

YOUR PARTNER FOR PRIMARY RUBBER PACKAGING COMPONENTS

Samsung Medical Rubber



- 01 | What can you do ?

- 02 | Final Treatment for all application
Process flow and quality concept

- 03 | Advanced Solution

- 04 | Products

- 05 | Who are you?

01

Quality System that satisfies customers

It maintains stable and continuous quality based on a quality management system created in accordance with GMP regulations and strict quality management system certified by ISO 15378, ISO 9001. Through the production of products based on such an uncompromising quality management system, we are striving to make products that customers can trust with confidence.



<ISO 15378 / ISO 9001>

02

Quick development response with various proven development options

Based on know-how accumulated over 40 years, we have 145 proven formulation recipes various designs, coatings, etc., and low extractable study, so customers can request new development with confidence. In the process of developing new products, each suitable options for customers is presented, and a short development lead time is provided to customers by speedy responding to customer requirements. Even now, we are constantly developing the formulation and the design in preparation for future customer requirements.



<PATENT>

03

Transparent management of all production processes

By applying MES system (barcode system) into the production process, it is possible to transparently manage the entire production from raw materials to inished products. In addition, if the customer needs, by applying the patented Hybrid Laser Marking to the stopper, the customer can complete the perfect traceability of the each stopper one piece by one piece. (Korea Patent Application 10-2020-0102905)



<NON-CYTOTOXIC CERTIFICATION>



<EXTRACTABLE STUDY>

Final Treatment for all application Process flow and quality concept

Final treatment for all application

We are striving to produce low particle products in an extremely clean production environment through WFI in cleanroom Class A /ISO 5.

SILICONIZATION

- SLPC™: Samsung Low particle Coating
- SPIC™ Samsung Proprietary Inert coating : Teflon Coating on Standard Formulation and most common design on drug contact and/or top side of the closures

PACKING

- RFS packing / RTU packing

EXTRA TREATMENT

- Gamma Irradiation

CAMERA INSPECTION

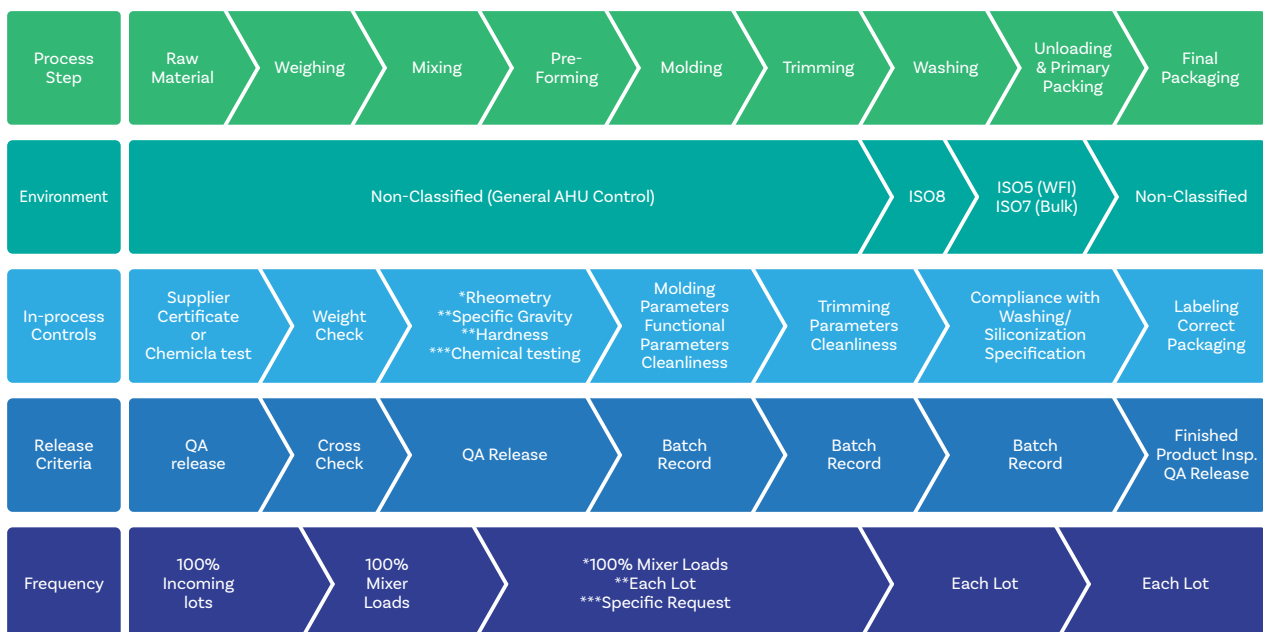
- SICV™ (Samsung Inspection Camera Vision available for specific needs)

Certificate of Analysis in compliance with the requirements of USP, EP and JP

ISO CERTIFICATE

- ISO 9001 and ISO 15378

Process flow and quality concept



True Traceability System™

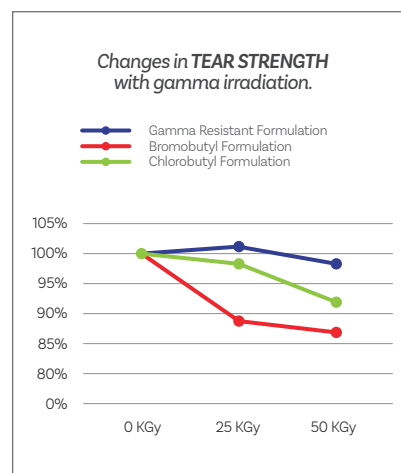
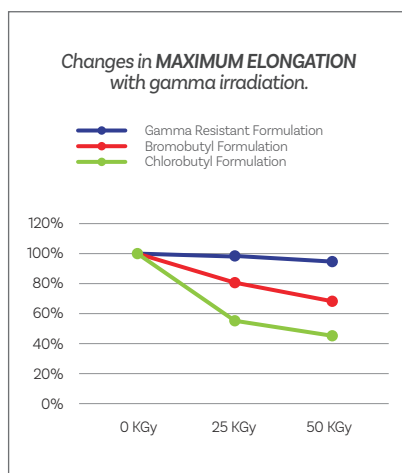
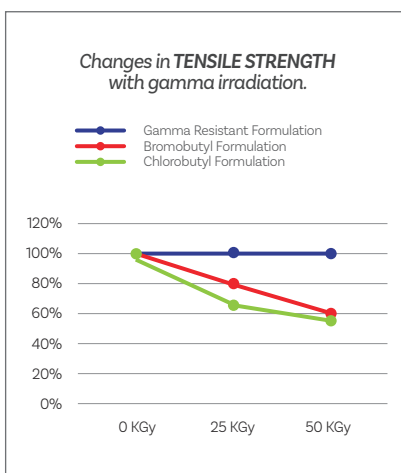
MES System enables complete the traceability from raw materials to finished products, and In addition, If a customer requests the application of patented Hybrid Laser Marking on a product, the traceability of the each products one piece by one piece can be completed.



Gamma Resistant Formulation

The formulation was developed that responds to the trend of high-dose gamma sterilization (Over 25KGy) is required.

This formulation minimizes the deterioration of the physical properties of the product due to the breaking of the cross-link of the molecular structure at the high dosage of gamma sterilization.



< COMPARISON OF GAMMA RESISTANT FORMULATION AND EXISTING FORMULATION PROPERTIES >

Components for Prefilled Syringe

• 1ml PFS Plunger, 10ml Plunger, Needle Cap, Tip cap



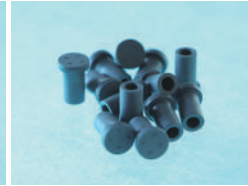
1ml PFS plunger



3ml PFS plunger



5ml PFS plunger



9ml PFS Tip cap



10ml PFS Plunger stopper



20ml PFS plunger

TEFLON Coated

• 13mm Iyo Igloo, 20mm Iyo 3leg top coated, 20mm 2leg top coated, 20mm ETFE Coated, 32mm ETFE Coated, 20mm Iyo JDT2



13mm Iyo igloo top coated



15mm back side coated



20ml Iyo JDT 2leg top coated



20mm Iyo 3leg Teflon top coated



32mm Teflon coated_back side

Small Volume Parenterals

1. Liquid & Sterile Powder Standard Designs

• 13mm ISO, 13mm No POP, 20mm ISO, 20mm No POP, 20mm OP



13mm No pop



20mm No pop



20mm stopper OP

2. Freeze-drying standards designs

• 13mm Iyo, 20mm Iyo 1 UK



13mm Iyo2leg



20mm Iyo window



32mm Iyo 2 leg

Large Volume Parenterals

• 32mm ISO IV, 29mm IV, 32mm Iyo



29mm ISO IV



32mm ISO IV

Cartridges

- Dental Plunger



7ml Dental plunger

Aluminum Cap

- We are supplying the aluminum cap with variety of colors depending on customer's needs and preference



Short term Contact and Diagnostic Application

- IV components : Injection ports and giving sets | IV Port Stopper, IV Connectors



IV Injection point



IV Port liner



Latex free sleeve stopper



Latexfree flash bulb



NR Flash Bulb

Plunger

- 2.5ml, 5ml, 10ml, 20ml, 50ml, 100ml | 0.3ml, 0.5ml, 1ml for insulin plunger



0.3ml insulin plunger



0.5ml insulin plunger



1ml insulin plunger



5ml plunger_syringe

ETC

We are developing and producing pharmaceutical products with variety of materials and colors depending on customers' needs and preference.



20mm lyo window Yellow



Blood Collection Blue



Blood Collection Purple



Dropper



Vaccum Blood Stopper

Samsung Medical Rubber Co., Ltd. is striving with the top priority to introduce products that our families can trust and feel at ease in the present and future when health / sanitation is the focus of attention and importance is rising.

Our Vision and Values

- Uncompromised Business Ethics
- Trust and Respect for every individual and organization
- Responsibility towards our workers and shareholders, our business partners, our social environment
- Honesty and transparency in all activity and communication

History

- 2020 • Introduction of True Traceability System™ Korean Patent applicaton 10-2020-0102905
- 2016 • New cleanroom plant in Hwaseong
- 2015 • R&D: Extractable Test (Toxicon) Completion
- 2014 • ISO 15378 Certified
- 2008 • FDA DMF Type III deposited
- 1999 • Patent for ETFE coated stoppers
- 1998 • ISO 9001 Certified
- 1993 • KS (Korea Standard) mark certified.
- 1979 • Company established in Seongnam





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