

## **National Quality Control Laboratory**

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NQCL/F76 - 01

## ANALYSIS REQUEST FORM FOR MEDICAL DEVICES

2. Company Tel. No. & Email Address:  3. Name and Presentation of Product:  4. Name and Address of Manufacturer:  5. Sample Information: a) Date of Manufacture: b) Batch/Lot Number: c) Name and Amount of Active Ingredients on Label: d) Quantity Submitted: 6. Applicant's Reference Number: 7. Tests required by applicant. Mark (**) against each test required on the table below:    TEST	1.	Name and Address of	f Applicant (C	ompan	y): 				
4. Name and Address of Manufacturer:    Date of Expiry:	2.	Company Tel. No. &	Email Addres	s:	_				
5. Sample Information:  a) Date of Manufacture: b) Batch/Lot Number: c) Name and Amount of Active Ingredients on Label: d) Quantity Submitted: 6. Applicant's Reference Number: 7. Tests required by applicant. Mark (*) against each test required on the table below:    TEST	3.	Name and Presentation	<u> </u>						
a) Date of Manufacture: b) Batch/Lot Number: c) Name and Amount of Active Ingredients on Label: d) Quantity Submitted: 6. Applicant's Reference Number: 7. Tests required by applicant. Mark (*) against each test required on the table below:  TEST (*) *METHOD TES	4.	Name and Address of	<u></u>						
a) Date of Manufacture: b) Batch/Lot Number: c) Name and Amount of Active Ingredients on Label: d) Quantity Submitted: 6. Applicant's Reference Number: 7. Tests required by applicant. Mark (*) against each test required on the table below:  TEST (*) *METHOD TES	-	Campala Information			_				
b) Batch/Lot Number: c) Name and Amount of Active Ingredients on Label: d) Quantity Submitted: 6. Applicant's Reference Number: 7. Tests required by applicant. Mark (*) against each test required on the table below:    TEST	э.	_	1140				Data o	f Evnimu	
c) Name and Amount of Active Ingredients on Label: d) Quantity Submitted: Applicant's Reference Number: 7. Tests required by applicant. Mark (*) against each test required on the table below:    TEST		,							
d) Quantity Submitted: 6. Applicant's Reference Number: 7. Tests required by applicant. Mark (*) against each test required on the table below:    TEST		•						_	
7. Tests required by applicant. Mark (*) against each test required on the table below:    TEST			_	eatents	on Label:				
TEST (*) *METHOD TEST (*) *METHOD TEST (*) *METHOD TEST GLOVES    Sterility	6.	Applicant's Reference	e Number:						
TEST (*) *METHOD TEST (*) *METHOD TEST (*) *METHOD TEST GLOVES  2 Bacterial endotoxin	7.	Tests required by app	olicant. Mark (	(✓) aga	inst each test	requ	ired on the table belo	ow:	
Sterility			·	1 .		T			( <b>✓</b> ) *METHC
2 Bacterial endotoxin	1	Sterility		<del>  `                                   </del>			G	L	
Microbial contamination 13 Dimensions - Width 14 Dimensions - Thickness 14 Total lubricant 5 Burst volume 15 Syringe function 6 Freedom from holes (Conductivity) 16 Syringe package integrity 7 Visual leak test 17 Syringe air leak 18 Dimensions - Length 18 Syringe determination of pH 19 Dimensions - Width 19 Needle penetration 10 Dimensions - Thickness 10 Dimensions - Thickness 11 Wet package integrity 12 Appearance of needle point 14 Wet package integrity 12 Appearance of needle point 15 Appearance of needle point 16 Syringe determination of pH 19 Needle patency of lumen 10 Dimensions - Thickness 10 Dimensions - Thickness 10 Dimensions - Thickness 11 Wet package integrity 10 Dimensions - Thickness 11 Wet package integrity 10 Dimensions - Thickness 11 Syringe determination of pH 19 Needle patency of lumen 10 Dimensions - Thickness 10 Needle patency of lumen 11 Wet package integrity 10 Dimensions - Thickness 11 Syringe determination of pH 19 Needle patency of lumen 11 Wet package integrity 10 Dimensions - Thickness 11 Syringe air leak 10 Needle patency of lumen 11 Wet package integrity 10 Dimensions - Thickness 11 Syringe air leak 10 Needle patency of lumen 11 Wet package integrity 10 Dimensions - Wispard Phase Internationally recognized standards for testing.  Clients have three days to contact NQCL if they desire to change or use a method that was not identified at the time of sample receipt. 10 Name, Designation and Signature of Person Authorizing Request for Analysis:  Name:	2	· · · · · · · · · · · · · · · · · · ·		+		12			
CONDOMS  4 Total lubricant  5 Burst volume  6 Freedom from holes (Conductivity)  7 Visual leak test  8 Dimensions - Length  9 Dimensions - Width  10 Dimensions - Thickness  110 Dimensions - Width  110 Dimensions - Width  120 Needle patency of lumen  131 Wet package integrity  140 Name, Designation and Signature of Person Authorizing Request for Analysis:  150 Name, Designation and Signature of Person Authorizing Request for Analysis:  161 Name, Designation and Signature of Person Authorizing Request for Analysis:  175 Needle patency of Laboratory USE ONLY: Payment Details  186 Receipt Amount Paid:  196 Accountant:  197 Syringe function  198 Syringe package integrity  198 Syringe determination of pH  199 Needle penetration  199 Needle penetration  190 Needle patency of lumen  190 Needle patency of lumen  290 Needle patency of lumen  291 Appearance of needle point  291 Appearance of needle point  292 Needle patency of lumen  293 Needle patency of lumen  294 Needle patency of lumen  295 Needle patency of lumen  296 Needle patency of lumen  297 Needle patency of lumen  298 Needle patency of lumen  298 Needle patency of lumen  299 Needle patency of lumen  290 Nee	3		ึดท			13		-	
4 Total lubricant						14	Dimensions - Thickr	ness	
Burst volume	4		5112 G112						
6 Freedom from holes (Conductivity) 7 Visual leak test 8 Dimensions - Length 9 Dimensions - Width 10 Dimensions - Thickness 10 Dimensions - Thickness 11 Wet package integrity 12 Appearance of needle point 13 Wet package integrity 14 Amount 15 Name:  Designation:  Designature:  FOR LABORATORY USE ONLY: Payment Details  Receipt No.:  Amount Paid:  Accountant:  Signature:  Date:				1		15		THILD ILLEDI	
7 Visual leak test			Conductivity)	+			, ,	rity	
8 Dimensions - Length   18 Syringe determination of pH   9 Dimensions - Width   19 Needle penetration   10 Dimensions - Thickness   20 Needle patency of lumen   11 Wet package integrity   21 Appearance of needle point   11 Wet package integrity   21 Appearance of needle point   12 Appearance of needle point   13 Appearance of needle point   14 Appearance of needle point   15 Appearance of needle point   16 Appearance of needle point   17 Appearance of needle point   18 Appearance of needle point   18 Appearance of needle point   19 Appe		· ·	zonauctivity)	1				,,	
9 Dimensions - Width 19 Needle penetration 10 Dimensions - Thickness 20 Needle patency of lumen 11 Wet package integrity 21 Appearance of needle point 22 Appearance of needle point 22 Appearance of needle point 23 Appearance of needle point 24 Appearance of needle point 25 Appearance of needle point 26 Appearance of needle point 27 Ap				1				n of nH	
10 Dimensions - Thickness		O		+			' '	ii or pri	
Wet package integrity			ec .	<del>                                     </del>			=	nen	
The client must specify method of analysis to be used.  Note: In all cases, preference is given to use of internationally recognized standards for testing.  Clients have three days to contact NQCL if they desire to change or use a method that was not identified at the time of sample receipt.  D. List any other items submitted:  10. Name, Designation and Signature of Person Authorizing Request for Analysis:  Name: Designation: Signature: Date:  Contact details (Phone Number):  FOR LABORATORY USE ONLY: Payment Details  Receipt			-55	<del> </del>			- ,		
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Name: Designation: Signature: Date: Contact details (Phone Number):  FOR LABORATORY USE ONLY: Payment Details  Receipt	<u>Note:</u> l Clients	In all cases, preference is given shave three days to contact leads to con	ven to use of inter NQCL if they des	nationall				e time of sample	e receipt.
Contact details (Phone Number):  FOR LABORATORY USE ONLY: Payment Details  Receipt		9	O		O	-	•	D.	
FOR LABORATORY USE ONLY: Payment Details  Receipt			_			_	nature:	Date:	
Receipt Amount Signature: Date:	Cont	act details (Phone Nun	nber):			_			
Receipt Amount Paid: Accountant: Signature: Date:			FOR LAB	ORAT	ORY USE ON	NLY:	Payment Details		
	Rec	eipt							
D ( D ' )	No.	:	Paid:		Accountar	nt:	Signature:		Date:
Date Received:	Date	e Received:							
Received by: Authorized by:	Rec	eived by:					Authorize	ed by:	
Laboratory Reference No. NDQ	Lab	oratory Reference No.	NDQ						

## SAMPLE RECEIVING CHECKLIST

(For Laboratory Use Only)

			✓ Appropriate box						
ANALYSIS REQUEST FORM									
1.	Duly filled and signed in du	Yes: □No: □							
2.	Appropriate tests selected a	Yes: No:							
3.	Right Method Indicated aga	Yes: ☐No: ☐							
	SAMPLE INSPECTION								
1.	Quantity as per sample sub	mission guidelines	Yes:□No:□						
2.	Sampling labelling requirer Label claim, Manufacturer, M	Yes:□No:□							
3.	Sample packaged in a comm	nercial pack in good condition	Yes: No:						
4.	Storage conditions maintain	ned as per manufacturer's instructions	Yes: No:						
5.	More than 1 year remaining	Yes: No:							
6.	Sample details match detail	Yes:□No:□							
		ACCOMPANYING DOCUMENTS							
1.	Manufacturer's Method of A	Analysis provided	Yes:□No:□n/a:□						
2.	Specifications included with	Yes:□No:□n/a:□							
3.	Validation data on CD		Yes:□No:□n/a:□						
4.	Amount paid corresponds t	to the Quotation provided	Yes: \_No: \_						
DEVIATIONS									
1.	Any deviations from the sar	Yes:□No:□							
If yes please give detailed reasons;  Deviation Initiated by:  Deviation Approved by:									
		ation Approved by:							
	Name:								
	Signature:								