93% OXYGEN SELF-PRODUCTION: EXPERIENCE IN AN ITALIAN HOSPITAL

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Background and importance The introduction of 93% oxygen (±3%) in the EU Pharmacopoeia has allowed its therapeutic use. Production costs are related to electricity and maintenance. Each oxygen cubic meter (m³) produced consumes 0.75 kWh, approximately € 0.21/m³, while gaseous oxygen in cylinders for system backup costs about € 0.50/m³. The production plant works at low pressures (8 vs 200 bar) and is compact.

Aim and objectives The objective was to estimate 93% oxygen consumption in 2018 in a hospital equipped with this system to compare the cost versus the purchase 99% oxygen.

Material and methods Data were acquired from the plant located in a small hospital (33 places): percentage purity, energy consumption, possible interruption of operation and quantity produced. Data were subsequently processed by Microsoft Excel software.

Results In 2018, 12 095 m³ of 93% oxygen were produced for an electricity charge of € 2539.95. During the year before the installation (2014), 18 000 m³ of oxygen 93% were consumed for a cost of around € 55 000. The cost reduction was over 50%. Oxygen content always remained within the range (average 94.88%, maximum 95.89%, minimum 93.22%). The randomised controlled trial (RCT) that took place in the first year of use to demonstrate the overlapping efficacy of the two alternatives gave the following results:

- 93% oxygen group: 95% l/min flow, 91% sat O₂, in range, 92% EGA T1 in range;
- Oxygen group 99%: 97% l/min flow, 90% sat O₂, in range, 93% EGA T1 in range.

Conclusion and relevance This analysis highlights the goodness of the investment and the reliability of the system. The annual consumption of oxygen was reduced due to less waste compared with the use of 99% oxygen cylinders. Significant savings have been made for the hospital, maintaining the quality, safety and efficacy of the drug, as demonstrated by the RCT performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-036 CASE STUDY: DEVELOPMENT OF AN OINTMENT ACCORDING TO THE PHARMACEUTICAL INSPECTION CONVENTION GUIDELINE

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Background and importance Haemorrhoid treatment has a significant community and hospital pharmacy burden. Treatment options are varied but in non-severe cases, topical is usually the form of administration selected. In this ointment, three pharmacological effects are combined, mainly found in commercial forms through a simple manufacturing procedure, accessible to the facilities of a hospital pharmacy laboratory.¹

The Pharmaceutical Inspection Convention, published in March 2014, is a guideline for healthcare establishments to ensure the quality of medicines manufactured in pharmaceutical services.

Aim and objectives To develop a semisolid pharmaceutical form for haemorrhoid treatment. This form contained a vasoconstrictor, local anaesthetic and glucocorticoid. Application of the current guidelines to the elaboration of medicines in the hospital pharmacy was applied.²

Material and methods Material: ointment base—vaseline, paraffin and levomethol; APIs—phentolamine hydrochloride, lidocaine hydrochloride and hydrocortisone. Equipment: electronic analytical scale pinacle; Agilent Series 1100 with quaternary pump and diode array detector; and ThermoScientific Haake Viscotester 550. The organoleptic characteristics and rheologic properties were assessed. Content homogeneity of the three APIs was proved through a high performance liquid chromatography (HPLC) validated method.³

Results A manufacturing system in the hospital pharmacy was developed following the concept of quality by design.⁴ A quality assurance system was established to supervise the whole manufacturing process and documentation. Full pharmaceutical characterisation was developed, including the development and validation of a HPLC method to quantify the three APIs in the ointment.

Conclusion and relevance This work corroborates the fact that application of these guidelines in combination with the International Conference of Harmonisation instructions is both feasible and convenient in terms of manufacturing medicinal products in healthcare establishments. This methodology will be implemented in the manufacture of more complex medicinal products in subsequent work.

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