



**SAMSUNG  
MEDICAL  
RUBBER**



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# Your partner for the development and production of high quality pharmaceutical primary packaging components

# Management philosophy

create added value by honest way,  
customers and members  
being happy and well-doing,  
which has strong life force organization

### OUR PROMISE

We Samsung Rubber, apply the strictest Quality standards to supply our customers and final users with high performance, user-friendly components



## SAMSUNG MEDICAL RUBBER

### KNOW-HOW

35 years of experience in pharmaceutical rubber, proprietary formulation and film coating.

### COMPLIANCE

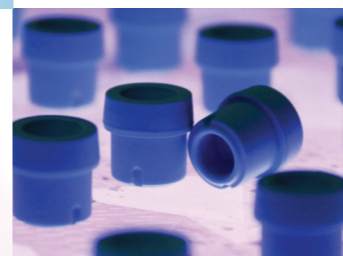
Raw materials aligned with international safety standards.

### HIGH PERFORMANCE

Our technologies on rubber formulation guarantee remarkable physical and chemical performances which meet customers' needs.

## History

- 2012** Upgrade of Clean Room to class A standard and validation of new washing process
- 2012** New R&D Center established
- 2012** Injection molding process applied
- 2011** Acquires the certification for a component and material specialist company
- 2010** Expansion 2nd factory
- 2008** FDA's drug master file TYPE III (DMF 21539)
- 2006** Utility model for connection port system
- 2004** ISO 13485 certification (TUV)
- 2001** Registers the design of Ringer's solution giving set
- 1999** Patent for laminated serum stopper  
EN46001 (TUV)
- 1998** ISO 9001 certification (TUV)
- 1993** KS mark obtained for quality system and production process
- 1980** Compliance with the Korea Pharmacopeia of formulation
- 1979** Company foundation



## We value the pursuit of quality, safety and health

Samsung medical rubber established in 1979 with the goal to contribute to the customers & Pharmaceutical company.

We have duty for social responsibility of enterprises through the supplying world first class product & fulfilling the customer service.

We have acquired not only KS standards certification in 1993 against rubber stopper for pharmaceutical use for the first time over Korean medical equipment manufacturers but also ISO 9001 & ISO 13485 certification to assure our quality control.

our advanced laminated stoppers are patented in Korea through laminating technical development & reserch during 3 years.



Our standard formulation include Butyl rubber (Chloro, Bromo) Natural rubber, Isoprene rubber, Butadiene rubber, Silicone rubber. Specially, we are proud of highest quality of IR formulation which is specialized for intravenous dispensing systems.

Our product meet the standards of the European, Korean, Japanese and United States Pharmacopoeia's. For FDA approval we provide USP Class VI test approval formulation with test reports.

Our low extractable/low moisture vapor transmission formulations are designed for a variety of lyophilization applications as well.

The right elastomeric formulation is the key to a safe and successful products. SAMSUNG MEDICAL RUBBER's standard formulations meet the requirements of the major pharmacopoeias.

When a standard formulation does not meet the needs of unique custom application, we will apply our expertise in formulation technology and rubber compounding to develop a custom solution to meet our customer's requirements.

# PRODUCTS

## Stoppers

We offer a wide product range suitable for all application.

Pharmaceutical containers must be made with non\_active rubber formulations and designed to ensure tight sealing of containers and long-term contact with the pharmaceutical products. To prevent fragmentation, a low-core rubber material must be selected for multi-dose purposes.

Rubber Stoppers	SIZE	UOD	LOD	H
	13mm(Gray)	12.50	7.80	6.30
	13mm(Red)	12.50	7.80	6.30
	15mm	14.20	9.20	6.00
	20mm(A)	18.80	13.20	8.00
	20mm(B)	18.90	13.20	8.80
	30mm (A)	30.50	23.50	14.20
	30mm (B)	31.50	21.80	13.00

Lyophilizaion Stoppers	SIZE	UOD	LOD	H
	13mm (A)	12.50	7.80	12.30
	13mm (B)	12.40	7.80	11.20
	15mm	14.50	9.50	11.00
	20mm (A)	18.80	13.10	15.00
	20mm (B)	19.20	13.30	14.30
	20mm (C)	19.10	13.55	14.00

Rubber Stoppers for Blood Collection tube	UOD	LOD	H	
	EDTA	16.40	11.20	14.80
	VACUJECT 13.6	16.80	14.30	17.00
	VACUJECT 10.8	16.20	10.80	15.50
	MONO CAP	OD	ID	H
MONO CAP	16.60	11.00	17.00	

Laminated Stoppers	We are proud to offer our advanced laminated stoppers coated with ETFE & FEP film. They Provide excellent barrier properties, lubricity, cleanliness and enhanced quality, all of which contribute added quality to your packaged drug product. Laminating film presents an inert barrier and is unsurpassed at significantly reducing interaction between the drug and stoppers.					
	Our advanced laminated stoppers are patented in Korea (No. 0247709).					

Ready-to-Sterilize Stopper	Our advanced ready-to-sterilize packaging offers an excellent solution to reduce costs for our customers. Stoppers can be packed in a sterilizable bag after they are rinsed and siliconized appropriately for direct introduction to steam sterilizers. Ready-to-Sterilize stoppers are low in particulate levels and can streamline the manufacturing process through elimination of the wash, rinse and siliconizing process.					

# PRODUCTS

## Disc / Spoid / Plungers / Intravenous dispensing system

Samsung Medical Rubber has developed products to meet customers' needs and wants of rubber raw materials formulated standards and by use of the customer base and accumulated technologies developed to provide special services.

Rubber Disc	SIZE	OD	ID	H
	30mm	29.80		4.75
	30mm	29.80		4.80

Spoid	SIZE	UOD	LOD	H
	0.5ml	9.00	15.70	20.90
1ml	11.00	17.00	29.50	

Rubber Plungers	Insulin Gasket	SIZE	OD	H	
		0.3ml	3.32	5.10	
		0.5ml	4.30	5.50	
		1ml	5.00	5.90	
	General Rubber Gasket	1CC	A1	5.15	6.50
			G1	5.05	4.40
		3CC	A3	10.00	8.50
			SY3	9.30	4.80
		5CC	A5	13.05	8.70
			SY5	12.40	6.90
		10CC	A10	16.40	9.30
			SY10	15.20	7.20
20CC		SY20	20.20	9.60	
50CC		AS50	27.75	11.00	
100CC	AS100	36.80	10.50		

Intravenous dispensing system	TYPE	UOD	LOD	OD	ID	H
	Y-Sleeve stopper (Type I)			7.60	4.40	10.40
	Y-Sleeve stopper (Type II)	5.20	7.60			16.30
	Y-Sleeve stopper (Latex Free)	4.40	7.00			16.00
	Sleeve stopper 30mm	15.60	20.80			31.20
	IV-2.6 (Latex)			9.20	2.60	44.00
	IV-3.0 (Latex)			12.30	3.00	48.50

Intravenous dispensing system	IV-3.0 (Latex Free)	OD	ID	H
	IV-3.0 (Latex Free)	12.30	3.00	48.50

# Typical Worldwide Pharmacopoeia Test Specifications

Test Items	KP(10)	JP(15)	EP(6)	ISO(8362-2)	USP 381_2009
<b>Cadmium(Heavy Metal)</b>	Less than standard	Not more than 5ppm	-	-	-
<b>Lead (Heavy Metal)</b>	Less than standard	Not more than 5ppm	-	-	-
<b>Decription and Transparency of the test solution 430nm / 650nm</b>	Colorless and transparent 430nm:not less than 99% 650nm:not less than 99%	Colorless and transparent 430nm:not less than 99% 650nm:not less than 99%	-	-	-
<b>Appearance of solution</b>	-	-	Not exceeding solution of Reference suspension II(2.2.1) Not exceeding solution of GY5(2.2.2, Method II)	Not exceeding solution of Reference suspension II Not exceeding solution of GY5	Not exceeding solution of Reference suspension B Not exceeding solution of Color standard
<b>Acidity or alkalinity</b>	-	-	NMT 0.3 ml of 0.01 N NaOH / NMT 0.8 ml of 0.01 N HCl	NMT 0.3 ml of 0.01 N NaOH / NMT 0.8 ml of 0.01 N HCl	NMT 0.3 ml of 0.01 N NaOH / NMT 0.8 ml of 0.01 N HCl
<b>pH</b>	The difference of pH:NMT±1.0	The difference of pH:NMT±1.0	-	-	-
<b>Foam test</b>	The foam disappears within 3min	The foam disappears within 3min	-	-	-
<b>absorbance (220nm~360nm)</b>	NMT 0.2 Abs	NMT 0.2 Abs	NMT 0.2 Abs Type I	NMT 0.2 Abs Type I	NMT 0.2 Abs Type I
<b>Reducing substances</b>	NMT 2.0mL	NMT 2.0mL	Not greater than 3.0ml	Not greater than 3.0ml	Not greater than 3.0ml
<b>Ammonium</b>	-	-	NMT 2 ppm	NMT 2.0mg/L	NMT 2 ppm
<b>Extractable Zinc</b>	Less than standard	NMT 1ug/ml	NMT 5ug/ml	NMT 5mg/L	NMT 5ppm
<b>Extractable Heavy Metals</b>	-	-	NMT 2 ppm	NMT 2.0mg/L	NMT 2 ppm
<b>Residue on evaporation</b>	NMT 2.0mg	NMT 2.0mg	≤2mg/50ml Type I	≤2.0mg/50ml Type I	-
<b>Volatile sulphides</b>	-	-	Not more intense than a standard	Not more intense than a standard	Not more intense than a standard
<b>FRAGMENTATION</b>	-	-	Not exceed 5	Not exceed 5	Not exceed 5
<b>Penetrability</b>	-	-	Not greater than 10N	Not greater than 10N	Not greater than 10N
<b>Self-sealing test</b>	-	-	None any trace	None any trace	None any trace
<b>Conductivity</b>	-	-	-	≤15 uS/cm Type I	-
<b>Acute systemic toxicity</b>	Meet the requirements	Meet the requirements	-	-	-
<b>Pyrogen test</b>	Meet the requirements	Meet the requirements	-	-	-
<b>Hemolysis test</b>	Meet the requirements	Meet the requirements	-	-	-



# Technology of Samsung Medical Rubber

## Siliconization

We are aiming the minimum quantity of silicon use and monitoring coating level through silicon residue amount test.

## Permanent siliconization

SAMSUNG S-1 coating provides excellent barrier and reduced friction even after wash. The advanced coating was developed for those who require the parts to be washed before they are used.

## Technical Support

SAMSUNG MEDICAL offers excellent technical support for its customers. Our Technical support team provides advanced recommendations for formulations and coatings and packaging.

## Gamma treatment compatibility

Samsung Medical Rubber provides compatible formulation for Gamma Sterilization.

## Washing

Proprietary washing treatment, pass through washing line; unloading in class A

## Production traceability system

Production traceability system guarantees that the supplier's operations as well as organizational structure. The system assures that all product manufactured based on GMP standard. Furthermore, all production traceability is stored in our computer through production traceability system. According to this system, we are operating strict tracking management service.

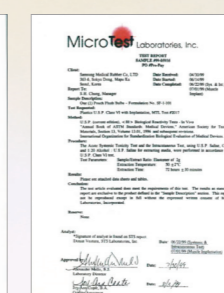
Samsung medical rubber has obtained the ISO 13485 certificates from the world well-known product services and are following USP class VI requirement for FDA.



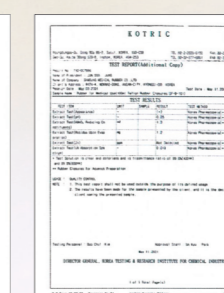
USP Class VI  
Test report for rubber stopper



USP Class VI  
Test Report for Rubber Components for Infusion Set



USP Class VI  
Test Report for L/F Rubber Gasket



Certificate of Laminated Stopper