National Quality Control Laboratory
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NQCL/F76 - 01

ANALYSIS REQUEST FORM FOR MEDICAL DEVICES

1. **Name and Address of Applicant (Company):** _____
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:** _____ **Date of Expiry:** _____
   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		TEST	(✓)	*METHOD
1	Sterility			GLOVES			
2	Bacterial endotoxin			12	Dimensions - Length		
3	Microbial contamination			13	Dimensions - Width		
CONDOMS				14	Dimensions - Thickness		
4	Total lubricant			SYRINGES AND NEEDLES			
5	Burst volume			15	Syringe function		
6	Freedom from holes (Conductivity)			16	Syringe package integrity		
7	Visual leak test			17	Syringe air leak		
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		

*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.

9. 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 No.:		Amount Paid:		Accountant:		Signature:		Date:	

Date Received: _____

Received by: _____ **Authorized by:** _____

Laboratory Reference No. NDQ _____

SAMPLE RECEIVING CHECKLIST

(For Laboratory Use Only)

		✓ Appropriate box
ANALYSIS REQUEST FORM		
1.	Duly filled and signed in duplicate	Yes:☐ No:☐
2.	Appropriate tests selected as per quotation	Yes:☐ No:☐
3.	Right Method Indicated against each test	Yes:☐ No:☐
SAMPLE INSPECTION		
1.	Quantity as per sample submission guidelines	Yes:☐ No:☐
2.	Sampling labelling requirements met (*Name, Expiry date, Batch number, Label claim, Manufacturer, Manufacturer's address, Country of origin*)	Yes:☐ No:☐
3.	Sample packaged in a commercial pack in good condition	Yes:☐ No:☐
4.	Storage conditions maintained as per manufacturer's instructions	Yes:☐ No:☐
5.	More than 1 year remaining on shelf life	Yes:☐ No:☐
6.	Sample details match details filled on analysis request form	Yes:☐ No:☐
ACCOMPANYING DOCUMENTS		
1.	Manufacturer's Method of Analysis provided	Yes:☐ No:☐ n/a:☐
2.	Specifications included with the method of analysis	Yes:☐ No:☐ n/a:☐
3.	Validation data on CD	Yes:☐ No:☐ n/a:☐
4.	Amount paid corresponds to the Quotation provided	Yes:☐ No:☐

DEVIATIONS

1.	Any deviations from the sample submission guidelines	Yes:☐ No:☐

If yes please give detailed reasons;

	Deviation Initiated by:	Deviation Approved by:
Name:		
Signature:		
Date:		