical Overview ● a) Current Section B: Clinical Overview b) Proposed Section B: Clinical Overview • Dipposed Section B: Clinical Overview	Part W	k al Documentation	✓ Labeis Checklist



FG55	*		✓ Labels Checklist
FG55		Section A-B Section C	
		Section D-E Section C - Clinical Documentation	
		1. Please Fill All Required fields	
		2. Multiple Upload are allowed.	
		3. You are allowed to Upbad PDFAPEGAPG 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	
		Q Remarks [PT4C1]	
		C2. Summary of Clinical Pharmacology Studies O a) Current Summary of Clinical Pharmacology Studies	
		b) Proposed Summary of Clinical Pharmacology Studies	
		Choose File Please Select A File	
		Q Remarks [PT4.C2]	
		C3. Summary of Clinical Efficacy a) Current Summary of Clinical Efficacy	
		b) Proposed Summary of Clinical Efficacy	
		Choose File Plesse Select A File	
		Q Remarks [PT4C3]	
		C4. Summary of Clinical Safety O a) Current Summary of Clinical Safety	
		b) Proposed Summary of Clinical Safety	
		Choose File Please Select A File	
		Q Remarks [P74-C4]	
		AP Aussis sfladuidud Abulias A	
		C5. Synopsis of Individual Studies a) Current Synopsis of Individual Studies	
		b) Proposed Synopsis of Individual Studies	
		Choose File Please Select A File	
		Q Remains [PT4-CS]	
	Exp	planation:	
EX55		ck on Part 4 / Section C	
	Clic	ck on Choose File button to select and upload attachment.	



FG56	Image: With the second of t	
	Section D: Tabular Listing of all Clinical Studies a) Current Section D: Tabular Listing of all Clinical Studies	
	b) Proposed Sector D: Tabular Listing of all Clinical Studies Choose File Please Select A File Q Remarks [FT4-SD]	
	Section E: Clinical Study Reports a) Current Section E: Clinical Study Reports	
	b) Proposed Section E: Clinical Study Reports Choose File Please Select A File Q Remarks [FT4-SE]	
EX56	Explanation: Click on Part 4 / Section D-E	
	Click on Choose File button to select and upload attachment.	



	*	Product Validation • Part I • Part II • Part III •	Part IV 👻		✓ Labels Checklist
FG57			Section A-B Section C		
			Section D-E Section F	Section F - Clinical Documentation	
		1. Please Fill All Required fields			
		2. Multiple Upload are allowed. 3. You are allowed to Upload PDF/JPEG/JPG file			
		Section F: Other Supporting Documents F1.1. List of Key Literature References O a) Current List of Key Literature References			
		b) Proposed List of Key Literature References			
		Choose File Q Remains [F714F1-1]	Please Select A File		
		F1.2. Published Clinical Papers a) Current Published Clinical Papers			
		b) Proposed Published Clinical Papers			
		Choose File Qa Remarks [PT4-F1-2]	Please Select A File		
		F1.3. Periodic Safety Updates Report(PSUR) a) Current Periodic Safety Updates Report(PSUR)			
		b) Proposed Periodic Safety Updates Report(PSUR)			
		Choose File Q Remarks [PT4F13]	Please Select A File		
		F1.4. Risk of Management Plan(RMP) a) Current Risk of Management Plan(RMP)			
		b) Proposed Risk of Management Plan(RMP)			
		Choose File Q Remarks [PT4-F1-4]	Please Select A File		
		F1.4. Risk Management Plan a) Current Risk Management Plan			
		b) Proposed Risk Management Plan			
		Choose File Q Remarks [PT4-F1-5]	Please Select A File		
EX57	Ехр	planation:			
EX5/	Clic	k on Part 4 / Section F			
		k on Choose File button to select a	and upload a	ttachment.	
FG58		✓ Submit Vanistion			
EX58		planation:			
		er finish filling all the required field shown in FG58	ls. Click on h	ome-icon and scroll down to bottom of page. Click	on Submit Variation button



2.2	Saved F	orm					
FG59	⊡ Va	ariation					
1033		lew Application					
		aved Form					
	he P	ayment Pending					
	≓ \	/ariation Correspondenc	9				
	ע פ	Vithdrawal					
	\$ P	ayment History					
	6 V	ariation Status					
EX59	Explana		~				
	CIICK OII	Variation / Saved For	111				
FG60	🖺 Saved I	Form					
	Show	10 • entries			Search:		
	# 🔺	Product MAL Number	Product Name	Product Category	Date 🕴	2 †	±
	1	MAL19961014A	FAMOFAST 40 TABLET	PRESCRIPTION - FULL	21 October 2016	8	۵
	2	MAL19985097A	DICLORAN GEL	PRESCRIPTION - FULL	21 October 2016	8	٠
	3	MAL15015032NZ	PP Vitamin C 500mg Tablet	HEALTH SUPPLEMENT - GENERAL	21 October 2016	8	٠
	4	MAL19972991A	LASTUSS COUGH SYRUP 30MG/5ML	PRESCRIPTION - FULL	20 October 2016	8	۵
	5	MAL19972098A	TRITOFEN SYRUP 1MG/5ML	PRESCRIPTION - FULL	20 October 2016	2	٠
	6	MAL19950523A	MORPHINE SULPHATE INJECTION BP 10MG/ML	PRESCRIPTION - FULL	20 October 2016	ø	٠
	7	MAL19971257T	ZANDU CHYAVANPRASH	NATURAL PRODUCT - TRADITIONAL(GENERAL)	20 October 2016	Ø	•
	8	MAL19900475A	METOCLOPRAMIDE INJ BP 10MG IN 2ML	PRESCRIPTION - FULL	20 October 2016	Ø	a
	9	MAL19971306A	PROCHLORPERAZINE INJECTION 12.5MG/ML (1ML)	PRESCRIPTION - FULL	20 October 2016	2	ŧ.
	10	MAL19900631A	PROMETHAZINE HCL INJ 25MG/ML	PRESCRIPTION - FULL	20 October 2016	8	٠
	Showing	1 to 10 of 63 entries			2 3 4	5 6	7
EX60	Explana	tion:					
EVON	FG60 sh	ow a list of saved for	n.				
	Click on	the edit-icon to oper	the saved form				
	Click on	the trash-icon to dele	ete the saved form				
2.3	Paymen	t Pending					



FG61	🕼 Varia	tion 🔺				
	🗅 New	Application				
	🖺 Save	ed Form				
	🐂 Payr	nent Pending				
	≓ Varia	ation Correspondence				
	່ວ With	drawal				
	\$ Payn	nent History				
	taria	ation Status				
	Explanatio	on:				
EX61		ariation / Payment Pen	ding			
		indion, ruyment en				
FG62	t PAYMENT	PENDING TRAY - Please Make Paym	ient to Proceed			
	🗅 List Of Pen	ding Payment				
	Show 10 T	entries		Search	1:	
	Show 10 •	entries Product MAL Number	Product Name	Search Product Category	t: Total	
			Product Name Axcel Famotidine-20 Capsule			
	# *	Product MAL Number		Product Category	Total	
	# A	Product MAL Number MAL20152458AE	Axcel Famotidine-20 Capsule	Product Category PRESCRIPTION	Total RM 450.00	
	# * 1 2	Product MAL Number MAL20152458AE MAL19970353T	Axcel Famotidine-20 Capsule	Product Category PRESCRIPTION NATURAL PRODUCT	Total RM 450.00 RM 300.00	
	# ▲ 1 2 3	Product MAL Number MAL20152458AE MAL19970353T MAL16080066NCZ	Axcel Famotidine-20 Capsule ZEFS COUGH SYRUP Fish Oil 1000mg Softgel	Product Category PRESCRIPTION NATURAL PRODUCT HEALTH SUPPLEMENT	Total RM 450.00 RM 300.00 RM 150.00	
	# ▲ 1 2 3 4	Product MAL Number MAL20152458AE MAL19970353T MAL16080066NCZ MAL19872220AZ	Axcel Famotidine-20 Capsule ZEFS COUGH SYRUP Fish Oil 1000mg Sottgel AMPILIN CAPSULE 500MG	Product Category PRESCRIPTION NATURAL PRODUCT HEALTH SUPPLEMENT PRESCRIPTION	Total RM 450.00 RM 300.00 RM 150.00 RM 300.00	
	# ▲ 1 2 3 4 5	Product MAL Number MAL20152458AE MAL19970353T MAL16080066NCZ MAL19672220AZ MAL16100078TCZ MAL19672165AZ	Axcel Famotidine-20 Capsule ZEFS COUGH SYRUP Fish Oil 1000mg Softgel AMPILIN CAPSULE 500MG RTA 500mg Tablet	Product Category PRESCRIPTION NATURAL PRODUCT MEALTH SUPPLEMENT PRESCRIPTION NATURAL PRODUCT	Total RM 450.00 RM 300.00 RM 150.00 RM 300.00 RM 300.00	
	# 1 2 3 4 5 6	Product MAL Number MAL20152458AE MAL19970353T MAL16080066NCZ MAL19672220AZ MAL16100078TCZ MAL19672165AZ	Axcel Famotidine-20 Capsule ZEFS COUGH SYRUP Fish Oil 1000mg Softgel AMPILIN CAPSULE 500MG RTA 500mg Tablet	Product Category PRESCRIPTION NATURAL PRODUCT MEALTH SUPPLEMENT PRESCRIPTION NATURAL PRODUCT	Total RM 450.00 RM 300.00 RM 150.00 RM 300.00 RM 300.00	
EX62	# 1 1 2 3 4 5 6 Showing 1 to 6	Product MAL Number MAL20152458AE MAL19970353T MAL16080066NCZ MAL19872220AZ MAL19872165AZ of6 entries	Axcel Famotidine-20 Capsule ZEFS COUGH SYRUP Fish Oil 1000mg Softgel AMPILIN CAPSULE 500MG RTA 500mg Tablet	Product Category PRESCRIPTION NATURAL PRODUCT HEALTH SUPPLEMENT PRESCRIPTION NATURAL PRODUCT PRESCRIPTION	Total RM 450.00 RM 300.00 RM 150.00 RM 300.00 RM 300.00	



FG63	Notification of payment	
	• Noulication of payment	
	Thank you for using QUEST 3+ Application Service	
	Processing Fee : RM 318	
	Please select payment method below.	
	VIA PERSONAL ACCOUNT VIA CORPORATE ACCOUNT ↓ A CORPORATE ACCOUNT ↓ A CREDIT CARD ↓ A CREDIT CARD	
EX63	Explanation: FG63 shows list of available payment method. Click on Payment Method icon to continue.	
FG64	BANK ISLAM	
	MODE Morchant name: BIRO PENGAWALAN FARMA SEUTIKAL KEBANG SAAN	
	Select your preferred payment method Pay securely using SSL- by clicking on the card tops below:	
	VISA meno	
	e 200-2019 MantoGard	
EX64	Explanation:	
	Select prefered payment method by clicking on the icon.	



FG65	BANKUSLAM
	TE ST Merchant name: BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
	Enter your card details
	MasterCard: You have chosen MasterCard as your method of payment. Please enter your card details into the form below and click "pay" to complete your purchase.
	Card Number = Expity Date = / month/year Security Code = The 3 digits after the card number on the signature panel of your card.
	Purchase Amount H MYR RM318.00
	MasterCard. SourceCode
	I hereby authorise the debit to my MasterCard Account in favour of BIRO FENGAWALAN FARMASEUTIKAL KEBANGSAAN
	© 205-209 MeterCard
	Explanation:
EX65	Enter card details and click pay button.
FG66	This is live status of your online payment. You can check the status at anytime on Payment History menu.
	✓ Your online payment is SUCCESSFUL.
	Reyment Details No Youther :16002551
	Total Amount (RM) : 318.00
	Payment History Payment Receipt
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.
	Variation Correspondence
2.4	
FG67	Variation
	C New Application
	Saved Form
	R Payment Pending
	S Withdrawal
	\$ Payment History
	Variation Status
EX67	Explanation:
	Click on Variation / Variation Correspondence



	Click to open saved & editable Variation									
IN TR	IN TRAY - List of Product Replied Correspondence									
List Of Correspondence Application										
Show	10 • entries					Sea	arch:			
#	Product MAL Number	Product Name	Product Category	Date	Correspor x Times		rrespond	w a	lithdraw	
1	MAL16100054HXCZ	NP290916	VETERINARY	20 October 2016	1st	≓ Co	rrespond	w ≈	fithdraw	
2	MAL19872165AZ	METROGYL TABLET 200MG	PRESCRIPTION	04 November 2016	1st	≓ Cor	rrespond	w ⇔	lithdraw	
Showing	1 to 2 of 2 entries								1	
C OUT	TRAY - List of Product Correspor	nded								
ListO	of Awaiting Reply Correspondence	3								
how	10 • entries					Sea	arch:			
#	Product MAL Number	Product Name			espond ïmes	≓ Stat	ррр 🕴	API 🕴	LAB	
1	MAL20081744A	Optivate POWDER FOR INJECTION BIOLOGICS - BLOOD PRODUCTS		2	?nd	Evaluation	,	-	-	
2	MAL19871727A	ZEET EXPECTORANT PRESCRIPTION - FULL		3	Brd	Evaluation		-	-	
3	MAL20081735A	THYROGEN (THYROTROPIN ALFA BIOLOGICS - BLOOD PRODUCTS		2	tnd	Evaluation		-	-	
4	MAL19870754AZ	SALBUTAMOL SULFATE TABLET PRESCRIPTION - FULL	4MG	2	nd	Evaluation	×	•	-	
5	MAL19900474A	BUPIVACAINE INJ BP 0.5% W/V (1 PRESCRIPTION - FULL	OML)	2	nd	Evaluation	× .	•	-	
6	MAL20041000AZ	IGANTET ANTI-TETANUS IMMUNC IU/ml BIOLOGICS - BLOOD PRODUCTS	DGLOBULIN GRIFOLS INJECTION		tnd	Evaluation	,	-	-	
	1 to 6 of 6 entries								1	
plan ie IN ie OU ick or	ation: TRAY table shows a IT TRAY table show n the Correspond bi	l list of Variation Applica s a list of Variation Appl utton to reply correspor ton to withdraw/cancel	ication that has be ndence.	en replie	ed by use	er/applica	ants	ser/ap	oplicant	
a plan a ne IN ne OU ick or	ation: TRAY table shows a IT TRAY table show n the Correspond bi	s a list of Variation Appl utton to reply correspor ton to withdraw/cancel Var	ication that has be ndence.	en replie efer (FG7	ed by use	er/applica	ants	ser/ap	oplicant	
plan ne IN ne OU ick or ick or	ation: TRAY table shows a IT TRAY table show n the Correspond bi	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel Var Please Fil in	ication that has be ndence. the application. Re riation Workstation	en replie efer (FG7	ed by use	er/applica	ants		opplicant	
plan ne IN ne OU ick or ick or	ation: TRAY table shows a IT TRAY table show In the Correspond bo In the Withdraw but	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel Var Please Fil in	ication that has be ndence. the application. Re riation Workstation	en replie efer (FG7	ed by use	er/applica	ants			
xplana ne IN ne OU ick or ick or	ation: TRAY table shows a IT TRAY table shows In the Correspond bun In the Withdraw but Aud Validation - Part - Part I For the required supporting documents/state	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel Please Fill in Please Fill in In Variation Checkles by clicking on the Insert balance. Please	ication that has be ndence. the application. Re riation Workstation n Applicable forms & File Attachm	en replie efer (FG7	ed by use	er/applica	ants - EX75)	✓ Lab		
splana ne IN ¹ ick or ick or ick or	ation: TRAY table shows a IT TRAY table shows a IT TRAY table show in the Correspond but in the Withdraw but the Withdraw but at lick on the section table above to refer to the a submet other supporting decuments (IF RELT	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel	ication that has be ndence. the application. Re riation Workstation Applicable forms & File Attachm Note to applicant Note to applicant	en replie efer (FG7 ents	ed by use 74 – FG7	er/applica 5, EX74 –	- EX75)	✓ Lab		
splana ne IN ¹ ick or ick or ick or	ation: TRAY table shows a IT TRAY table shows a IT TRAY table show in the Correspond but in the Withdraw but the Withdraw but at lick on the section table above to refer to the a submet other supporting decuments (IF RELT	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel Please Fill in Please Fill in in Variation Checklist by clicking on the Inset button. Ple he current approved data.	ication that has be ndence. the application. Re riation Workstation Applicable forms & File Attachm Note to applicant Note to applicant	en replie efer (FG7 ents	ed by use 74 – FG7	er/applica 5, EX74 –	- EX75)	✓ Lab		
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splana ne IN ¹ ne OU ick or ick or Pess Pass	ation: TRAY table shows a JT TRAY table shows a JT TRAY table show in the Correspond br in the Withdraw but het Validation - Part - Part I a fill in the register supporting documents Valid a siden other supporting documents (F REL a siden other supporting documents (F REL a siden other supporting documents (F REL	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel	ication that has be ndence. the application. Re riation Workstation n Applicable forms & File Attachm Note to applicant Note to applicant asse make sure every Telf required is checked mit battow when it is completed. Once submit Product information	en replie efer (FG7 ents	ed by use 74 – FG7	er/applica 5, EX74 –	- EX75)	✓ Lab		
splana ne IN ¹ ne OU ick or ick or ick or Plass Plass Plass Plass	ation: TRAY table shows a JT TRAY table shows a JT TRAY table shows in the Correspond but in the Withdraw but het Withdraw but het Withdraw but an elde on the sector table downers (F FEL an elde on the sector table downers (F FEL e make sum Mendor Checkler is savet before Name	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel	ication that has be ndence. the application. Re riation Workstation n Applicable forms & File Attachm Note to applicant Note to applicant Note to applicant Product Information	en replie efer (FG7 ents	ed by use 74 – FG7	er/applica 5, EX74 –	- EX75)	✓ Lab		
splana ne IN ¹ ne OU ick or ick or ick or Plass Plass Plass Plass	ation: TRAY table shows a UT TRAY table shows a UT TRAY table shows a IT TRAY table shows a the Correspond but the Withdraw but at the Withdraw but at the Withdraw but a like weight a supporting documents/lata a cick of the required supporting documents/lata a cick of the section table above therefored a submit other supporting documents (F REL e make sure Multiton Checkits is saved before Name Call No. Rhef No. Rheg No.	s a list of Variation Appl utton to reply correspon ton to withdraw/cancel	ication that has be ndence. the application. Re riation Workstation n Applicable forms & File Attachm Note to applicant Note to applicant asse make sure every Telf required is checked mit battow when it is completed. Once submit Product information	en replie efer (FG7 ents	ed by use 74 – FG7	er/applica 5, EX74 –	- EX75)	en.		



EX69	Explanation: FG69 shows a Variation Workstation Opened when user click on Correspond button in FG68.
FG70	1.1 Brand Name: a) Current Approved Brand Name: N b) Proposed Brand Name: New Meister Brand
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	D1. Label (mock-up) for immediate Container: a) Current Label (mock-up) for immediate Container:								
	No Ci	urrent Approved Data							
	#	Attachment				Date of Attach	面		
	1	foil.pdf				08-02-2016			
	h) Pronose	ed Label (mock-up) for immediat	te Container						
		ose File		Please Select A File					
	#	Attachment				Date of Attach	面		
							_		
	1	Penguins.jpg				2016-11-05 09:50:17	۵		
	2	Koala.jpg				2016-11-06 11:10:25	•		
	Q, Re	ernarks [D1]							
EX72	Explana	tion:							
	FG72 sh	ow a sample label wi	ith multiple attachments	(D1) that requires the	e users to	correspond.			
	Click on	Choose File button to	o select and upload new	attachments.					
	Click on	the file name to view	w the uploaded files.						
	Click on	red trash-icon butto	n to delete the uploaded	l files					
			open popup Remarks/Co						
				ation Submission					
FG73			Valia						
	≓ 0	orrespond							
EX73	Explana	tion:							
			on located at the botton	n of home page in the	Variation	Workstation after f	inish cor	npleting the	
	correspo	onded label.							
	Variatio	n Withdrawal							
FG74	🕼 Var	iation							
FG74									
		w Application							
	🖺 Sa	ved Form							
	🍟 Pa	yment Pending							
	≓ Va	riation Correspondence							
	iW פ	thdrawal							
	¢ Pay	yment History							
	Va	riation Status							
	Explana	tion:							
EX74			wal						
	CIICK ON	Variation / Withdraw	wai						



				an Mithdrawal			
FG75		V	O Variatio Withdrawal of Submitted Application	n before Approval/Rejection of Variat	ion		
	List Of Submitte	d Form					
	Show 10 •	entries			Search:		
		roduct MAL Number	Product Name	Product Categ		Date	
		MAL16100056TCZ	ginkgo superman™®	NATURAL PROD		October 2016	
	2	MAL14095066HX	Catosal 10% w/v Injectable Solution	VETERINAR	r 19	October 2016	
	3	MAL20061558A	IMMUNATE 100 IU/ML POWDER FOR INJECT	TION BIOLOGICS	20	October 2016	
	Showing 1 to 3 o	3 entries				1	
X75	Explanation:						
	FG75 shows a	list of withdra	awn Variation Application.				
	Payment His	tory					
	Variation						
G76			^				
	🗅 New App	lication					
	Saved F	orm					
	🌹 Paymen	t Pending					
		t Pending n Correspondence	9				
		1 Correspondence					
	ະ Variation ອ Withdrav	n Correspondence val	2				
	≓ Variation	n Correspondence val					
	ະ Variation ອ Withdrav	n Correspondence val History					
	≓ Variation ৩ Withdraw \$ Payment	n Correspondence val History					
	≓ Variation ৩ Withdraw \$ Payment	n Correspondence val History					
X76	⇒ Variation • Withdraw \$ Payment • Variation Explanation:	n Correspondence val History					
X76	⇒ Variation • Withdraw \$ Payment • Variation Explanation:	n Correspondence val History I Status	ıt History				
EX76	⇒ Variation • Withdraw \$ Payment • Variation Explanation:	n Correspondence val History I Status	ıt History	Payment History			
EX76	⇒ Variation • Withdrav • Payment • Variation • Variation Explanation: Click on Varia	n Correspondence val History I Status tion / Paymen	ıt History	Payment History			
EX76	⇒ Variation • Withdraw \$ Payment • Variation Explanation:	n Correspondence val History I Status tion / Paymen	ıt History	Payment History			
EX76	⇒ Variation • Withdrav • Payment • Variation • Variation Explanation: Click on Varia	n Correspondence val History I Status tion / Paymen	ıt History	Payment History	Search		
EX76	× Variation Variation Variation Variation Variation Click on Variat Show 10 •	a Correspondence val History a Status tion / Paymen d Payment entries	t History O Variation	Payment Status	Total (RM)	Voucher	
EX76	× Variation Variation Variation Variation Variation Variation Click on Varia Show 10 • # ▲ REF N 1 17057	a Correspondence val History 2 Status tion / Paymen 4 Payment entries v. Voucher# 4 16002541	t History D Variation	Payment Status SUCCESSFUL SUBMITTED	Total (RM)	(01)	
X76	× Variation Variation Variation Variation Variation Variation Click on Varia Click on Varia Show 10 • # ▲ REF N 1 17057 2 17017	a Correspondence val History a Status tion / Paymen entries val 4 0002541 1 6002540	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:10 AM 28 Oct 2016 11:01 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 159.00 0.00	(1)	
X76	Variation Withdraw Payment Variation Explanation: Click on Variation Click on Variation Show 10 • # A REF N 1 17057 2 17017 3 17017	a Correspondence val History I Status tion / Paymen entries Voucher# 1 6002541 1 6002540 1 6002540 3 1 6002540	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:01 AM 28 Oct 2016 11:01 AM 28 Oct 2016 11:01 AM 28 Oct 2016 11:00 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 159.00 0.00 0.00		
X76	Variation Withdraw Payment Variation Explanation: Click on Variation Click on Variation Show 10 • # REF N 1 17057 2 17017 3 17017 4 17061	a Correspondence val History I Status Status d Payment entries No Voucher# 16002540 16002540 16002539 3 16002539	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:00 AM 28 Oct 2016 10:49 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 159.00 0.00 0.00 318.00		
X76		a Correspondence val History I Status d Paymen entries x. Voucher# 4 16002540 3 16002530 3 16002530 3 16002538	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:00 AM 28 Oct 2016 11:00 AM 28 Oct 2016 11:00 AM 28 Oct 2016 10:49 AM 28 Oct 2016 10:21 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 159.00 0.00 318.00		
X76		a Correspondence val History I Status I Status d Paymen entries A. Voucher# 16002541 16002541 16002530 a 16002530 a 16002530 a 16002530 a 16002530 a 16002530 a 16002530 a 16002530 a 16002530 b 1600250 b 1600250	Payment Date 28 Oct 2016 11:0 AM 28 Oct 2016 10:49 AM 28 Oct 2016 10:21 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 0.00 0.00 318.00 318.00		
EX76		a Correspondence val History Status Status d'Paymen d'Pa	Payment Date 28 Oct 2016 11:00 AM 28 Oct 2016 11:01 AM 28 Oct 2016 11:01 AM 28 Oct 2016 11:02 AM 28 Oct 2016 10:23 AM 21 Oct 2016 10:52 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 0.00 0.00 318.00 318.00 318.00 318.00 318.00		
X76		a Correspondence val History Status Status d'Paymen d'Pay	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:21 AM 28 Oct 2016 11:21 AM 28 Oct 2016 10:24 AM 28 Oct 2016 10:24 AM 21 Oct 2016 10:52 AM 21 Oct 2016 10:44 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 0.00 0.00 318.00 318.00 318.00 318.00 318.00 318.00		
EX76		a Correspondence val History a Status tion / Paymen dPaymen dPaymen dentis den	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:01 AM 28 Oct 2016 11:01 AM 28 Oct 2016 10:21 AM 28 Oct 2016 10:21 AM 21 Oct 2016 10:52 AM 21 Oct 2016 10:52 AM 21 Oct 2016 10:44 AM 21 Oct 2016 10:44 AM 21 Oct 2016 10:44 AM 21 Oct 2016 00:20 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 0.00 0.00 0.00 0.00 318.00 318.00 318.00 318.00 9318.00 9318.00 9318.00 9318.00 9318.00 9318.00 9318.00		
EX76		a Correspondence val History a Status titor / Paymen dentrespondence dentresp	Payment Date 28 Oct 2016 11:10 AM 28 Oct 2016 11:21 AM 28 Oct 2016 11:21 AM 28 Oct 2016 10:24 AM 28 Oct 2016 10:24 AM 21 Oct 2016 10:52 AM 21 Oct 2016 10:44 AM	Payment Status SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED SUCCESSFUL SUBMITTED	Total (RM) 0.00 <td></td> <td></td>		



Explanation:						
FG77 show a list of payment made by user.						
Click on the c	ard-icon to view pa	ayment Voucher.				
		S Payme	ent Voucher			
View Payment V	oucher					
Payment Vou	cher					
#53, Jalan Ten	nbaga SD 5/2B, Bandar Sri Damar		Date: 05-11-2016 Time: 12:35 PM Payment Amount: RM 318 00			
MALAYSIA			Payment Method: CC			
Dof No #	Transaction Dotail	Draduat Nama	Tupo	Dotail		
218	Transaction Detail	METROGYL TABLET 200MG				
Thank you.						
,,				Total Fee: 318.00		
0 Drint Aust	and the second se					
e Print Vouch	ier Lei view Rece	ipt				
Explanation:						
FG78 shows a	a sample voucher g	generated by the system	n.			
Click on Print	Voucher button to	print the voucher				
Click on View	Receipt button to	view the receipt (Recei	pt can only be view	with a successful payment)		
	FG77 show a Click on the c View Payment Vou Payment Payment Payment Payment Payment Payment Payment Payment Payment Paymen	FG77 show a list of payment ma Click on the card-icon to view p View Payment Voucher Payment Voucher PAYMENT VOUCHER #: 16002551 National Pharmaceutical Control Bureau Company Info: UNIMED SDN BHD #33, Jalan Tembaga SD 5/2B, Bandar Sti Damar 52200 KUALA LUMPUR WILAYAH PERSEKUTU MALAYSIA Ref No.# Transaction Detail 218 Thank you. Company Info: Explanation: FG78 shows a sample voucher ag Click on Print Voucher button to	FG77 show a list of payment made by user. Click on the card-icon to view payment Voucher. Payment Voucher View Payment Voucher Payment Voucher Payment Voucher Payment Voucher Payment Voucher Payment Voucher Payment Voucher Payment Voucher Company Info: UNIED SDN BHD #53, Jain Tembags SD 5/2B, Bandar Sri Damansara 5/200 KUALA LUMPUR WILAWAH PERSEKUTUAN KUALA LUMPUR MaLAYSIA Ref No.# Transaction Detail Product Name 2/16 MetROGYL TABLET 200MG Thank you. Point Voucher Explanation: FG78 shows a sample voucher generated by the system Click on Print Voucher button to print the voucher	FG77 show a list of payment made by user. Click on the card-icon to view payment Voucher. Payment Voucher View Payment Voucher Payment Vou	FG77 show a list of payment made by user. Clock on the card-icon to view payment Voucher Payment Voucher Payment	



FG79				ent Receipt				
	🗅 View Pa	yment Receipt						
	🖨 Paym	ent Receipt						
		KEMENTERIAN KESI	RESIT	MALAYSIA ENGAWALAN FARMASEUTII RASMI AAL	KAL KEBANGSAAN			
	Diterir No. Da Alama #53, J:	alan Tembaga SD 5/2B, Bandar Sri Damansara I KUALA LUMPUR WILAYAH PERSEKUTUAN KUALA LUMPU	R	i Maklumat Pembaya No. Resit: BPFK161105 Tarikh Bayaran: 05-11- Masa Bayaran: 12:35 P Kaedah Bayaran: CC Bank: WA No. Ruj. Transaksi: 110	18272 2016 M			
	Butiran E	Bayaran Terperinci						
	Bil.	Keterangan Bayaran/Transaksi	Product Name		No. Dokumen	Kod	Amaun (RM)	
	1		METROGYL TABLET 20	DOMG	16002551		318.00	
							318.00	
		Ini a No.	dalah cetakan komputer Sila cetak dan simpan i	dan tidak perlu ditandatang esit ini sebagai rujukan. an: KK/BSKK/10/600-2/1/2(3)				
EX79	Click on I	c ion: ow a sample Receipt. Print Receipt button to print the re View Voucher button to view vouc						
FG80	B Sa Tre Pa ≕ Va D Wit \$ Pay	iation w Application wed Form wrent Pending rriation Correspondence thdrawal yment History rriation Status						
EX80	Explanat	ion: Variation / Variation Status						



+ STATU	S TRAY - Applica	ation Status				
C SIATU.	з тюл - Арріса	non status				
			Pending	🗸 App	proved/Rejecter	d/Withdrawn
		ding Tab or Approved/Rejected Status of COS/Variation				
	ending Approva	I Variation/COS				
Show 10	 entries 			Search:		
#	Variation Code	Product Name	Status	РРР	API	LAB
21	212	MAL16100061TCZ SUPERMAN ® TONGKAT ALI 500MG NATURAL PRODUCT - HERBAL (MEDIUM)	SUBMITTED (PAID)	11	-	۶
22	5	MAL19900633A NEOSTIGMINE INJ BP 2.5MG IN 1ML PRESCRIPTION - FULL	EVALUATION APPROVED	*	-	~
23	136	MAL19870754AZ SALBUTANOL SULFATE TABLET 4MG PRESCRIPTION - FULL	EVALUATION APPROVED	~	~	-
24	191	MAL20051437A HAEMATE PINJECTION 250IU & 500IU BIOLGGICS - BLOOD PRODUCTS	EVALUATION APPROVED	×	-	-
25	205	MAL19973583A FRUSEMIDE INJECTION BP 10MG/ML,2ML PRESCRIPTION - FULL	EVALUATION APPROVED	*	-	-
26	213	MAL16100079TC TINGGI ™© HERBAL MEDIUM cap NATURAL PRODUCT - HERBAL (MEDIUM)	EVALUATION APPROVED	•	-	-
27	218	MAL19872165AZ METROGYL TABLET 200MG PRESCRIPTION - FULL	CORRESPOND EVALUATOR TO USER	#		~
28	18	MAL20081744A Optivate POWDER FOR INJECTION BIOL OGICS – BLOOD PRODUCTS	CORRESPOND USER TO EVALUATOR		-	-
29	27	MAL19871727A ZEET EXPECTORANT PRESCRIPTION - FULL	CORRESPOND USER TO EVALUATOR	,	-	-
30	91	MAL20081735A THYROGEN (THYROTROPIN ALFA) BIOLOGICS - BLOOD PRODUCTS	CORRESPOND USER TO EVALUATOR		-	-
Showing 21	to 30 of 33 entrie				1 2	3 4
	ows a list	of variation application with their status. d/Withdrawn/Rejected tab button to view Approved, V	Vithdrawn, or Re	ejected	variatio	on applic
↓ª QUI	EST3+ Variatio	un/COS Chronology				
Product	Info					
Product	Name	SALBUTAMOL SULFATE TABLET 4MG				
Registra	tion Number	MAL19870754AZ				
	ce Number	1986042471A				
	Category	PRESCRIPTION				
Category		FULL				
	n/CO S Inf o					
Applicat	ion Number	00000042				
Date Cre	eated	17 October 16				
Explanat	tion:					



FG82 show the detail of a Variation application.