

# Stock holding of compounded cytostatics – how do SPC's support this?

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## Background

Increasing demand for compounded cytostatics has forced Danish hospital pharmacies to develop solutions which support effective work flow in decentralized and future centralized production units. One way to optimize the logistics is stock holding of compounded cytostatics for 1-3 months. This requires documentation of extended shelf lives of the compounded products.

## Objective

The aim was to bring a survey of the shelf lives and the usefulness of the information stated in section 6.3 in the SPC's for 13 selected compounded cytostatics.

## Materials and methods

The SPC's was identified on [www.produktresume.dk](http://www.produktresume.dk) and [www.ema.europa.eu](http://www.ema.europa.eu) the 5<sup>th</sup> of May 2011.

## Results

For the 13 cytostatics 150 SPC's were identified.

ACTIVE INGREDIENT	NO. OF SPC'S	MIN SHELF LIVE	MAX SHELF LIVE
Carboplatin	7	8 hours	24 hours
Cisplatin	4	12 hours	14 days
Cyclophosphamid	2	12 hours	12 hours
Cytarabin	4	12 hours	12 hours
Docetaxel	13	Immediately	24 hours
Doxorubicin	13	24 hours	28 days
Epirubicin	22	Immediately	28 days
Fluororacil	2	Not started	Not started
Gemcitabin	30	24 hours	28 days
Irinotecan	16	24 hours	28 days
Oxaliplatin	18	12 hours	7 days
Paclitaxel	17	8 hours	14 days
Vincristin	2	Not started	Not started
<b>In total</b>		150	

Table 1. The minimum and maximum shelflives identified for 13 active ingredients.

STATED STABILITY	NO. OF SPC'S	DISTRIBUTION
≤ 24 hours	59	39%
> 24 hours	55	37%
No data presented	36	24%

Table 2. The distribution of SPC's with shelflives above/under 24 hours or not stated.



## Discussion

The longest shelf life identified for compounded cytostatics was 28 days for Doxorubicin, Epirubicine, Gemcitabine and Irinotecan.

Great variation between the minimum- and maximum shelf lives for the same drug substance between different producers was observed. The biggest discrepancy occurred for Epirubicin with a minimum shelf life was "use immediately after compounding" and a maximum shelf life of 28 days after compounding.

Table 2 shows that 24% of all the SPC's do not state shelf live for the compounded product, but only for the original- or reconstituted product.

Other observations were that besides few exceptions the concentration interval of which the shelf lives can be applied is not stated in the SPC's, and also consistent terminology in the SPC's is lacking.

## Conclusions

Due to the limited information in the SPC's it is generally not possible to produce cytostatics in DK for stock based on the information given in the SPC's.