A SCIENCE- AND RISK-BASED STRATEGY TO QUALIFY STERILISED PREFILLED SYRINGES AS PRIMARY PACKAGING MATERIAL IN A HOSPITAL PHARMACY

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Background To improve medication safety in hospitals, the Joint Commission International standard recommend implementation of ready-to-administer (RTA) drugs. Many hospital pharmacies facilitate this in aseptic filling of polypropylene single-use syringes. The main disadvantages of this product, though the container is not meant for storage, are the aseptic process, the shelf life and the refrigerator capacity. The solution was found in a cyclic olefin polymer (COP) syringe, which can be terminally sterilised. All individual components of the syringe comply with the regulatory demands but to ensure that the new product does not adversely affect patient safety or product quality qualification is required.

Purpose A science- and risk-based strategy to qualify COP syringes as primary packaging material for the production of terminally sterilised RTA syringes with a high speed (semi-) automatic filling and closing machine in a hospital pharmacy.

Material and methods A 50 ml COP syringe with a polypropylene/butyl rubber tip cap and a butyl rubber stopper and a 5 ml COP syringe with an elastomer tip cap and a butyl rubber stopper were used for qualification. Validation batches of NaCl 0.9% with phosphate buffer pH 2, 5.8, 8 and 11, NaCl 0.9%, isopropyl alcohol (IPA) 5% in water and water for injections were produced. On t=0, 1, 2, 3, 4, 5, 6, 9, 12, 18 and 24 months the following tests were performed on the batches; clarity and degree of opalescence of the solution (Ph. Eur. 2.2.1), degree of colouration of the solution (Ph. Eur. 2.2.2), pH of the solution, absorbance (Ph. Eur 3.2.2.1), reducing substances (Ph. Eur. 3.2.2.1), transparency (Ph. Eur. 3.2.2.1), weight loss, subvisible particles (Ph. Eur. 2.9.19), silicon, closure integrity and sterility (Ph. Eur. 2.6.1).

Results All performed tests complied with acceptance criteria according to the Ph. Eur. Monographs. High pH value (11.8) showed higher absorbance, indicating more extractables and leachables; maximum 0.06 at t=24 months) than neutral pH ranges (5–8); and maximum 0.02.

Conclusion The syringes are suitable as primary packaging material for producing RTA products in a hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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