YTY INDUSTRY (MANJUNG) SDN BHD
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

SECTION (i) - AMENDMENT LOG

Old Revision	New Revision	Page Affected	Effective Date	Changes	Revised By	Approved By
Nil	Issue 1 Rev. 0	All	1/1/2003	New Procedure	Kumari	Arivalagan
0	1	5	1/9/2004	Revise the Calcium Carbonate spec from 1-3% to 1-4%	Kumari	Arivalagan
1	2	5	15/6/05	Revise the Calcium Carbonate spec from 1-4% to 3-8% and Calcium Nitrate from 8-14% to 10-16% & Chlorine rpm from 300-900 to 300-1100	Kumari	Arivalagan
2	3	3 & 4	15/3/2010	Revise to remove the Iodine Test under ref. & note for Block A gloves	Julia	Arivalagan
3	4	4&5	1/4/2011	Force at Break revise from 9N to 6N Before Aging and additional records and remove issue	Punitha	Arivalagan
4	5	3	25/4/2011	Add YTY 1004/05 in clause 6.1.5	Punitha	Arivalagan
5	6	2-5	16/10/2013	As per current practice.	Sugumaran	Arivalagan
6	7	3	17/2/2014	Revise clause 6.1 (Table a). Add Polymer.	Thava	Arivalagan
7	8	All	1/5/2015	Change to new logo	Syamsida	Arivalagan
8	9	Page 3	01/09/2018	Revise clause 6.4.2 (b) to add sampling time	E. Jaya	Punitha
9	10	Page 3	01/12/2018	Revise clause 6.4.2 (b) to add sampling time	E. Jaya	Punitha
10	11	Page 2 & 4	28/08/2019	Add clause 5.3. 5.4, 6.2.5 and 6.2.6	Punitha	Jayan
11	12	Page 4 & 6	20/10/2019	Revised cause 6.1, 7.8,7.9 and 7.10	A'ain Hidayah	Monichan
12	13	Page 5	09/03/2020	Revised clause 6.1.2 a & 6.1.2 b	Nesamany	Punitha
13	14	Page 3, 4	01/12/2023	Revise clause 6.1.2 a) and 6.1.2 b), Add for Aloe Vera Surface Coating	A'ain Hidayah	Vengatesh

YTY 1004 INSPECTION AND TESTING – ON LINE CHLORINATED POWDER FREE NITRILE EXAMINATION GLOVES

1.0 OBJECTIVE

The objective of this inspection and testing is for ensuring that materials used and product produced are meeting the specification set.

2.0 SCOPE

This procedure applies to in-process inspection and tests and final random inspection for On Line Chlorinated Powder Free Nitrile Examination Gloves.

3.0 REFERENCE

Final Random Inspection - YGD1002
Procedure for Testing of Residual Powder Content of Gloves – QA III 100125
Physical Properties Test Method (ASTM Standard) – QA III 100126
Physical Properties Test Method (EN 455 Standard) – QA III 100127
Determination of Moisture Content of Gloves – QA III 100118

4.0 DEFINITION

Nil

YTY INDUSTRY (MANJUNG) SDN BHD
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

5.0 RESPONSIBILITY

5.1 The Lab Assistant is responsible for ensuring all testing on in-process materials are performed as per documented procedure.

5.2 The QA Inspector is responsible for ensuring that gloves are checked and graded correctly and ensuring finished products are meeting in house or customer's specification before delivery.

5.3 WIP personnel is responsible to inform QA for lots that have been stored for more than 2 months for the glove condition.

5.4 Packing QC personnel is responsible to randomly check the glove condition before packing

6.0 PROCEDURE

6.1 IN-PROCESS MATERIALS TESTING

6.1.1 Compounded nitrile and chemicals shall be tested and approved before being issued to production.

6.1.2 The tests and frequency of the testing for the chemicals and solutions are as follows:

a) Compounded Nitrile Latex and Chemicals

ITEMS	PARAMETERS (UNIT)	FREQUENCY	SAMPLING QUANTITY
Nitrile Latex	Total solid content (TSC %)	Every batch	100 ml
	pH		
Coagulant	Calcium Nitrate Content (CN %)	Every batch	100 ml
	Coagulant Powder Free (CPF %)		
Polymer	Total Solid Content (TSC %)	Every batch	100 ml
Polyslip Polymer	Total Solid Content (TSC %)	Every batch preparation & 6 hourly for in use bulk	100ml
	pH		
	Hardness		
	Total Dissolve Solid (TDS) (ppm)		
Aloe Vera Surface Coating	Total Solid Content (TSC %)	Every batch preparation & 6 hourly for in-use bulk	100ml
	pH		
	Bioburden (CFU/ml)	Every batch	Direct from source

b) On Line Testing

YTY INDUSTRY (MANJUNG) SDN BHD
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

ITEMS	PARAMETERS (UNIT)	FREQUENCY	SAMPLING QUANTITY	SAMPLING TIME	
Nitrile Latex	Total solid content (TSC %)	6 hourly	100 ml	7 am	Bottom for Side A and B
				1 pm	Top for Side A and B
	pH			7 pm	Bottom for Side A and B
				1 am	Top for Side A and B
Coagulant	Calcium Nitrate Content (CN %)	6 hourly	100 ml	7 am	Both side A & B
				1 pm	
	Coagulant Powder Free (CPF %)			7 pm	
				1 am	
Chlorine	Chlorine Strength (ppm)	6 hourly	100 ml	7 am	One sample for each line
				1 pm	
				7 pm	
				1 am	
Acid	Percentage of Nitric Acid (% of Nitric Acid Strength)	12 hourly	100 ml	11 am	Both Tank (1& 2)
				11 pm	
Alkaline	Percentage of Alkalinity (% of Alkalinity)	12 hourly	100 ml	11 am	Both Tank (1& 2)
				11 pm	

Polyslip Polymer	Total Solid Content (TSC %)	6 hourly	100ml	7 am	One sample for each line
	pH			1 pm	
	Hardness			7 pm	
	Total Dissolve Solid (TDS) (ppm)			1 am	
Aloe Vera Surface Coating	Total Solid Content (TSC %)	6 hourly	100ml	7 am 1 pm 7 pm	One sample for each line
	pH			1 am	
	Bioburden (CFU/ml)	Once per day	Direct from source	Once per day	Once per day

6.1.3 For batches that failed the testing, a CAR will be issued to the production department to carry out corrective action.

6.1.4 A retest will be done on the reworked compounded material before issuing for production use.

6.1.5 All testing results are to be documented in the On Line Laboratory Testing format, YTY 1004/01,YTY 1004/05, YTY 1004/11, YTY 1004/12 and YTY 1004/13.

6.2 QA Buy Off On Gloves – Process Inspection and QA Re inspection

6.2.1 Nitrile powder free gloves will be inspected by QA Inspectors as per Defect Criteria, YGD 1001/03.

6.2.2 Sampling and inspections are carried out as per documented procedures in YGD 1001 for process inspection.

6.2.3 Passed batches will be sent to packing. Failed batches will be sent for QC screening.

6.2.4 Screened gloves will be re-inspected as per procedure QA III 100113, any batch that failed the 2nd buy off will be downgraded.

6.2.5 WIP before delivering the 2 months stock gloves to Packing will request QA to check the condition before sending to Packing.

6.2.6 Packing Line Inspector will check glove condition for every basket before giving to Weighing Operator. If found any sticky issue they will reject and pass back to WIP.

YTY INDUSTRY (MANJUNG) SDN BHD
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

6.3 Finished Product Inspection

6.3.1 A Final Random Inspection (FRI) and the sampling and inspection will be carried out as per documented procedures in YGD 1002.

6.4 PRODUCT TESTING

6.4.1 The Lab Assistant/QA Inspectors will carry out product testing of the powder free nitrile gloves.

6.4.2 The following tests are carried out in house.

TEST	SAMPLING	SPECIFICATION
Residual Powder	Minimum one batch per week Sampling: 5 pcs per size and per type	Average of 5 pcs Max 2.0mg/glove
Moisture Content	Minimum one batch per week Sampling: 5 pcs per size and per type	Average of 5pcs Max 2.0%
Tensile Strength i) ASTM D6319 ii) EN 455 Part 2	One batch per week production ASTM D6319 Sampling plan: S-2 AQL: 4.0 Accept: 1 Reject: 2 Sample size: 13 pcs <u>EN 455 Part 2</u> Sample size : 13 pcs Acceptance: Median to meet minimum specification	ASTM D6319 <u>Tensile Strength</u> B.A: Min 14 MPa A.A: Min 14 MPa <u>Ultimate Elongation</u> B.A: Min 500% A.A: Min 400% EN 455 Part 2 <u>Force at Break</u> B.A: 6 N min A.A: 6 N min

Note: For specific customer requirements, sampling plan and acceptance criteria will be based on the customer specification.

YTY INDUSTRY (MANJUNG) SDN BHD
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

7.0 RECORDS

7.1 On Line Laboratory Testing – YTY 1004/01
7.2 List of Defects – YTY 1004/02
7.3 Specification – YTY 1004/03
7.4 QA Grading Result – YTY 1004/04
7.5 On Line Laboratory Testing – On Line Chlorination (NBR Gloves) – YTY 1004/05
7.6 QA Grading - On Line Polymer Coated Nitrile (YTY 1004/06)
7.7 Production Specification YTY 1004/07
7.8 QA Grading Result – YTY 1004/09 (for Halyard product only)
7.9 Compounding and Nitrile Specification YTY 1004/10
7.10 Polyslip Polymer Testing (Compounding Preparation) YTY 1004/11
7.11 Polyslip Polymer Testing (Compounding in use) YTY 1004/12
7.12 Polyslip Polymer Testing (Production Dipping) YTY 1004/13
7.13 Durability Test Record YTY 1004/14
7.14 Pure Aloe Testing YTY 1004/15