Hospital preparation of sterile Vaseline oil: a rapid response to a global shortage

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Context

Sterile Vaseline Oil (HP2L, CAS 8012-95-1 monograph Ph.eur 07/2018:0240) is required for adjuvant treatment of burns, skin grafts and probe insertion into peripheral and deep organs. Following a halt in the production and national distribution of the only sterile vaseline oil speciality, the use of a hospital preparation was suggested in order to mitigate the risk of shortages. In this work, we report on a process for the production, sterilisation and packaging of sterile vaseline oil in type I amber vials (50 mL). A control of this hospital preparation completes this work.Translated with DeepL.com (free version)

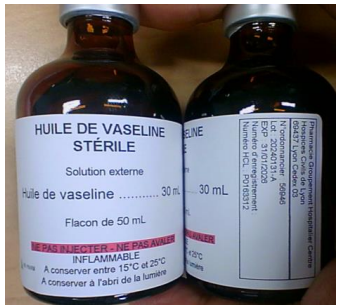
Materials and Methods

1. Production method : HP2L aseptically distributed, using an aseptic peristaltic pump, in a class A area, in amber type I sterile vials (50 mL) capped (chlorobutyl caps) and crimped using aluminium caps.
2. Sterilisation and validation of the sterilisation cycle : After production, the HP2L vials were wet-steam sterilised at 121°C (i.e. < flash point 149°C) for one hour. The efficacy of this sterilisation cycle was assessed by artificially contaminating HP2L vials with strips adsorbed with bacillus stearothermophilus spores. At the end of the sterilisation cycle, the strips were inoculated into a culture medium (Tryptone-Soya broth) and then incubated at 60°C for 7 days. Non-sterilised HP2L control vials containing spores, culture medium (Tryptone-Soy broth) with and without spores (positive and negative controls, respectively) were incubated as described above.
3. Infrared analysis and rheological properties of HP2L, particle counts (visible and non-visible) and microbiological controls were carried out at the end of production and sterilisation.

Results and Discussion

- The microbiological results confirmed the effectiveness of the sterilisation process, with no bacterial growth in the autoclaved bottles.Rheological analysis, using a falling ball viscometer, showed no change in the apparent viscosity of HP2L after autoclaving (25 mPa.s to 80 mPa.s).
- The particle counts were in line with the specifications for parenteral drugs.
- No change in the infrared spectrum of HP2L was shown after autoclaving.

A feasibility and risk analysis was carried out to validate a production method and physico-chemical and microbiological controls for a sterile HP2L hospital preparation.



Conclusion

This preparation method makes it possible to obtain an oil sterilised by moist heat, to be stored at room temperature and protected from light, thus making it possible to compensate for the cessation of marketing of this preparation.This study illustrates the importance of hospital preparations in the therapeutic arsenal, particularly in situations where there is a shortage of medicines with low market value but a therapeutic value chain with high added value or essential to medical practice.