Editorial

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Quality in Stability Testing

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The last editorial of our journal was entitled "Stability Studies: A Scientific Mission of the Hospital Pharmacist". In the special issue Dr Jean Vigneron from the University Hospital of Nancy in France emphasized the importance of stability studies for assigning a proper shelf life to compounded products [1]. In this issue we have three further examples of stability studies and a paper on the Stabilis® database implemented online by Jean Vigneron more than 15 years ago (www.stabilis.org). This highlights the importance of those studies for the hospital pharmacist's work. As mentioned before, a good communication of these results obtained by colleagues worldwide is essential for our profession. This is, thus, one of our journal's missions. The Stabilis® database is the resource to gather worldwide data on stability studies from scientifically validated sources in one place. It helps pharmacists in their everyday jobs. However, the details of these studies have to be published and peer-reviewed in order to assess the quality of the results and also to allow the readers to form their opinions on the suitability of a particular published work for their proper needs.

Good quality of stability studies is essential as their results will be used to guarantee the safe use of compounded products. The first step to ensure the quality of those studies is a good design of the experimental protocol. To do so, the GERPAC/SFPC "methodological guidelines for stability studies of hospital pharmaceutical preparations" published in 2013 are a good starting point [2]. A good physical or chemical stability study has some key features: 1) it has to rely on a validated analytical procedure, which is stability indicating, i. e able to detect and quantify degradation products; 2) The conservation conditions should be monitored and be reproducible (light, humidity, temperature); 3) global stability assessments such as viscosity determination, pH measurement, osmolarity and visual inspection should also be performed; 4) different stresses and forced degradations (light, heat, oxidising agents, acids etc.) are needed to determine the degradation pathways and to validate the analytical method; 5) if relevant, a microbiological stability test should be performed; 6) statistical analysis of data is mandatory on samples prepared at least in triplicates; 7) materials and staff are properly qualified. Those could be called the 7 golden rules to ensure reliability and quality of stability studies. Stability testing is thus performed in specialized hospital pharmacies or university research teams that are able to fulfil those 7 rules. In March 2018, the Stabilis® database lists 595 such teams from the five continents, which published stability studies dating back to 1974.

All of the published studies are not of the same quality regarding the rules proposed above. Some criteria to judge a work describing stability assessment have already been proposed [3]. In order to help the Stabilis® user to evaluate the quality of a published paper, the database now provides a level of evidence between A + and D for some selected publications. The method to determine this rating and the analysis of the obtained results is described in the first paper of this PTHP issue. This work is presented by the team of Jean Vigneron in Nancy, France. The same team proposes also, in another paper, a good example of a stability study with the determination of the influence of sodium chloride concentration, temperature and container on the conservation of bendamustine, an anticancer drug. The work includes also the interaction between the container and the solutions.

In this issue you will furthermore find a study by the team of Prof. Jean-Daniel Hecq from CHU UCL Namur in Belgium. This work describes the stability of vancomycine hydrochloride in syringes for intensive care units and diluted in glucose or sodium chloride after 48 h. This is also a good example of how such a study should be run as it includes physical stability by visual and microscopic inspection plus optical density measurements and chemical stability by liquid chromatography (HPLC). This kind of work opens the door for large batch in advance compounding in a centralised intra venous additive service (CIVAS), as explained before in a previous opinion paper [4]. The third example of a stability

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study is the work presented by the team of Pierre-Nicolas Boivin from CHU Rennes in France on the conservation of nitrendipine, a calcium channel blocker, in an oral suspension for use in children. Once again, besides HPLC determination of the drug and its degradation products, some global stability tests have been implemented i. e. osmololality determination, pH measurements, visual inspection, and a microbiological study. This allowed a very complete stability monitoring along the 90-days duration of this experiment.

PTHP is also a journal that aims to help pharmacy staff in acquiring and maintaining scientific and technical skills. Thus, continuing education, and also education of newcomers in pharmacy facilities from the very beginning is of primary importance. In order to do so, some educational innovations such as virtual reality have already been described in our journal in the past [5]. In this issue you will find the description of a new educational serious game for sterilization units. This game is called SteriDefi® and is accessible online on the website (http://www.sf2s-sterilisation.fr/infos/steridefi/) of the French society for sterilization sciences (SF2S). The paper describes how the game was designed and what its educational purposes are. It is truly an original way to help technical staff learn the procedures to be followed in a sterilization unit. This new game can be adapted to many professional skills found in hospital pharmacies if its questions are modified. Therefore, this article is interesting to read considering a wide range of pharmaceutical applications. The experience of the game was described by the gamers as really enjoyable while meeting educational objectives.

As you can see, issue after issue, PTHP is becoming one of the scientific reference media for our profession in its technological aspects. We are very proud of this as we are entering the third year of existence of our journal.

References

1. Vigneron J. Stability studies : A scientific mission of the hospital pharmacist. Pharm Technol Hosp Pharm 2017;2:143–44.
2. Sautou V, Bossard D, Chedru-Legros V, Crauste-Manciet S, Fleury-Souverain S, Lagarce F, et al. Methodological guidelines for stability studies of hospital pharmaceutical preparations, 1st ed. GERPAC and SFPC, editor. 2013:75.
3. Hecq J-D, Bihin B, Jamart J, Galanti L. Criteria for judging the quality of a publication on physicochemical stability of ready to use injectable drugs. Pharm Technol Hosp Pharm 2017;2: 79–84.
4. Vrignaud S. Resolution CM/Res(2016)2 and Centralised Intra Venous Additive Services (CIVAS): challenges and opportunities. Pharm Technol Hosp Pharm 2017;2:137–42.
5. Denami M. Simulation: a powerful tool for training professional skills in cleanrooms. Pharm Technol Hosp Pharm 2015;1:45–53.