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13th January 2020

Review of BBraun NRFit syringe testing protocols and results against NHS protocols

Products: **BBraun NRFit Lock Syringes with BBraun NRFit Syringe Caps.**

The NHS Pharmaceutical Aseptic Services Group published its requirements for the introduction of NRFit neuraxial syringes and caps for the purposes of drug storage on 13th October 2016. This is necessary as, in line with other standard plastic syringes, these are CE marked for the administration of drug products but not for storage. Hence in order to allow aseptic facilities to draw up medication in advance and store ahead of administration the additional data was requested.

This additional testing involved:

1) Syringe integrity testing (microbiological and dye intrusion testing) in accordance with Protocols for the Integrity Testing of Syringes 2nd edition April 2013' – NHS Pharmaceutical Quality Assurance Committee.
2) Extractives and leachables testing in accordance with British Pharmacopoeia Sterile Single-use Plastic Syringes monograph and testing as per Appendix XIX G, and the additional requirements for extended testing for a minimum of 7 days at 4°C & 20°C to reflect normal hospital pharmacy practice and up to a maximum of 14 days.
3) Chemical stability and drug adsorption assessment in accordance with Chemical stability testing has been carried out as per 'A Standard Protocol for Deriving and Assessment of Stability Part 1 Aseptic Preparations (Small Molecules) 3rd edition December 2015' – NHS Pharmaceutical Quality Assurance Committee. Using Fentanyl 2micrograms/ml (with Bupivacaine 0.1%) in Sodium Chloride 0.9% stored at Room Temperature 15-25°C to represent adsorption risks and Hydrocortisone sodium succinate 1mg/ml in Water For Injections stored Refrigerated at 2-8°C to assess stability risks. These compounds were selected as markers to allow extrapolation to other drugs normally stored in neuraxial syringes that are more stable and less susceptible to adsorption.

   Following agreement with BBraun I was permitted to review the various testing protocols carried out with or relevant to BBraun NRFit neuraxial syringes in accordance with the above.

1) <u>Stability studies – Fentanyl with Bupivacaine</u>

   The study was carried out in accordance with standards and the data generated indicates that Fentanyl (2mcg/ml) and Bupivacaine (1mg/ml) was stable at both 5°C and 25°C throughout the 42 days of the study period. This is in-line with expectations and shows that the syringes have no impact on drug stability and that there are no issues with adsorption of the drug onto contact surfaces

2) <u>Stability studies – Hydrocortisone sodium succinate</u>
   The study was again carried out in accordance with standards and the data generated indicates the Hydrocortisone sodium succinate (1mg/ml in WFI) was stable for approximately 12 days at 5°C or 3

days at 25°C, this is in-line with expectations from other studies and indicates that the syringes have no impact on drug stability and that there are no issues with adsorption of the drug onto contact surfaces

3) Extractables testing / BP plastic syringe testing

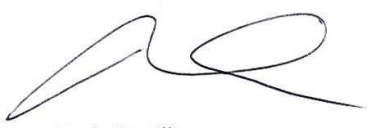
Testing for extractables in accordance with BP protocols and for extended periods of storage of 14 days at 5°C, 25°C and 37°C showed that extractives levels were well within the specification, indicating that extractives are not an issue of concern with these syringes

4) Integrity testing

The microbiological integrity test was carried out using the *Brevundimonas diminuta* method, on the initial test the syringes were filled to the full nominal volume at the request of BBraun, this did result in some failures for the 5ml syringe size (although the 20ml size passed). The test was repeated in line with the NHS standard test at 85% fill and all syringes then passed. Hence this stresses the importance of following the NHS guidance for maximum 85% fill for all syringes being used for drug storage even in the short term.

Conclusion

BBraun NRFit syringes in combination with BBraun NRFit Syringe Caps can be safely used for short term storage of intrathecal drugs, this applies across the whole range of sizes. The shelf life of these products can be in line with that used in other validated syringe and closure combinations. This is of course limited to seven days in aseptic units operating under section 10 exemption where suitable drug stability data exists to cover this period. Units working under a Specials Licence can assign a longer shelf life where stability data and in-house process validations support this. For all units NRFit syringes should be included in ongoing media validation studies or other relevant process / product validation studies as appropriate.



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