465 N. Berry Street
Brea, CA 92821
(844) 641-3814 Tel
(844) 641-3813 Fax

Technical Data Sheet

Comparative data sheet of MPS Pharma branded syringes

1. General

MPS Pharma branded syringes are sterile luer lock syringes which are intended to be used as an injection device. Products will be manufactured, packaged, and sterilized by an FDA registered device manufacturer who is authorized for the distribution of an approved syringe device in the United States through an approved 510k.

The product will be labeled as 'Manufactured for: MPS Pharma & Medical, Inc,' with MPS's brand found on the barrel of the syringe.

MPS Pharma will receive product from manufacturer, perform secondary inspections, sponsor additional testing via domestic labs for final release, re-pack for shipping and distribute product. MPS Pharma will also act as the final certifying party before final distribution to the field.

Attribute	Conforms?
510k	*Conforms*
Sterile	*Conforms*
Endotoxin Testing	*Conforms*
USP 788 Particulate Testing	*Conforms*

Available Packaging Configurations and Part Numbers:

MPS Part Number	Description
SYR-P-03	3 mL Carton Pack, 50 syringe per unit, double pouched
SYR-B-03	3 mL Loose Bulk Pack, XX syringe per unit, triple pouch
SYR-P-05	5 mL Carton Pack, 60 syringe per unit, double pouched
SYR-B-05	5 mL Loose Bulk Pack, XX syringe per unit, triple pouch
SYR-P-10	10 mL Carton Pack, 55 syringe per unit, double pouched
SYR-B-10	10 mL Loose Bulk Pack, XX syringe per unit, triple pouch
SYR-P-20	20 mL Carton Pack, XX syringe per unit, double pouched
SYR-B-20	20 mL Loose Bulk Pack, XX syringe per unit, triple pouch
SYR-P-30	30 mL Carton Pack, XX syringe per unit, double pouched
SYR-B-30	30 mL Loose Bulk Pack, XX syringe per unit, triple pouch
SYR-P-60	60 mL Carton Pack, XX syringe per unit, double pouched
SYR-B-60	60 mL Loose Bulk Pack, XX syringe per unit, triple pouch

465 N. Berry Street
Brea, CA 92821
(844) 641-3814 Tel
(844) 641-3813 Fax

2. Certifications and Registrations

Syringe Manufacturing Operations and Registered Device Manufacturer:

Manufactured by: *Proprietary Class 2 FDA Registered Medical Device Manufacturer*
ISO Certification: ISO 13485
FDA Establishment Registration / FEI Number: Yes

Secondary Release Testing USP 788 and LAL/Endotoxin Testing:

Lab: ARL Bio Pharma
Location: 840 Research Parkway Ste. 546 Oklahoma City, OK 73104
ISO Certification: ISO 17025
FDA FEI Number: 3003644883

Distributor, Secondary Testing Sponsor, Final Certifying Party:

Establishment: MPS Pharma & Medical, Inc
Location: 465 Berry St, Brea, CA 92821
FDA Establishment Registration / FEI Number: 3018125942

510k Information:

Attribute	MPS
510k Number	Yes, Available
Regulation Name	Piston Syringe
Regulatory Class	II
Product Code	MEG, FMF, FMI

3. Materials

Component	MPS
Barrel	Polypropylene
Plunger	Polypropylene
Stopper	Polyisoprene
Lubricant	Medical Grade Silicone Oil (<0.25 mg/cm2)

465 N. Berry Street
Brea, CA 92821
(844) 641-3814 Tel
(844) 641-3813 Fax

4. Materials of Concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment	MPS
Phthalates	The products do not contain phthalates in general and as such the products do not contain di (2ethylhexyl) phthalate DEHP as CAS number 117-81-7, EC number 204-211-0.	Conforms
Latex	The products do not contain natural latex.	Conforms
Bisphenol A	The products do not contain Bisphenol A.	Conforms
Substances of animal origin BSE/TSE	The products do use industrial raw materials which contain small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Such substances are not considered as derivatives of animal tissues for the purpose of this rule (EU regulation 722/2012) which therefore does not apply	Conforms
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride	Conforms

5. Biocompatibility

Products conform to biocompatibility requirements stated in the ISO 10993 series standards

Testing Required	MPS
No Cytotoxicity	Conforms
No Irritation to Skin	Conforms
No significant evidence of sensitization	Conforms
No system toxicity	Conforms
No Hemolysis	Conforms
Non-pyrogenic	Conforms

6. Performance & Safety Testing

Standard	MPS
ISO 7886 - *Sterile hypodermic syringes for single use*	Conforms
ISO 80369-7 - *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*	Conforms

7. Sterilization

Products are sterilized at SAL of 10^{-6} via method established through ISO 11135-1. ETO residues are within applicable regulations. MPS Pharma branded syringes are sterilized via ETO sterilization.

Sterilization Method	MPS
ETO	Conforms