Physical-chemical stability of docetaxel concentrated solution during one month

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Résumé en anglais	**Background** Docetaxel is an antineoplastic agent widely used in combination with others cytotoxic agents in many cancers (breast cancer, non-small cell lung cancer, prostate cancer, etc.). Today, this costly cytotoxic agent is marketed by several pharmaceutical companies who suggest discarding any remainder immediately after use, making it a very costly drug. **Purpose** The aim of this study was to determine the physical-chemical stability of docetaxel stock solution after the first sampling in the vial. **Materials and methods** The study was conducted in accordance with European consensus guidelines for the practical stability of anticancer drugs (1) and by two societies GERPAC and SFPC (2). The physical-chemical stability was assessed on 3 different vials of docetaxel (Taxotere 20 mg/mL). On day 0, 2, 4 and 30 triplicate samples of each vial of docetaxel were assayed by a high performance liquid chromatography (HPLC) method with UV detection at 230 nm (method validated following ICH guidelines). Docetaxel concentration at day 0 was considered to be 100% and if the docetaxel concentrations in samples were greater than 90% in the following days they were considered stable. The reference concentration was degraded by 20% by addition of a quantity of 0.01N NaOH in order to produce and observe primary degradation products. On each vial and on different days, docetaxel UV absorption spectra between 200 and 600 nm, pH and colour change were compared by a visual inspection with reference at T = 0, and finally a turbidimetry method at 350, 410 and 530 nm was used to evaluate the formation of visible and sub-visible particles. **Results** After 30 days, for each sample, no colour or pH change were observed, all UV spectra and turbidimetry measures were strictly similar. From day 2 to day 30, docetaxel concentrations were not significantly different to the day 0 solution and no degradation products were observed in any samples. According to these results, no significant drug loss was shown during the study period. **Conclusions** At a storage temperature between 20 to 25°C for 30 days, docetaxel solution at 20 mg/mL was seen to be stable. The sterility of the solution was not tested because the handling environment (Iso 5) was strictly controlled and operator validations are regularly checked.
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[1] http://okina.univ-angers.fr/t.briot/publications
[2] http://okina.univ-angers.fr/publications?f[author]=19338
[3] http://okina.univ-angers.fr/publications?f[author]=10682
[4] http://okina.univ-angers.fr/frederic.lagarce/publications
[5] http://dx.doi.org/10.1136/ejhpharm-2013-000436.302
[6] http://okina.univ-angers.fr/publications/ua10961