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# Particulate contamination of sterile syringes and needles

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Commercially available sterile needles and syringes have been examined for particulate contamination using the Hiac light blockage technique. The number of particles delivered was small compared with the total number permitted for large volume parenterals. Where syringes are used in particle counting techniques, the contribution of particles should be taken into account.

Most injections are given by means of a syringe fitted with a needle. In addition, syringes and needles are used to inject additives into large volume parenteral solutions, and for sample transfer during testing for particulate material.

The British and American pharmacopoeias contain limits for particulates in large volume parenteral injections (British Pharmacopoeia 1980, United States Pharmacopeia/N.F 1980), and limits could possibly be introduced for small volume injections in the future. An additional source of contamination is the syringe and needle, and it has been suggested that when used in testing, the syringe is cleaned with filtered water before use (Longe 1980).

The use of terminal membrane filters has been advocated (Hammer 1974; Dorris et al 1977), but the filters will not affect the contamination due to the needle. In this study, the particles released from prepacked sterile syringes fitted with needles and particles released from needles alone were determined.

The syringes and needles examined were from three manufacturers and were the plastic sterile disposable type in individual packs. The syringe sizes examined were 2, 10, 50 and 60 $cm^3$.

## METHODS

### *Particle counting*

Particle counts were determined using a Hiac PC320 light blockage system, with a small volume sampler and 0·8–60·0 μm sensor attached. The size levels examined were particles greater than or equal to 0·8, 2·0, 5·0, 10·0, 20·0 and 40·0 μm.

### *Preparation of samples*

Deionized water which had been filtered through a 0·22 μm millipore filter was used.

(i) *2 $cm^3$ and 10 $cm^3$ syringes (Table 1)*

About 75 $cm^3$ of filtered water was placed in a rinsed 100 $cm^3$ beaker containing a 1 cm magnetic follower. Background counts of 4 × 2 $cm^3$ counts were taken whilst the water was stirred. The excess water was then poured off to leave 50 $cm^3$.

Table 1. Syringes and needles examined.

| | Syringe | | | Needle | |
|---|---|---|---|---|---|
| Test ref. | Vol $cm^3$ | Manuf. | Batch | Size | Batch |
| 1 | 2 | B–D plastipak | A78E6779G25 July 77 | — | — |
| 2 | 2 | Brunswick (packed with needles) | 79C2615 Mar 79 | 21 g × 5/8″ | — |
| 3 | 10 | Brunswick | 80LO515 Dec 80 | — | — |
| 4 | 10 | Sabre | 059 21 May 79 | — | — |
| 5 | 10 | Sabre | Unknown | — | — |
| | | Yale needles | — | 19 g ×1½″ | A78E478H31 Aug 78 |
| 6 | 10 | Sabre | Unknown | — | — |
| | | Sabre needles | — | 21 g × 1½″ | E09009 July 80 |
| 7 | 50 | Sabre | 0490503 Apr 79 | — | — |
| 8 | 60 | B–D plastipak | A78E7878G18 July 78 | — | — |

For the experiments without the needle fitted, the syringe was removed from the sterile pack and the tip of the nozzle was immersed in the water. For tests with the needle fitted, the tip of the needle was immersed in the water. Water was drawn into the syringe up to the maximum gradation mark and then flushed back into the same beaker. This was repeated four times during approximately 45 s. After allowing sufficient time for the removal of air bubbles (approximately 2 min), 4 × 2 $cm^3$ counts were taken.

(ii) *50 $cm^3$ and 60 $cm^3$ syringes (Table 1)*

The method was essentially the same as (i) except that a 150 $cm^3$ beaker was used, background counts

were taken on 125 cm³ water and excess water was poured off to leave 100 cm³.

Ten determinations were performed on each test in Table 1, except test 8 where only 5 syringes were available. Counts are expressed as the mean total number of particles and standard deviation per syringe (plus needle where appropriate) at each size level.

## RESULTS AND DISCUSSION

The background counts, mean number of particles for each syringe type and the mean number of particles for each cm³ delivered are given in Tables 2, 3 and 4 respectively.

Table 2. Background counts.

| Size μm | Mean no. of particles cm⁻³ | s.d. |
|---|---|---|
| 0·8 | 65·3 | 67·0 |
| 2·0 | 30·0 | 36·7 |
| 5·0 | 6·5 | 9·4 |
| 10·0 | 1·4 | 1·7 |
| 20·0 | 0·2 | 0·4 |
| 40·0 | 0 | 0 |

Data calculated from the background counts generated from all the tests.

The particulate matter emanating from the syringes must be due to particles on the internal surface and piston tip. The number of particles cm⁻³ of fluid delivered would be expected to be greater for the smaller volume syringes which have the higher surface area: volume ratio. The results (Table 4) confirm this.

The internal surface areas of the syringes were calculated to be:

| | | |
|---|---|---|
| 2 cm³ | (Brunswick) | Surface area 9·4 cm² |
| 10 cm³ | (Sabre) | Surface area 28·1 cm² |
| 50 cm³ | (Sabre) | Surface area 80·0 cm² |

taking the mean number of particles per syringe, the mean number of particles cm⁻² of internal surface can be calculated and are as shown in Table 5.

Statistical analyses show that the 10 and 50 cm³ syringe data (Table 5) are not significantly different ($P = 0{\cdot}05$) at 2·0 or 5·0 μm. Whereas the 2 cm³ syringe data are significantly different to the 10 cm³ syringe data ($P = 0{\cdot}05$) at both 2·0 and 5·0 μm. This suggests that the higher counts obtained for the 50 cm³ syringes compared with the data for 10 cm³ syringes (Table 3), is due to a surface area:volume relationship. This is not the case for the 2 cm³ syringes which are now seen to contain a greater

Table 3. The mean number of particles for each syringe type.

| | Mean total number of particles per syringe (plus needle) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Size μm | 2 cm³ B–D plastipak | 2 cm³ Brunswick | 10 cm³ Brunswick | 10 cm³ Sabre | 10 cm³ Sabre and Yale needles | 10 cm³ Sabre and Sabre needles | 50 cm³ Sabre | 60 cm³ B–D plastipak |
| 0·8 | 16715 (12348) | 15346 (5610) | 47340 (32309) | 21450 (10944) | 44200 (15199) | 29345 (13266) | 49970 (15988) | 100300 (49250) |
| 2·0 | 10215 (7592) | 7770 (2567) | 23480 (16977) | 7830 (4505) | 18900 (9183) | 11015 (5247) | 18020 (6772) | 39840 (18042) |
| 5·0 | 2935 (2095) | 1845 (1222) | 5075 (3933) | 1010 (505) | 4000 (3408) | 1398 (657) | 2230 (1045) | 5920 (2366) |
| 10·0 | 555 (430) | 250 (129) | 635 (562) | 85 (34) | 700 (753) | 135 (67) | 170 (106) | 700 (316) |
| 20·0 | 40 (46) | 55 (28) | 85 (67) | 5 (15) | 0 | 10 (21) | 0 | 100 (71) |
| 40·0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

( ) standard deviation.
N.B. these figures = actual count − background count = no. of particles contributed by syringe (plus needle where appropriate).

Table 4. Mean number of particles for each cm³ delivered.

| | Mean number of particles for each cm³ delivered | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Size μm | 2 cm³ Plastipak | 2 cm³ Brunswick with needle | 10 cm³ Brunswick | 10 cm³ Sabre | 10 cm³ Sabre and Yale needle | 10 cm³ Sabre and Sabre needle | 50 cm³ Sabre | 60 cm³ Plastipak |
| 0·8 | 8385 | 7673 | 4734 | 2146 | 4420 | 2935 | 999 | 1672 |
| 2·0 | 5108 | 3885 | 2348 | 783 | 1890 | 1102 | 360 | 664 |
| 5·0 | 1468 | 623 | 508 | 101 | 400 | 139 | 45 | 99 |
| 10·0 | 278 | 125 | 64 | 9 | 70 | 14 | 3 | 12 |
| 20·0 | 20 | 28 | 9 | 1 | 0 | 1 | 0 | 0 |
| 40·0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

N.B. these figures = actual count − background count = no. of particles delivered in each cm³ from the syringe (plus needle where appropriate).

Table 5. Mean no. of particles $cm^{-2}$ of internal surface of syringes.

| Size/μm syringe | 2·0 Mean | 2·0 s.d. | 5·0 Mean | 5·0 s.d. |
|---|---|---|---|---|
| 2 $cm^3$ B–D plastipak | 1086 | 807 | 312 | 223 |
| 10 $cm^3$ Sabre | 280 | 160 | 36 | 18 |
| 50 $cm^3$ Sabre | 225 | 85 | 28 | 13 |

amount of particulate material than the larger syringes.

*Addition of needles*

*t*-Tests were carried out on the data obtained at 2·0 and 5·0 μm levels for the Sabre 10 $cm^3$ syringes (unknown batch no.) with and without the B-D, Yale microlance needles. At both size levels the distributions were found to be significantly different ($P = 0{\cdot}05$). Overall, the contamination present appears to be due to particles below 20·0 μm with no particles greater than 40·0 μm.

There is a British Standard Specification which permits the addition of a limited quantity of silicone oil to syringes and needles to facilitate lubrication. This silicone oil will quite probably have a significant effect on the particle counts. However, since the medical significance of the introduction of this quantity of silicone oil as droplets in an injection is uncertain (Leong et al 1982), it seems valid to include them in an estimation of the particulate contamination contributed by syringes and needles.

If the contamination is viewed as a total patient burden injected, it can be seen that the contribution provided by the syringe and needle is small compared with the limits allowed by the British Pharmacopoeia for large volume parenteral injections (L.V.P) (Table 6).

## CONCLUSIONS

The results obtained show that currently available prepacked sterile syringes contribute to the overall particulate contamination of injections.

Table 6. Particulate contribution of syringes compared with limits set by the British Pharmacopoeia (1980).

| | No of particles. 500 $cm^{-3}$ | | | |
|---|---|---|---|---|
| | | Contribution of syringes | | |
| Size/μm | BP limits for L.V.P's | 2 $cm^3$ syringe | 10 $cm^3$ syringe & needle | 50 $cm^3$ syringe |
| 2·0 | <250 000 | 10215 | 11015 | 18020 |
| 5·0 | <40 000 | 2935 | 1398 | 2230 |

Values for other sized L.V.P's e.g.: 100 $cm^3$ and 1 $dm^3$, are multiples of the values in this Table.

The total number of particles injected is small compared with the total number of particles that may be present in a large volume parenteral injection, and within the limits set by the British Pharmacopoeia on these preparations.

Particles greater than 40·0 μm were not found. The addition of a sterile needle to a sterile syringe causes a significant increase in the level of particulate contamination compared with that introduced by the syringe alone.

The contribution from the syringe and needle should be recognized if they are used in particle counting techniques.

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