

Annex I

A. Typical Condom manufacturing process

INTRODUCTION

The male contraceptive condoms are manufactured from natural rubber latex. The salient processes involved in the manufacture are as follows.

1. Compounding
2. Moulding
3. Vulcanizing
4. Inspection
5. Packing

COMPOUNDING

The first and most important step in the manufacture of condoms is the compounding process. Various chemicals such as vulcanizing agent, activator, accelerator, anti oxidant, stabilizer, dispersing agent etc. are finely ground and are compounded with rubber latex in the predetermined ratio in the mixing tanks. The mixture of latex and chemicals are continuously agitated, heated and maintained at specified temperature for several hours for pre-vulcanization. It is then cooled. After cooling, a quality inspection of the compound is performed for checking the physical properties such as total solids, pH, Viscosity, MST, tensile strength and elongation. The compounded latex is then transferred to supply tanks.

MOULDING

The latex from supply tanks is fed to the dipping tanks of the moulding machine by gravity. During the dipping operation, the glass moulds mounted on the conveyor dips into soap solution tank and these moulds are immediately brushed and washed with the help of a mould-washing unit. After washing, these moulds are dried when the conveyor passes through a mould-drying booth. These moulds are cooled in the mould-cooling bath immediately after the drying. Then the moulds are dipped in the dipping tank, kept in the dipping room, in which a constant latex level is maintained.

After first dipping these moulds are passed through a drying chamber to which hot air is supplied at a controlled temperature. This single dipped product is again brought back to the dipping tank for the 2nd dipping after which it again passes through the drying chamber. The temperature of dipping room, hot air supply and drying chamber are precisely controlled to get the correct quality of the product. After drying, these moulds

pass through the edge-rolling unit. The edge rolled condoms then passes through the vulcanizing booth before the same is dipped into swelling agent and thereafter through the anti sticking agent. The condoms are stripped from the glass moulds using slurry jets and the product along with the slurry is conveyed through PVC pipeline to the dehydrator. The moulds are then washed, cleaned, dried and cooled before the next dipping.

VULCANISING

In this process area, the slurry supply tank, agitator for mixing the slurry, slurry pumps etc. are installed. Slurry from slurry supply tank is pumped to the stripping unit of moulding machine. The return slurry from dehydrator goes to the slurry supply tank. The stripped products are separated from the slurry in the Dehydrator and further drying is achieved by hot air.

Dehydrator consists of rotary mesh barrel fabricated out of stainless steel material. This barrel rotates at a low speed. The condom along with the slurry is conveyed into the rotary barrel. Most of the slurry is discharged into the SS hopper provided underneath and it goes to the slurry supply tank. The discharge end of the barrel rotates inside a hot air chamber and at this point the condoms are completely de-hydrated and then pneumatically carried to the vulcanising machines.

The products are then transferred pneumatically to the vulcanising barrels of the Automatic Vulcanising Machines. The product are dried and vulcanised for fixed duration at a fixed temperature. After vulcanisation the condoms are transferred to a quenching machine where it is air cooled by rotating in barrels.

INSPECTION

The products after the vulcanization and quenching undergo various quality control checks (Half Product Inspection). The selected lots then go to the inspection section where 100% pinhole testing is performed in an electronic pinhole testing (inspection) machine. Inspection machine consists of a conveyor on which steel moulds are mounted in two rows. The vulcanised condoms are covered on the moulds manually. The condoms are tested for pinholes and rolled in this machine. Condoms with and without pinholes are separated. Once started the complete operation of the inspection machine, other than covering of condoms, is automatic.

QA

After 100% pinhole test, the product passes through QA section for random sampling and test. Here the specified samples are drawn from each batch/lot and subjected for various

tests as stipulated in the standards/documented procedure. The batch passed these tests will flow the next stage of operation.

PACKING

After Inspection the final product quality control section checks the accepted products. Here the condom samples are again tested. The lots that pass the tests are sent for packing. In the packing section, depending on the customer requirement, the condoms are lubricated and packed as rectangular or square shaped packs, (called primary packaging). They are then further packed in wallets, dispenser cartons and master cartons as per the customer requirement before dispatch.

B. Brief information on HLL Irapuram Factory ,Cochin (HLL IFC)

HLL IFC unit located at Irapuram, Cochin was set up in 2014 with an annual production capacity of 276 million pieces of Male Latex Condoms. The facility is equipped with modern machines and equipment for production, inspection and quality testing

HLL IFC commenced its machine installation by refurbishing of two moulding machines at Irapuram in Kerala on Jan 04, 2014 under the technical collaboration with M/s. KENDEK, MALAYSIA for manufacture of Male Latex Condoms and these moulding machines are identified as M2 and M3. Two more machines are additionally fabricated and installed indigenously in April 2014 and named as M4 and M5.

Male Latex Condom production at HLL IFC includes compounding, moulding, vulcanizing and half product testing. The other activities like electronic testing, primary packing, secondary packing and QA are carried out in other HLL Lifecare units. In near future, HLL IFC plan to manufacture Female Latex Condom with a capacity of 25 Mpcs per annum.

Location :

**HLL Lifecare Ltd
Plot No.1& 2,
Rubber Park,Irapuram
Valayanchiagara Post
Ernakulam dist-683 556
Kerala,India.**

Land Area	: 306 Cents
Building area	: 3168 Sqm
Technology used	: Latex dipping technology
No.of Production lines	: 4 Nos (2 Kendek Machines + 2 Lifecare Machines)
Production Capacity	: 276Mpcs/Annum Natural Male Latex

HLL IFC -Manufacturing license Details:

License No	Scope	Issued by	Validity
17/25/14	Manufacture of male condoms at Primary Production stage	Drugs controller and licensing authority	23/09/2019

Staff Strength :

Section	Controlling officer	Supervisor	Assistants	Total
Production	1	5	32	38
Quality Assurance	1	3	9	13
Engineering	1	4	7	12
Stores	-	-	1	1
Purchase	1	-	1	2
Finance	1	-	1	2
HR	1	-	2	3
Total	6	12	53	71

No.of Shifts :

Section	No.of Shifts	Shift time
Production	3	6.00-14.00 , 14.00-22.00, 22.00-06.00
Quality Assurance	3	6.00-14.00 , 14.00-22.00, 22.00-06.00
Engineering	3	6.00-14.00 , 14.00-22.00, 22.00-06.00
Stores	1	09.15 -17.15
Purchase	1	09.15 -17.15
Finance	1	09.15 -17.15
HR	1	09.15 -17.15

Process Flow Chart – Condom Production

Incoming material

