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Pharmacy

THE DEVELOPMENT OF HOSPITAL MANUFACTURED READY TO USE HEPARIN SOLUTION TO FLUSH CATHETERS

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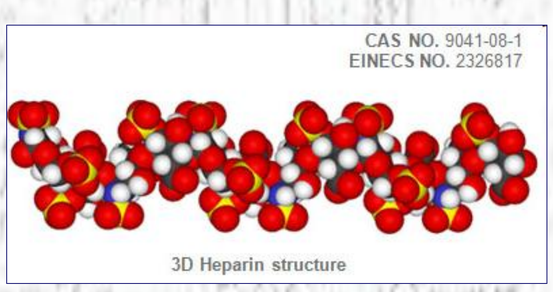
BACKGROUND

Heparin flush solution is a sterile preparation of heparin sodium with sufficient sodium chloride to make it isotonic with blood. So far heparin has been mainly prepared on wards from concentrated solution (25.000 IU/ml) prior to application.



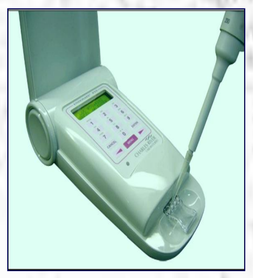
PURPOSE

- ✓ **A key component: Managing medicines safely.**
- ✓ **To streamline the preparation.**
- ✓ **Provide products that meets all the quality criteria**

Data information about the desired concentrations and quantities of different concentrations of heparin in saline solution were obtained using a 3-month data collection on pediatric hospital wards.

MATERIAL

Heparin Sodium injectable grade, sodium chloride low in endotoxins, suitable for the biopharmaceutical production.



METHOD OF PREPARATION

- ✓ **Suitable amount of heparin sodium and sodium chloride are weighed in sterile glass and dissolved in chilled water (20 °C) for injections.**
- ✓ **After homogenization the sample for in process control is taken.**
- ✓ **Solution is filtered through 0.2 µm membrane filter in 100 ml Asolvex glass bottles.**
- ✓ **Sterilization by steam sterilization 15 min by 121 °C.**

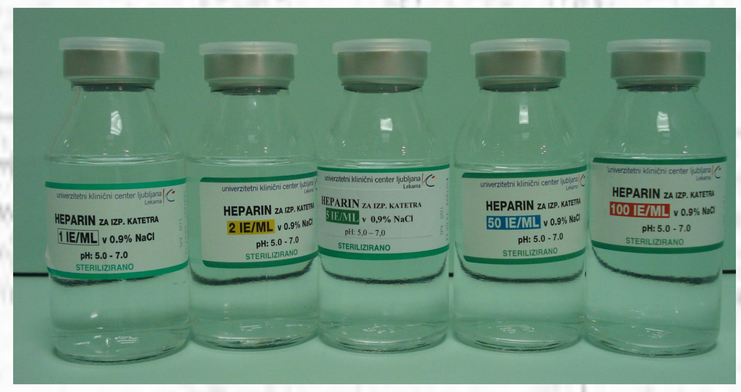
ANALITICAL TESTING

We have prepared a series of solutions of various content of Heparin Sodium in 9 mg/ml Sodium Chloride solution. Heparin content was measured before and after filtration and before and after sterilization. Tests were made in accordance with the European Pharmacopoeia chapter 2.7.5. At the same time the pH value and the content of sodium and chloride was measured. All samples were tested for Pyrogens and sent for Sterility testing.

CONCLUSIONS

Our final products of Heparin Sodium in Sodium Chloride solution are 100ml solutions with concentrations:
1IU, 2 IU, 5 IU, 50 IU and 100 IU/ml.

All concentrations in sodium chloride solution are stable under sterilization conditions. No significant decrease in heparin activity during autoclaving cycle at 121 °C 15 minutes was detected.



LITERATURE:

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