



WEIBEL CDS AG

safer, easier and faster drug delivery

DRUG DELIVERY SYSTEM FOR STANDARD 1 ML LONG PREFILLED SYRINGES

How can drug delivery systems help in patient compliance? What are the challenges to be encountered with novel drugs filled in 1 mL long prefilled syringes? These questions are discussed in this article by Ludwig Weibel, Chief Executive Officer, and Hans Peter Manser, Business Director, of Weibel CDS. A novel and innovative approach is presented meeting the requirements of today's and future drug applications.

SAFER, EASIER AND FASTER DRUG DELIVERY

Following our mission to support safer, easier and faster preparation and administration of drugs, we have developed and produced innovative, user friendly, application-oriented injection systems and devices. All functions and parts needed for a specific drug application are integrated into one product. The user only opens one package and the complete handling is done in a closed system in order to reduce contamination, handling errors and needlestick injuries, combined with saving time.

TODAY'S SITUATION

Prefilled syringes are increasingly becoming the primary packaging standard for new drugs, especially for biologic drugs. Changes in drug administration to improve drug acceptance require strict adherence to the regimen given by the pharmaceutical company or the doctor prescribing the drug.

Today's solutions are often based on the use of autoinjectors with two limiting factors. Firstly, although the injection itself is automated it still depends on the patient's ability to handle the system as well as more importantly their adherence to the timing given to inject. Secondly, using autoinjectors means always making a bolus injection within seconds, not allowing for

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a regimen spread over minutes, hours or even days, thus limiting the possibilities for long-term treatment.

CHALLENGES TO MEET

Besides the requirements defined by the drug itself, the cost factor is, and will increasingly be, a major element in the decision-making process of pharmaceutical companies. The overall cost of applying a specific drug will be focussed on the healthcare setting rather than the cost of the drug itself as outpatient and homecare treatments gain importance.

Yet, as described by the authors in a previous article,¹ the big challenge for such systems is to be ready to use as well as preloaded, since handling by the patient may lead to dangerous situations due to the toxicity of the drug or handling errors.



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Figure 1: The system is small yet all the functions are incorporated.



Figure 2: The plastic holder includes the 1 mL long syringe.

“Patient compliance with the regimen is the key to the efficacy of the drug prescribed achieving the desired result.”

Another set of challenges is given by the drug itself. High viscosity of drugs for stability reasons is increasing. In some cases the viscosity may even exceed values of 1000 centistokes. Also shear forces can have a negative effect on biological drugs in either turbidity or molecular weight due to damage done to the protein chains during application, for example by the pump.

Last but not least, patients’ rising expectations in mobility as well as having total freedom to move about are adding to the list.

IMPROVED PATIENT COMPLIANCE

Patient compliance with the regimen is the key to the efficacy of the drug

prescribed achieving the desired result. Various elements may impact on this, for example, the preparation required since self-medication is heavily dependent on the ability of the patients to prepare and manipulate the injection device. This can be a major issue especially for elderly patients.

The exact starting time of the injection or infusion as well as the speed of injection or infusion is another critical element. Speed is especially important as a low speed may positively reduce side effects.

SYRINGE-BASED DRUG DELIVERY SYSTEM

This system is designed to accept standard 1 mL long syringes (Figure 1). It is extremely small yet still incorporates all functions required including a unique pump system, a needle insertion system, a battery, a drive and an electronic control unit.

Designed to suck out the drug instead of pushing it out, the system doesn’t require any type of plunger rod so the overall length is barely larger than a 1 mL syringe.

The system is designed as a patch pump with all required functions built-

in. The device may be operated via an external control unit. Depending on the drug, it may be attached to the patients’ body – often the abdomen – by healthcare personnel or eventually by the patient themselves.

If attached by healthcare personnel all the required settings including the starting time of the injection or subcutaneous infusion may be pre-set so not requiring patient interaction at all. Visual and audio signals will alert and inform the patient once the administration starts and when it is finished.

Syringe Pre-loaded in Plastic Holder

The 1 mL long syringe is pre-loaded in a plastic holder (Figure 2) enabling healthcare personnel or the patient to control the drug prior to its use. The needle shield is taken off with a plastic cover protecting it prior to the insertion of the holder including the syringe into the system. The needle size of the 1 mL long syringe is non-critical and can be chosen by the pharmaceutical company. The length should preferably be half an inch (12 mm).



Figure 3: Automatic needle insertion system with soft cannula remaining in the body after insertion.

Automatic Needle Insertion System

The automatic needle insertion system, including a soft cannula, assures the highest comfort to patients (Figure 3). After launch, the steel needle penetrates the tissue and sets the soft cannula in place. Immediately thereafter the steel needle is retracted and

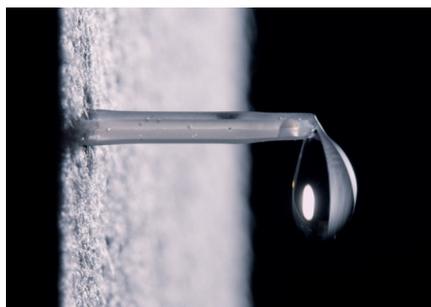


Figure 4: The proven pump system can deliver drugs at a high viscosity.

moves into a locked position making a dual use impossible and most importantly eliminating the risk of needlestick injuries.

Proven Pump System

The proven pump system, also used for 3 mL insulin cartridges, is extremely powerful overcoming the break-loose forces and offering a smooth gliding of the rubber stopper during injection (Figure 4). Depending on the pump size, the lowest dose increments of 16 nL to 5.6 µL are achievable resulting in highest accuracy for both basal and bolus injections. If required, a purge function may be included prior to administration.

The pump system has been tested for accuracy as well as for its ability

to deliver drugs with a viscosity of 1000 centistokes and more (Figure 4). Furthermore it has been proven that there is no damage to proteins due to shear forces and thus no negative effect on biological drugs in either turbidity or molecular weight.

System Control

The software used to control the DRUGDELIVERYSYSTEM offers the highest degree of flexibility. Various levels of access are provided to guarantee its proper use. The pharma company can set the overall limits relative to the drug administered, doctors or healthcare personnel can define the patient's specific settings and the patient can, for example, start the injection or infusion by pressing a button – or this step can be done by healthcare personnel.

Options

Other syringes sizes besides the 1 mL long are possible requiring only a change of the device housing as the connection of the syringe with the device remains the same.

CONCLUSION

The DRUGDELIVERYSYSTEM offers full integration of all functions and parts. The advantage for the end user is a saving in time and a reduction in:

- Contamination
- Handling errors
- Needlestick injuries.

Pharmaceutical companies can differentiate themselves from competition. The final design is according to your specific needs from a functional as well as design perspective.

REFERENCES

1. Weibel LD, Manser HP, "DrugDeliverySystems: Ready to Use for highest Patient Comfort". *ONdrugDelivery Magazine*, 2015, Issue 58, pp 16-18.
2. Manser HP, Weibel LD, "A Cartridge-based DrugDeliverySystem for Pump Systems". *ONdrugDelivery Magazine*, 2016, Issue 67, pp 44-46.
3. Weibel LD, Manser HP, "Reconstyringe: Full Integration of all Functions & Parts, Fully Automated Reconstitution". *ONdrugDelivery Magazine*, 2015, Issue 55, pp 66-67.

PORTFOLIO

Weibel CDS also offers:

- LVDs (Large Volume DRUGDELIVERYSYSTEM) based on our MiniBagSystem concept for micro infusions of up to 30 or even 50mL.¹
- DRUGDELIVERYSYSTEM 3mL cartridge based.²
- DRUGDELIVERYSYSTEM with automatic reconstitution functionality.

The SuperCapSyringe® product family upgrades your vial practically to a prefilled syringe. Based on a modular design, the syringe is fully adaptable to your application needs. It is supplied in different sizes and, as a novel offering, with staked needles including a passive safety device.

The Reconstyringe® product family is first in offering a fully automated reconstitution of lyophilised drugs. The drug is contained in its original vial, the solvent in the MiniBagSystem. With a spring mechanism and holder plates the content of the MiniBagSystem is emptied into the vial. Like a Swiss watch, it runs through the full reconstitution cycle. Finally, the drug is drawn into the SuperCapSyringe® for injection.

Both the SuperCapSyringe® and the Reconstyringe® were discussed in greater detail in previous issues of ONdrugDelivery Magazine.³

Squeezer Test and Application System for stability testing of drugs in the MiniBagSystem. For clinical studies and small-scale productions Weibel CDS offers CMO filling services, facilitating your project and giving you a head start without the need for large investment.

International patents pending. SuperCapSyringe® and Reconstyringe® are registered trademarks of Weibel CDS AG, Switzerland.

DRUG DELIVERY SYSTEM

Syringe based



Designed to accept 1mL long syringes, yet barely larger than the syringe itself, the system is extremely small and still incorporates all functions needed.

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International patents pending



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