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New Advances In Injectable Dosage Systems

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Abstract:

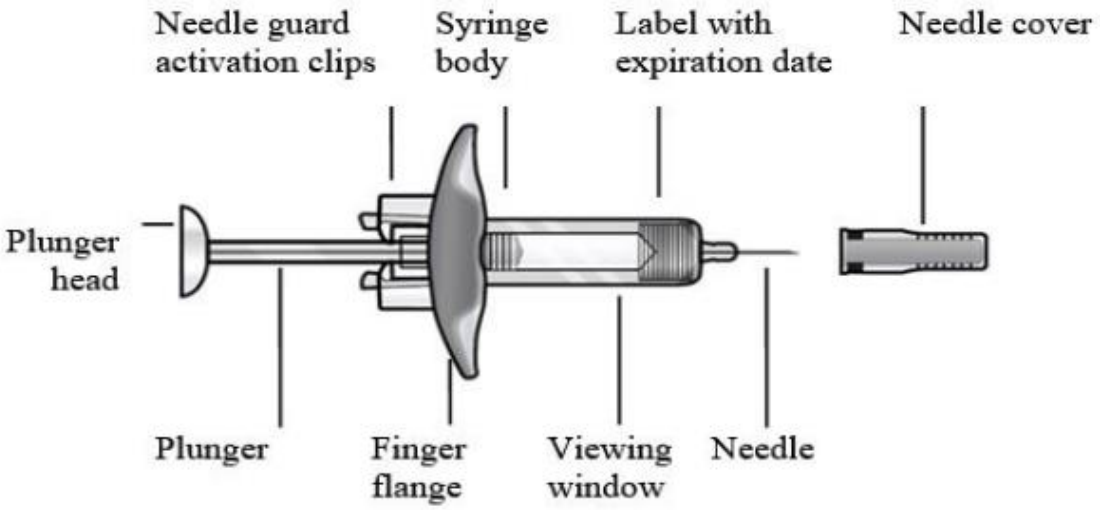
Prefilled syringe are more beneficial device for the purpose of drug delivery of parental dosage form. They are more convenient to manufacture and delivering the dosage of medicine. The review article discusses the components of Prefilled syringe, its applications and its compatibility with the packing material, Extractable and leachable and challenge's with the Prefilled syringe. This type of knowledge can familiarize the formulation scientist. In the use of Prefilled syringe as both packing and delivery system for pharmaceutical drug product is accelerating. Prefilled syringe must have good quality, stability and efficiency for both system including with the drug product. In that, the incompatibility study between the drug product and Prefilled syringe including the safety of the drug product.

Introduction:

The advances of pre-filled syringes in recent years has changed the face of human services experts. The parenteral medication part has come up recently with the advances of new biopharmaceuticals for accurate conditions including diabetes, numerous sclerosis, haemophilia, malignancy and other illnesses. Because of this development, there is a remarkable improvement in prefilled syringes.

The prefilled syringes are becoming popular day by day. The main reasons for this is reduced risk of contamination, reduced handling requirements, sterility assurance, elimination of the need for overfill of costly therapeutics and consequent reduced waste.

Components of prefilled syringes:



Types of prefilled syringes:

1. Glass based system

2. Plastic based system

Europe and US markets manufactures most of the prefilled syringes out of glass. Materials like Cyclo olefin copolymer and cyclo olefin polymer has straightforwardness, low surface authoritative and low degrees of extractables. The COC and COP materials will continuously contribute in the pre-filled syringe showcase. The decision among glass and plastic depends on their material attributes but on the other hand is influenced by the commonness of assembling lines used to fill and finish glass syringes.

Advantages of prefilled syringes technology

Pre-filled syringes make injections easier for both doctors and patients. With the help of pre-filled syringe, a patient always receives the accurate dosage. Pharmaceutical companies can overcome loss in pre-filled syringes.

Disadvantages of prefilled syringes technology

Some of the extractables and leachables can contact with the drug molecules and could adversely effect the effectiveness of a drug. In the prefilled syringes, drugs can contact with all component and there are chances to extractables and leachables problems.

Application of prefilled syringes

Prefilled syringe need to meet different necessities, for example heat opposition, unclogger coasting powers, squander removal, etc. Prefilled syringes comprise of different parts and materials, for example, glass, polymers and elastomers, which must be chosen properly to guarantee they meet the prerequisites for their proposed use.

In creating prefilled syringe frameworks, different advancements are thought of. A few productions have quality issues with biomolecules in prefilled syringe frameworks.

Comparison of drug stability in glass versus plastic containers

A commonly prescribed drug combination, (hydroxyzine hydrochloride, meperidine hydrochloride, and atropine sulfate) was studied to compare differences in stability between mixtures stored in glass and plastic containers. Combinations of drugs were stored in both glass and plastic syringes at 250 C and 30 C, for a ten-day period. Analysis were performed at intervals throughout the time period, pH determination, ultraviolet absorption spectra, and gas chromatography.

Table 1. pH changes in syringe contents after 10 days storage

		3 C		25 C	
		Initial	Final	Initial	Final
Hydroxyzine HCl 50 mg/mL	Glass	5.18 ± 0.02	5.25 ± 0.00	5.16 ± 0.02	5.17 ± 0.02
	plastic	5.15 ± 0.00	5.18 ± 0.02	5.15 ± 0.00	5.16 ± 0.00
Meperidine HCl 50 mg/mL	Glass	3.55 ± 0.00	3.57 ± 0.02	3.54 ± 0.00	3.54 ± 0.02
	plastic	3.55 ± 0.00	3.57 ± 0.03	3.5 ± 0.02	3.47 ± 0.04
Atropine sulfate	Glass	5.1 ± 0.00	5.3 ± 0.02	5.09 ± 0.00	5.2 ± 0.00
	plastic	5.09 ± 0.01	5.25 ± 0.03	5.08 ± 0.00	5.17 ± 0.03
Sample 1	Glass	4.5 ± 0.00	4.58 ± 0.02	4.46 ± 0.04	4.55 ±0.02
	plastic	4.5 ± 0.00	4.54 ± 0.06	4.5 ± 0.00	4.45 ± 0.02
Sample 2	Glass	4.58 ± 0.02	4.68 ± 0.03	4.55 ± 0.02	4.65 ± 0.02
	plastic	4.58 ± 0.02	4.62 ± 0.02	4.51 ± 0.02	4.58 ± 0.05

Values shown are means ± 1 standard deviation
Sample 1 concentration: hydroxyzine HCl 50 mg and meperidine HCl 50 mg per 2.0 mL
Sample 2 concentration: hydroxyzine HCl 50 mg, meperidine HCl 50 mg, and atropine sulfate 0.4 mg per 2.5 mL

Table 2. Hydroxyzine Hydrochloride Concentration (µg/mL) and % variance in concentration in syringe mixture after 10 days

Hydroxyzine					% Variance in
Hydrochloride	Syringe	Temp ©	Absorbance	Concentration	Concentration
with meperidine HCl	Glass	25	1.02	24.2	-3.2
(Initial concn		3	0.98	23.3	-6.8
About 25 µg/mL)	plastic	25	1.01	23.9	-4.4
		3	1	23.7	-5.2
with meperidine HCl	Glass	25	0.79	19.2	-4
and atropine sulfate		3	0.77	18.7	-6.5
(Initial concn	plastic	25	0.79	19	-5
About 25 µg/mL)		3	0.78	18.8	-6

Table 4: Chemical resistance of TOPAS		
pH < 7 (acidic/aqueous)	hydrochloric acid 36%	+
	sulfuric acid 40%	+
	nitric acid 65%	+
	acetic acid > 94%	+
pH = 7 (neutral/aqueous)	water	+
	aqueous solution of soap	+
	saline solution	+
pH > 7 (basic/aqueous)	sodium hydroxide 50%	+
	ammonia (aq. sol.) 35%	+
Polar organic solvents	ethanol, methanol, butanol, isopropanol (short chain alcohols)	+
	acetone, butanone (short chain ketones)	+
Aromatic solvents	benzaldehyde	o
	toluene	–
	benzene	–
	chlorinated solvents	–
Non-polar organic solvents	pentane, hexane, heptane etc. (alkanes)	–
	gasoline (petrol ether)	–
	norbornene	–
Other	oleic acid	–

+	o	–
resistant increase of weight < 3% or loss of weight < 0.5% elongation at break not substantially altered	limited resistance increase of weight 3 to 8% or loss of weight 0.5 to 5% elongation at break reduced by < 50%	not resistant increase of weight > 8% or loss of weight > 5% elongation at break reduced by > 50%

Cyclo olefin copolymer for the manufacturing of prefilled syringes

Cyclo olefin copolymer were newly used to manufacture prefilled syringes as they are able to hold against glass. They have high heat resistance and low level of extractables and leachable. They also provide the benefits like more transparent, lighter in weight, enhanced visibility and ease of use. Cyclic Olefin Copolymer (COC) is an amorphous polymer made by several polymer manufacturers. COC is a relatively new class of polymers when compared to polypropylene and polyethylene.

Some of the remarkable features of COC are rigidity, dimensional stability, heat resistance and air permeability. COC has high moisture barrier, low water absorption. They also offer high transparency, adjustable heat deflection temperature and high rigidity.

Advantages of COC prefilled syringes over glass prefilled syringes

COC prefilled syringes offer good drug compatibility, hydrophobic surfaces and high design flexibility.

Conclusion

Pre-filled syringes offer advantages in the delivery of injectable biopharmaceutical products. Demand for cyclic olefin copolymers (COC) is growing rapidly. The continous expansion of global production capacities testifies to the high interest in this new material.

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