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ORIGINAL RESEARCH

Compatibility of PiC Insupen Needles with a Broad Range of Pens for the Injection of Subcutaneously Administered Drugs for Diabetes

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Purpose: To test the compatibility of PiC Insupen needles with a broad range of pens produced by different manufacturers for the injection of subcutaneously administered drugs.

Patients and Methods: The "extreme" products in PiC pen needles range were considered (G33x4 mm and G29x12 mm), to verify that the compatibility was not affected by the cannula diameter and length. Following the launch of the G34x3.5mm needle, additional tests were performed comparing G33x4 and G34x3.5 pen needles. A test medium with viscosity similar to insulin was used. Additional tests were performed with a liquid with a much higher viscosity. All the requirements of the technical standard ISO 11608-2 were satisfied, and the differences between G29, G33 and G34 were negligible. Therefore, the PiC Insupen needle G33x4mm was chosen as representative of the PiC pen needles. Dose accuracy and needle hub torque were assessed, according to the ISO 11608-2:2012 norms. For pens with variable volume, two different volumes were tested (Vlow and Vhigh) in random order, testing 60 needles with Vlow and 60 with Vhigh.

Results: Overall, 50 different pens were tested. Dose accuracy acceptance criteria were met for all the pens tested, with the only exception of Vhigh for Berlipen Precision pen. The removal torque was adequate for all pens, with the only exception of Berlipen 301 and Berlipen 302 pens.

Conclusion: We documented that Pikdare needles are compatible with a large array of different pens for the injection of insulin and other drugs administered subcutaneously.

Keywords: diabetes mellitus, injection therapy, pen needle, needle compatibility

Introduction

Insulin therapy represents the cornerstone of therapy for type 1 diabetes and an important therapeutic option for patients with type 2 diabetes who are not achieving glycemic goals.[1] However, subcutaneous injections can be associated with pain, discomfort, and anxiety[2,3] which can represent an important barrier to insulin use.

Nowadays, insulin injection pens are preferred over vials and syringes, and are designed to facilitate use, improve adherence, and provide accurate insulin delivery. To reduce the level of anxiety and discomfort associated with injections, and to improve treatment compliance in diabetes patients, new technologies have been applied for the development of thinner, shorter and tapered needles which can cause less pain and less skin trauma[4–9]. Furthermore, thin-wall technology allowed an increase in the internal diameter of the needle, producing a substantial reduction in flow resistance compared with standard needles of the same gauge.[10] These aspects are crucial, since insulin injection directly impacts on glycemic control, patient adherence, and quality of life.[11]

In recent years, the introduction on the market of GLP1 receptor agonists (GLP1-RAs) and amylin analogues extended the use of treatments administered subcutaneously in type 2 diabetes beyond insulin, thus making injection aspects even more relevant.

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Nowadays, a large number of reusable and prefilled injection pens is available; to provide reassurance and convenience to patients, it is important that injection pen needles fit and function correctly with the largest possible number of pens. This is a key aspect for patient trust and confidence, which can have an impact on treatment adherence.

Due to the large number of pen systems in circulation and the high frequency of launching new products with different characteristics, safety reasons require that the patient is always informed about the compatibility between the prescribed injection pen and the recommended needle.

For these reasons, the technical standard ISO 11608-2:2012 requires to declare on the packaging the list of pens with which the needle is compatible. To this purpose, the standard also requires the legal manufacturer of the needle to physically verify the compatibility between pen needles and pens with which compatibility is declared, by carrying out the test as specified by the standard. The test of compatibility entails two different aspects: the mechanical compatibility of the needle with the pen, and the dispensation of the correct fluid dose. This verification needs from the pen needle manufacturer to involve effort and resources to be performed but it's mandatory to declare the compatibility between a needle and a pen: in this way, the patient (or the caregiver) can be sure to use a needle which is fully compatible with the injection pen device and this guarantees the proper drug delivery by the needle and pen combination.

Aim of this study was to test the compatibility of the entire range of PiC Insupen needles with a broad range of pens produced by different manufacturers for the injection of subcutaneously administered drugs (especially insulin and other lower injection medicines).

Materials and Methods

As a first step, the "extreme" products in PiC pen needles range were considered, in order to verify that the compatibility was not affected by the cannula diameter and length. Therefore, the following pen needles were considered: G33x4 mm (the shortest and thinnest), and G29x12 mm (the longest and thickest). Furthermore, to reduce the variability of results due to external factors, the same injection system (Humapen Luxura from Eli Lilly, a reusable pen) was used to test both pen needle types, and a test medium instead of insulin was used (viscosity = 1 cP, similar to insulin viscosity; density = 1 g/mL).

Results show that all the requirements of the technical standard ISO 11608-2 were satisfied with both pen needles types (Supplementary Table 1), and that the differences between G29 and G33 were negligible.

Additional tests were performed to verify that a liquid with a much higher viscosity than insulin does not affect the dose accuracy; to this purpose, a test liquid with a viscosity of 10 cP (glycerol solution, density: 1,17,423 g/mL) was used. G33 was chosen as the test needle, since it is thinner, so the probability of cannula occlusion could be higher than with G29. Results show that all the requirements of the technical standard ISO 11608-2 were satisfied also with the high viscosity medium (Supplementary Table 2), and that the differences between G29 and G33 were negligible.

Following the launch of the G34x3.5mm needle, additional tests were performed to verify that the compatibility test produced the same results when tested on G33x4 and G34x3.5 pen needles, as already demonstrated in the comparison between G33x4 and G29x12. The Solostar system with Lantus Glargine insulin was used. Even in this case, all the requirements of the technical standard ISO 11608–2 were satisfied with both pen needles types (Supplementary Table 3); the differences between G34 and G33 were negligible.

Therefore, the PiC Insupen needle G33x4mm was chosen as representative of the PiC pen needles.

Dose accuracy and needle hub torque were assessed. Overall, 50 different pens were tested.

Needles were tested according to the norms dictated by the ISO 11608-2:2012, Needle-based injection systems for medical use, Requirements and test methods — Part 2: Needles. Each compatibility test consisted in mounting the needles onto the pens, verifying that the selected dose was properly ejected by the pen plus needle system and checking that the unscrewing torque to remove the needle from the pen was adequate. The devices were placed in the testing area under standard atmospheric conditions (18–25°C; 25–75% relative humidity) for a minimum of 4 hours to ensure acclimatization.

The number of needles tested for each needle type and the number of pens tested for each pen type was in line with the requirements of the ISO norm and calculated according to the specific pen's characteristics.

For pens with variable volume, two different volumes were tested (Vlow and Vhigh) in random order, testing 60 needles with Vlow and 60 with Vhigh. The volumes were calculated as follows:

Vlow ≤ 10% of injection system (NIS) maximum dosage.

Vhigh ≥ 90% of NIS maximum dosage.

For example, if the NIS maximum dosage was 60 IU, then Vlow ≤ 10% of 60 IU = 6 IU.

Vhigh ≥ 90% of 60 IU = 54 IU.

For NIS with fixed dosage, only 60 pen needles were tested, ejecting the fixed volume.

For some disposable NIS, prefilled with drugs different from insulin, not only one fixed dose but a limited number of prespecified doses is available. In this case, Vlow and Vhigh have been established to reflect the minimum and maximum injectable dose. As an example, the Victoza pen from Novo Nordisk can deliver three different doses of the GLP1-RA liraglutide: 0.6 mg, 1.2 mg, and 1.8 mg. Therefore, Vlow was fixed at the volume correspondent to 0.6 mg and Vmax at the volume correspondent to 1.8 mg.

So, 120 needles were tested with each variable dose pen and 60 with each fixed dose pen.

For reusable pens, one device was used and only the cartridges were changed.

Before starting the validation, the priming was done. For prefilled pens, a spare needle was assembled and 2 units of test medium were injected, in order to be sure that the piston of the NIS was in contact with the plunger of the vial and to purge air bubbles from the cartridge. For reusable pens, the first cartridge was inserted into the injection system, a spare needle was assembled and, as for prefilled pens, 2 units of test medium were injected, in order to be sure that the piston of the NIS was in contact with the plunger of the vial and to purge air bubbles from the cartridge.

The validation involved the following steps.

The needle was screwed on the pen with a torque of 0.07 ± 0.01 Nm. After at least 10 seconds, the target dose was set on the pen and the volume to be verified was expelled.

The liquid was dispensed directly on the scale, in a 10 mL flask, previously filled with a small amount of test medium and calibrated, waiting 5 seconds after the injection; then the liquid was weighted within 5 seconds after stabilization of the scale. Without moving the flask, the scale was recalibrated to be ready for the next injection. The needle was unscrewed. Steps were repeated, testing 60 different needles with Vlow and 60 with Vhigh (total 120 needles), according to a random or alternating dosing sequence, changing the cartridge (or the pen) when necessary and performing the priming again every time. The volume was calculated dividing the mass by the density of the liquid under test.

For NIS with fixed dosage, only 60 pen needles were tested, ejecting the fixed volume.

Statistical Methods

The needle type and pen type were judged as having passed the compatibility test if:

$$\mathrm{S}+(\mathrm{k} \times \mathrm{Sd}) \leq \mathrm{UL}$$

and

$$\mathrm{S}-(\mathrm{k} \times \mathrm{Sd}) \geq \mathrm{LL}$$

where:

S is sample mean,

Sd is sample standard deviation,

UL is upper specification limit,

LL is the lower specification limit,

k is the coverage factor (n=60, k=2.67 assuming a confidence interval of 95% and a reliability of 97.5%).

For doses ≤ 0.20 mL, the dose accuracy test was considered acceptable if the calculated values (of the collected dispensed fluid doses) were within ±0.01 mL of the targeted dose (Vlow or Vhigh).

For doses > 0.20 mL, the dose accuracy test was considered acceptable if the calculated values (of the collected dispensed fluid doses) are within ±5% of the targeted dose (Vlow or Vhigh).

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Table 1 Dose Accuracy results (as per ISO 11608–2 11.5.2)

Pen	V_{low}								V_{high}							
	S	S_{sd}	UL	LL	$S+(k*S_{sd})$	$S-(k*S_{sd})$	$S+(k*S_{sd}) \le UL$	$S-(k*Ssd) \ge LL$	S	S_{sd}	UL	LL	$S+(k*S_{sd})$	$S-(k*S_{sd})$	$S+(k*S_{sd}) \le UL$	$S-(k*Ssd) \ge LL$
Byetta 5 µg	0.0608	0.0016	0.070	0.050	0.0650	0.0566	Yes	Yes	0.5403	0.0029	0.5670	0.5130	0.5481	0.5325	Yes	Yes
Byetta 10 µg	0.0397	0.0012	0.0500	0.0300	0.0429	0.0365	Yes	Yes	Not applicable							
Victoza 6 mg/mL	0.0965	0.0022	0.1100	0.0900	0.1023	0.0906	Yes	Yes	0.293	0.0022	0.3150	0.2850	0.299	0.287	Yes	Yes
HumaPen Luxura HD	0.0307	0.0007	0.0400	0.0200	0.0326	0.0288	Yes	Yes	0.2703	0.0014	0.2835	0.2565	0.2742	0.2665	Yes	Yes
HumaPen Savvio	0.0608	0.0016	0.070	0.050	0.0650	0.0566	Yes	Yes	0.5403	0.0029	0.5670	0.5130	0.5481	0.5325	Yes	Yes
HumaPen Luxura	0.0613	0.0021	0.070	0.050	0.067	0.056	Yes	Yes	0.5437	0.0037	0.5670	0.5130	0.554	0.534	Yes	Yes
HumaPen Memoir	0.061	0.0010	0.070	0.050	0.064	0.058	Yes	Yes	0.542	0.0028	0.5670	0.5130	0.549	0.534	Yes	Yes
FlexPen	0.059	0.0012	0.070	0.050	0.062	0.056	Yes	Yes	0.532	0.0024	0.5670	0.5130	0.538	0.526	Yes	Yes
NovoPen Echo	0.031	0.0012	0.040	0.020	0.034	0.028	Yes	Yes	0.268	0.0019	0.2835	0.2565	0.273	0.263	Yes	Yes
Kwikpen	0.061	0.0013	0.070	0.050	0.064	0.057	Yes	Yes	0.540	0.0025	0.5670	0.5130	0.547	0.533	Yes	Yes
Innolet	0.050	0.0013	0.060	0.040	0.053	0.047	Yes	Yes	0.448	0.0021	0.4725	0.4275	0.454	0.443	Yes	Yes
NovoPen 3	0.070	0.0013	0.080	0.060	0.073	0.066	Yes	Yes	0.625	0.0033	0.6620	0.599	0.634	0.617	Yes	Yes
NovoPen 4	0.061	0.0019	0.070	0.050	0.067	0.056	Yes	Yes	0.540	0.0017	0.5670	0.5130	0.545	0.535	Yes	Yes
Lyxumia 10 µg	Not applicable								0.198	0.0021	0.2100	0.1900	0.203	0.192	Yes	Yes
ClikStar	0.083	0.0022	0.090	0.070	0.089	0.077	Yes	Yes	0.713	0.0026	0.756	0.684	0.720	0.706	Yes	Yes
SoloStar	0.080	0.0015	0.090	0.070	0.084	0.076	Yes	Yes	0.710	0.0016	0.756	0.684	0.715	0.706	Yes	Yes
Toujeo Solostar	0.01711	0.00067	0.02666	0.00666	0.01890	0.01532	Yes	Yes	0.24804	0.00168	0.26250	0.23750	0.25254	0.24354	Yes	Yes
JuniorStar	0.031	0.0013	0.040	0.020	0.034	0.028	Yes	Yes	0.267	0.0020	0.2835	0.2565	0.273	0.262	Yes	Yes
NovoPen Junior	0.036	0.0016	0.045	0.025	0.040	0.032	Yes	Yes	0.314	0.0014	0.3308	0.2993	0.318	0.311	Yes	Yes
Ypsopen	0.060	0.0016	0.070	0.050	0.064	0.055	Yes	Yes	0.537	0.0029	0.567	0.513	0.544	0.529	Yes	Yes
Autopen Classic 1–21 IU	0.020	0.0008	0.030	0.010	0.022	0.018	Yes	Yes	0.189	0.0019	0.1995	0.1805	0.194	0.184	Yes	Yes
Autopen Classic 2–42 IU	0.039	0.0010	0.050	0.030	0.042	0.036	Yes	Yes	0.378	0.0037	0.3990	0.3610	0.388	0.368	Yes	Yes
Autopen 24 1–21 IU	0.020	0.0009	0.030	0.010	0.022	0.017	Yes	Yes	0.189	0.0022	0.200	0.180	0.195	0.183	Yes	Yes
Autopen 24 2–42 IU	0.039	0.0020	0.050	0.030	0.044	0.033	Yes	Yes	0.381	0.0038	0.399	0.361	0.391	0.371	Yes	Yes

Gensupen	0.038	0.0013	0.050	0.030	0.042	0.035	Yes	Yes	0.358	0.0034	0.378	0.342	0.367	0.349	Yes	Yes
Flextouch	0.080	0.0014	0.090	0.070	0.084	0.076	Yes	Yes	0.719	0.0047	0.756	0.684	0.731	0.706	Yes	Yes
Berlipen Areo2	0.064	0.0023	0.070	0.050	0.070	0.058	Yes	Yes	0.549	0.0032	0.567	0.513	0.557	0.540	Yes	Yes
Berlipen 301*	0.019	0.0013	0.030	0.010	0.023	0.016	Yes	Yes	0.190	0.0031	0.200	0.180	0.198	0.182	Yes	Yes
Berlipen 302*	0.036	0.0022	0.050	0.030	0.042	0.030	Yes	Yes	0.381	0.0029	0.399	0.361	0.389	0.373	Yes	Yes
Berlipen Precision	0.027	0.0030	0.035	0.015	0.035	0.019	Yes	Yes	0.230	0.0049	0.236	0.214	0.243	0.217	No	Yes
Forsteo	0.081	0.0015	0.090	0.070	0.085	0.077	Yes	Yes	Not applicable							
NovoPen5	0.062	0.0025	0.070	0.050	0.069	0.055	Yes	Yes	0.540	0.0080	0.567	0.513	0.561	0.519	Yes	Yes
Soliqua/Suliqua (40 IU)	0.042	0.0010	0.050	0.030	0.044	0.039	Yes	Yes	0.362	0.0018	0.3780	0.3420	0.366	0.357	Yes	Yes
Soliqua/Suliqua (60 IU)	0.063	0.0013	0.070	0.050	0.066	0.059	Yes	Yes	0.541	0.0037	0.5670	0.5130	0.550	0.531	Yes	Yes
Humalog U-200 Kwikpen	0.031	0.0007	0.041	0.021	0.033	0.029	Yes	Yes	0.270	0.0010	0.284	0.257	0.273	0.267	Yes	Yes
Gensupen Improve	0.037	0.0012	0.047	0.027	0.040	0.034	Yes	Yes	0.3586	0.0052	0.378	0.342	0.373	0.345	Yes	Yes
Wangbangpen	0.044	0.0009	0.054	0.034	0.047	0.042	Yes	Yes	0.438	0.0031	0.473	0.428	0.446	0.430	Yes	Yes
Gansulin Pen	0.059	0.0006	0.069	0.049	0.061	0.058	Yes	Yes	0.540	0.0080	0.567	0.513	0.561	0.518	Yes	Yes
Sanofi Toujeo Max SoloStar/Toujeo DoubleStar	0.054	0.0008	0.064	0.044	0.056	0.052	Yes	Yes	0.480	0.0022	0.504	0.456	0.486	0.474	Yes	Yes
Humulin KwikPen 70–30	0.061	0.0005	0.070	0.050	0.062	0.059	Yes	Yes	0.541	0.0013	0.567	0.513	0.544	0.537	Yes	Yes
SymlinPen 60–120	0.061	0.0004	0.070	0.050	0.062	0.060	Yes	Yes	0.121	0.0013	0.130	0.110	0.125	0.118	Yes	Yes
SymlinPen 15–60	0.015	0.0004	0.025	0.005	0.016	0.014	Yes	Yes	0.060	0.0005	0.070	0.050	0.062	0.059	Yes	Yes
Gensupen2	0.056	0.0017	0.070	0.050	0.061	0.052	Yes	Yes	0.542	0.0033	0.567	0.513	0.551	0.533	Yes	Yes
Semgleé	0.079	0.0020	0.090	0.070	0.084	0.073	Yes	Yes	0.723	0.0052	0.756	0.684	0.737	0.710	Yes	Yes
Actiste	0.028	0.0017	0.040	0.020	0.033	0.024	Yes	Yes	0.264	0.0028	0.284	0.257	0.272	0.257	Yes	Yes

Note: *An assembly torque of 0.07 ± 0.01 Nm was always applied to assembled needles on pens; after that, the removal torque detected was ≤0.100 Nm for all pens, with the only exception of Berlipen 301 and Berlipen 302.

As an example, if Vlow is 0.06 mL and Vhigh is 0.54 mL, the acceptance criteria will be LL=0.05 and UL=0.07 for Vlow and LL=0.513 and UL=0.567 for Vhigh.

The same needles used for the dose accuracy testing were used for the needle hub removal torque testing.

For removal torque, a value of 0.100 Nm or less was deemed adequate.

Statistical analyses were performed using the SPSS software ver. 23.0 (IBM, Armonk, NY, USA).

Results

The list of the 50 pens tested along with dose accuracy parameters are reported in Table 1. Dose accuracy acceptance criteria were met for all insulin and GLP-1 RA pens tested, with the only exception of Vhigh for Berlipen Precision pen [S+(k*Ssd)=0.243; UL=0.236]. After assembling needles on pens with the required torque value, the removal torque was was ≤0.100 Nm, and therefore compliant for all the pens, except for Berlipen 301 and Berlipen 302 pens (in these cases the removal torque exceeded 0.100 Nm).

Discussion

The compatibility of needles with any brand of pens represents an important aspect of injective therapies, particularly in the case of complex schemes, such as an insulin basal-bolus regimen, or the combination of insulin therapy with a GLP1-RA. Furthermore, it avoids the need of changing the kind of needle used each time the treatment or brand of drug is changed. The possibility to use the same needle for different kinds of pens increases the confidence of the patient, at it is likely to reduce the anxiety associated with the injection.

These aspects are crucial, since insulin injection directly impacts on glycemic control, patient adherence, and quality of life.[10]

For these reasons, the technical standard ISO 11608-2: 2012 requires to declare on the packaging the list of pens with which the needle is compatible. The test of compatibility entails two different aspects: the mechanical compatibility of the needle with the pen, and the dispensation of the correct fluid dose. However, there is scant published information on the compatibility of injection pen needles with different injection pens. To our knowledge, only one study tested two types of pen needles with a range of injection pens for diabetes medication.[11] The study considered two 30G 8mm needles (NovoFine and NovoFine Autocover) to assess their compatibility with 21 different pens. The needles were tested by attaching them according to ISO 11608-2 and verifying penetration into the cartridge using air shots and two-dimensional X-rays. Needles were compatible with most of the injection pen types from other manufacturers in terms of correct attachment and detachment to the pen thread. Penetration was present in all cases where the needles could be mounted onto a pen. Dose accuracy was not evaluated in this study. No additional studies on the compatibility and dose accuracy of thinner and shorter needles are available. The lack of studies underlines the need for more extensive, formal tests of compatibility of pen needles.

Conclusion

We documented that Pikdare needles are compatible with a large array of different pens for the injection of insulin and other drugs administered subcutaneously. The amount of test fluid injected was always within the range recommended by the ISO standards, with only one exception, irrespective of the viscosity of the fluid and the size of the needle; the mechanical fitting of needle hub on the different pen types was also adequate.

Disclosure

Luca Leonardi is Pikdare S.p.A. employee. Antonio Nicolucci has received honoraria from AstraZeneca, Eli Lilly, Novo Nordisk, and research support from Alfasigma, Medtronic, Novo Nordisk, Pikdare, Sanofi, Shionogi, SOBI. The authors report no other conflicts of interest in this work.

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