

**XIII. SUMMARY OF SAFETY AND EFFECTIVENESS****SHIFA SYRINGES-STERILE DISPOSABLE**

**Manufacturer:** Alshifa Medical Supplies Industry  
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**Product Trade Name:** Shifa Sterile Disposable Syringes

**Common Name:** Sterile Disposable Syringes

**Classification:** Piston Syringe

**Predicate Devices:** Mediplus Marketing SDN BHD MDP Disposable Syringes  
Becton Dickinson Brand Disposable Syringes

**Description:** Shifa Syringes are sterile disposable medical piston syringes consisting of barrel with luer-lock or slip-lock nozzle, gasket, and a needle. They are sold with or without needles. The barrel, and plunger are polypropylene, the gasket is natural rubber, and the needle is stainless steel.

**Intended Use:** Shifa Syringes are intended for injection of hypodermic medication.

**Summary of Safety and Effectiveness (Cont'd).**

**Substantial Equivalence:** The Shifa Sterile Disposable Syringes are substantially equivalent to Mediplas Marketing SDN BHD MDP Disposable Syringes and to Becton Dickinson Brand Disposable Syringes in that they provide the following characteristics:

- Similar design
- Physical characteristics are essentially the same
- Material composition essentially the same
- Same intended use

**Summary of Testing:**

<u>Test</u>	<u>Result</u>
Water Extract Appearance	Transparent, colorless, and no foreign matter
Transmittance	Above 93%
Difference in level of pH	Lower than 2.0
Heavy metals	Less than 2 PPM
Incompatibility between syringe and injection fluid	No change in appearance, opacity, or color of syringe or fluid
Quantity of silicone lubricant	3cc-Below 8 mg/pc 5cc-Below 8 mg/pc 10cc-Below 15 mg/pc
Intravenous injection test	Complies with USP XXII
Intracutaneous	Complies with USP XXII
Pyrogen Test	Complies with USP XXII

**Summary of Safety and Effectiveness (Cont'd).**

Sterility Test	No microbial growth in fluid thioglycolate medium after 7 days @ 22-25°C and soybean casein digest medium after 7 days @ 30-32°C.
Air leakage during aspiration	No leakage past piston or seal , no fall in manometer reading. Piston not detached from plunger.
Air leakage under compression	No leakage past piston or seal.
Dead space of syringe	Less than 0.075 ml. in 3cc & 5 cc. Less than 0.1 ml. in 10cc.
Air leak test of package Wrapper	No bubbles within 10 seconds after pressurized @ 0.07 KGF/CM2.
Blister Package	No air bubbles within 10 seconds after pressurized @ 0.07 KGF/CM2.