Review Article

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SFPO and ESOP recommendations for the practical stability of anticancer drugs: second update

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Abstract A second update of the recommendations for the practical stability of anticancer drugs published in 2013 has been realized by the French Society of Hospital Pharmacists (SFPO); European Society of Oncology Pharmacists (ESOP); and members of the Stabilis® database (www.stabilis.org), a stability and compatibility database of drugs. Forty-six new molecules have been included. These new data make it possible to optimize anticancer drug preparations and achieve product savings. These new recommendations have to be taken into consideration only if the preparation is made according to the Good Manufacturing Practices in classified rooms.

Keywords: stability, anticancer drugs, monoclonal antibodies, Stabilis

1. Introduction

These recommendations for storage conditions of anticancer drugs are the result of the deliberations of the SFPO (French Society for Oncology Pharmacy) stability group. The first edition of the data was published in 2008 by the *Centre National Hospitalier d'Information sur le Médicament*, CNHIM–National Information Centre on Hospital Drugs. The stability group comprised Arnaud P, Astier A, Bellanger A, Bonan B, Breilh D, Burnel S, Daouphars M, Ferrio AL, Havard L, Helvig A, Husson MC, Pinguet F, Poisson N, Sarrut B, and Vigneron J. These recommendations were adopted as the European standard by ESOP in 2010 and published in the European Journal of Oncology Pharmacy.[1]

A new group with members of SFPO and European hospital pharmacists updated this work in 2012. This new group comprised Alain Astier, Mikaël Daouphars, Frédéric Pinguet, Bertrand Pourroy, and Jean Vigneron for SFPO and Jean Daniel Hecq from Belgium, Iben Larsson from Denmark, and Rainer Trittler from Germany. This updated article was published in 2013.[2]

Many molecules having been marketed since 2013; the objective of this work was to update these recommendations for the daily practice of centralized anticancer drug preparation units (optimization of preparation conditions, preparation in advance of standardized doses, savings of medicine).

2. Material and Methods

This third updated article was performed by members of the Stabilis team (www.stabilis.org) and of the SFPO stability group.

The Stabilis® database conducts a monthly search for articles concerning the stability and compatibilities of injectable or noninjectable medications. This research includes anticancer drugs. The articles are selected from mainly pharmaceutical journals publishing stability studies and using PubMed® with the keyword "stability."

The scientific relevance of the articles is assessed by analyzing the methods used to study stability: physical methods (visual assessment: looking for a change in color, a precipitate—subvisual assessment [turbidimetry, particle counting, microscopic examination]) and chemical method (validated separative method—linearity, precision, stability indicating capacity, pH measurement).

For monoclonal antibodies, a set of complementary analytical methods is sought, evaluating the different levels of protein structure and the search for aggregates.

The conclusions of the articles are compared with the recommendations of the drug manufacturers. If the conclusions of the publications do not provide additional information in relation to the SmPC, the indication "Follow SmPC" (Summary of Product Characteristics) is indicated in the results. For drugs for which no sufficiently relevant publication has been found, the indication "Follow SmPC" is also retained.

3. Results and Discussion

3.1. New drugs

Forty-six new drugs have been included and presented in Table 1 (aflibercept, aldesleukin, amsacrine, arsenic trioxide, atezolizumab, avelumab, belinostat, blinatumomab, brentuximab

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Table 1

SFPO and ESOP recommendations for the practical stability of anticancer drugs.

Product	Container	Vehicle	Concentration	Recommendation for Storage Conditions	References
Aflibercept	Polyolefin (PO) infusion bags	NaCl 0.9%	0.6 and 4 mg/mL	14 days at 2–8°C, protected from light	[3]
Aldesleukin				Follow SPC	
Alemtuzumab				Follow SPC	
Amsacrine				Follow SPC	
Arsenic trioxyde				Follow SPC	
Asparaginase				Follow SPC	
Atezolizumab	PVC, PO infusion bags	NaCl 0.9%	2.4 >> 16.8 mg/mL	90 days at 2–8°C, protected from light 24 hours at 30°C, not protected from light	[5]
Avelumab				Follow SPC	
A 0.22-μm in-line filter has to be used					
Azacitidine	Polypropylene (PP) syringes	Water for injection (WFI) at 4°C	25 mg/mL	30 days at −20°C 2–5 days at 2–8°C depending on the publication	[5–8]
Belinostat				Follow SPC	
A 0.22-μm in-line filter has to be used					
Bendamustine				Follow SPC	
Bevacizumab	PO infusion bags	NaCl 0.9%	1.4–16.5 mg/mL	90 days at 4 or 25 °C	[9–15]
	PP syringes		25 mg/mL	6 months at 2–8°C	
	Vials with a Spike device		25 mg/mL	60 days at 2–8°C, protected from light	
Bleomycin	PP infusion bags	NaCl 0.9%	0.75 mg/mL	7 days protected from light, at 22°C or 4°C	[16]
Blinatumomab				Follow SPC	
A 0.22-μm in-line filter has to be used					
Bortezomib	Glass vials—PP syringes	NaCl 0.9%	Reconstituted: 1 mg/mL	35 days at 2–8°C and 25 days at 25°C	[17–19]
	Glass vials—PP syringes	NaCl 0.9%	Reconstituted: 2.5 mg/mL	30 days at 2–8°C or 25°C	
Brentuximab vedotin				Follow SPC	
Busulfan	2-piece syringes		Nondiluted solution: 6 mg/mL	28 days at 2–8°C or at room temperature	[20]
Never freeze busulfan	PVC or PO infusion bags	NaCl 0.9% or Dextrose 5%	0.1 mg/mL	4 hours at 23°C	[21]
Incompatible with polycarbonate (Dimethylacetamide)			0.5 mg/mL	8 hours at 23°C	
	PP syringes	NaCl 0.9%	0.54 mg/mL	30 hours at 2–8°C, protected from light	[22–24]
	PP infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.5 mg/mL	19 hours at 2–8°C, protected from light	
	Glass vials	NaCl 0.9%	Diluted in administration vehicle: 0.5 mg/mL	48 hours at 2–8°C, protected from light	
	PP infusion bags or glass vials	NaCl 0.9%	Diluted in administration vehicle: 0.5 mg/mL	36 hours at 13–15°C, protected from light	
Cabazitaxel	Vials with a Spike device	—	20 mg/mL	28 days at 25°C	[25,26]
A 0.22-μm in-line filter is recommended	PP	NaCl 0.9% or Dextrose 5%	0.1 >> 0.26 mg/mL	28 days at 2–8°C (PP infusion bags) or 25°C (PE, PO infusion bags), protected from light	
	Polyethylene (PE), PO infusion bags				
Carboplatin	PO, PE infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.70–2.15 mg/mL	83 days at 4°C and 1 day at room temperature, protected from light	[27–30]
	PP infusion bags	Dextrose 5%	Diluted in administration vehicle: 3.2 mg/mL	30 days at 25°C, protected from light	
	PVC infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.5 and 4 mg/mL	21 days at 25°C, protected from light	
Carfilzomib	Glass vials	WFI	2 mg/mL	28 days at 2–8°C	[31]
	PO, PP infusion bags	Dextrose 5%	0.6 >> 0.8 mg/mL	10 days at 25°C and 28 days at 2–8°C	
Carmustine with propylene glycol				Follow SPC	
Carmustine with ethanol	Glass vials	Ethanol	3.3 mg/mL	24 hours at 2–8°C, protected from light	[32–34]
Never use PVC (adsorption)	PO, PE infusion bags, glass vials	Dextrose 5%	0.2 mg/mL >> 1 mg/mL	48 hours at 2–8°C, protected from light	
Should be protected from light	PO infusion bags	Dextrose 5%	1 mg/mL	8.5 hours at 22°C, protected from light	
	PO infusion bags	Dextrose 5%	0.2 mg/mL	6 hours at 22°C, protected from light	
	PE infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.1 mg/mL	2 hours at 25°C, protected from light and 48 hours at 4°C	
Cetuximab	Vials with a Spike device		5 mg/mL	3 days at 25°C	[35]

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Table 1 (*continued*)

Product	Container	Vehicle	Concentration	Recommendation for Storage Conditions	References
	PP infusion bags		5 mg/mL	90 days at 4°C and 3 days at 25°C	
	PO infusion bags	NaCl 0.9%	1 mg/mL	90 days at 4°C and 3 days at 25°C	
Cisplatin	Ethyl vinyl acetate (EVA)—PE—PVC—PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.5–0.9 mg/mL; 0.1–0.4 mg/mL (PVC)	28 days at room temperature, protected from light	29,36–39
Cladribine	PVC, PE infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.016 mg/mL	30 days at 4°C and at 18°C	40
Clofarabine	PO infusion bags	Dextrose 5% or NaCl 0.9%	0.2–0.6 mg/mL	28 days at room temperature, without protection from light or at 2–8°C, protected from light	41
A 0.22-μm in-line filter has to be used					
Crisantaspase				Follow SPC	
Cyclophosphamide	Glass vials	NaCl0.9%	0.4 mg/mL	14 days at 2–8°C protected from light and 6 days at 21–25°C	42,43
	PVC infusion bags	Dextrose 5% or NaCl 0.9%	Diluted in administration vehicle: 1 mg/mL	7 days at 4°C and 7 days at room temperature in NaCl 0.9% and 2 days in Dextrose 5%, protected from light	
Cytarabine	PP syringes	NaCl 0.9%	Diluted in administration vehicle: 1 >> 10 mg/mL	28 days 2–8°C, protected from light	44
			Diluted administration: 1 mg/mL	14 days at 25°C, protected from light	
			Diluted administration: 5 mg/mL	8 days at 25°C, protected from light	
			Diluted administration: 10 mg/mL	5 days at 25°C, protected from light	
	EVA infusion bags	Dextrose 5% or NaCl 0.9%	Diluted in administration vehicle: 1.25 and 25 mg/mL	28 days at 25°C or 4°C, protected from light	45
Dacarbazine	Amber glass vials	WFI	Reconstituted: 11 mg/mL	7 days at 4°C and 4 days at room temperature, protected from light	46
Toxic products may form if the solution is not protected from light	PVC infusion bags	Dextrose 5%	Diluted in administration vehicle: 1.4 mg/mL	7 days at 4°C and 3 days at room temperature, protected from light	
Must be administered protected from light (bag + tubing)	PVC—PE infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.640 mg/mL	2 days at room temperature or at 4°C, protected from light	34
Dactinomycin	PVC infusion bags or glass vials	Dextrose 5%	Diluted in administration vehicle: 0.01 mg/mL	24 hours, in the light and at room temperature	47
Daratumumab	PP syringes	—	120 mg/mL	28 days at 2–8°C or 20–24°C, protected from light	48
	Infusion bags	NaCl 0.9%	Diluted in administration vehicle	Follow SPC	
Daunorubicin	PVC infusion bags	Dextrose 5% or NaCl 0.9%	Diluted in administration vehicle: 0.1 mg/mL	43 days at -20°C, 4°C and 25°C	49–51
At concentrations >0.5 mg/mL daunorubicin is not photosensitive for at least 7 days	PP infusion bags	WFI	Diluted in administration vehicle: 2 mg/mL	43 days at 4°C	
	PO infusion bags	Dextrose 5% or NaCl 0.9%	Diluted in administration vehicle: 0.4 >> 3 mg/mL	14 days at 4°C or 22°C, protected from light	
Daunorubicin/cytarabine lip				Follow SPC	
Dexrazoxane	Glass Vials	WFI	10 mg/mL	8 hours at 25°C, in the light	52,53
	PVC infusion bags	Ringer Lactate	Diluted in administration vehicle: 3, 4 and 8 mg/mL	8 hours at 25°C, in the light	
			Diluted in administration vehicle: 1 mg/mL	24 hours at 25°C, in the light	
	PE infusion bags	Ringer Lactate	Diluted in administration vehicle: 8 mg/mL	8 hours at 25°C, in the light	
	PVC infusion bags	Dextrose 5% or NaCl 0.9%	Diluted in administration vehicle: 1 mg/mL	24 hours at 25°C, in the light	
			Diluted in administration vehicle: 3 mg/mL	8 hours at 25°C, in the light	
	PE infusion bags	Ringer lactate	Diluted in administration vehicle: 4 mg/mL	4 hours at 25°C, in the light	
Docetaxel (two vials) (after reconstitution: 10 mg/mL)	Glass vials	Special solvent	Reconstituted: 10 mg/mL	28 days at 2–8°C and at 25°C	54,55
	PP, PE, PO infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 0.3–0.9 mg/mL	28 days at 25°C, protected from light	
			Diluted in administration vehicle: 0.3–0.7 mg/mL	56 days at 25°C, 2–8°C, protected from light	
Docetaxel (one vial) (Solution at 20 mg/mL)	PO infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.24–1 mg/mL	28 days at 20°C, 5°C, protected from light	56
Avoid PVC containers					
Doxorubicin	PP syringes	NaCl 0.9%	Diluted in administration vehicle: 1–2 mg/mL	124 days at 4°C, protected from light and 23°C	57
At concentrations >0.5 mg/mL: doxorubicin is not photosensitive for at least 7 days	PP syringes	-	2 mg/mL	84 days at 4°C, protected from light	29
	PVC infusion bags		Diluted in administration vehicle: 0.1 mg/mL	24 days at 25°C and 43 days at 4°C or -20°C	49,50

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Table 1 (*continued*)

Product	Container	Vehicle	Concentration	Recommendation for Storage Conditions	References
		Dextrose 5% or NaCl 0.9%			
Doxorubicin liposome PEG				Follow SPC	
Durvalumab			Diluted in administration vehicle	Follow SPC	
A 0.22-μm in-line filter has to be used	Vials with a Spike device		50 mg/mL	28 days at room temperature or 2–8°C, protected from light	58
Epirubicin	PP syringes	NaCl 0.9%	Diluted in administration vehicle: 1–2 mg/mL	150 days at 23°C and at 4°C, protected from light	59
At concentrations >0.5 mg/mL, epirubicin is not	PP syringes	-	2 mg/mL	84 days at 4°C	29
photosensitive for at least 7 days	PVC infusion bags	Dextrose 5% or NaCl 0.9%	Diluted in administration vehicle: 0.1 mg/mL	20 days at 25°C and 43 days at 4°C or -20°C	49,50
	PP syringes	NaCl 0.9%	Diluted in administration vehicle: 8.33 mg/mL	72 hours at 4°C, protected from light	60
Eribulin mesylate	PP syringes	None	440 μg/mL	14 days at 4°C or 20°C, with or without protection from light	61,62
		NaCl 0.9%	205 μg/mL	28 days at 2–8°C or 25°C, protected from light	
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 15.4 and 43.3 μg/mL	14 days at 4°C or 20°C with or without protection from light	
			Diluted in administration vehicle: 20 μg/mL	28 days at 2–8°C or 25°C, protected from light	
Etoposide	PO infusion bags	NaCl 0.9%	Diluted in administration: 0.4 >> 0.6 mg/mL	21 days at 23–27°C	63
Risk of precipitation with a storage at 4°C	PO infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.38 >> 1.26 mg/mL	61 days at 25°C	64
			Diluted in administration: 1.75 mg/mL	28 days at 25°C	
Etoposide phosphate	PVC infusion bags	NaCl 0.9% or dextrose 5%	0.1–10 mg/mL	31 days at 23°C and at 4°C	65
Fludarabine	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.04–1 mg/mL	21 days at 25°C or at 8°C	66
Fluorouracil	Glass or PVC infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 1.5 mg/mL	8 weeks at room temperature in the light	67
	PO infusion bags	NaCl 0.9%	7 mg/mL	17 days at 21–25°C	68
			8 mg/mL	24 days at 21–25°C	
	Silicone elastomeric diffuser	None	50 mg/mL	21 days at 25°C and 31°C	69
		NaCl 0.9% or dextrose 5%	25 mg/mL	21 days at 25°C and 31°C	
		NaCl 0.9%	35–44 mg/mL	3 days at 30°C and 28 days at 21–25°C	70
Folinate calcium	Glass vials	WFI	Reconstituted: 20 mg/mL	4 days at 4°C or 25°C, protected from light	71
	Glass vials or PVC infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 1–1.5 mg/mL	4 days at 4°C or 25°C, protected from light	
Folinate sodium	PE infusion bags	Dextrose 5%	Diluted in administration vehicle: 3.2 mg/mL	90 days at −20°C or 30 days at 4°C, protected from light	72
Fotemustine	PVC infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.8–2 mg/mL	2 days at 4°C and 8 hours at room temperature, protected from light	73
Administer protected from light					
Gemcitabine	PP syringes or glass vials	NaCl 0.9%	Reconstituted: 38 mg/mL	35 days at room temperature	74
	PVC infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 0.1–10 mg/mL	35 days at 4°C and 23°C	
	PVC infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 0.1–10–38 mg/mL	7 days at 32°C, protected from light	
Gemtuzumab ozogamycin				Follow SPC	
A 0.22 μm in-line filter has to be used					
Glofitamab				Follow SPC	
Idarubicin	PP infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 0.1 mg/mL	28 days at 25°C, protected from light	75
	PP syringes	WFI	4 mg/mL	7 days at 2–8°C, protected from light	76

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Table 1 (*continued*)

Product	Container	Vehicle	Concentration	Recommendation for Storage Conditions	References
Ifosfamide	PVC infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 30 mg/mL	30 days at 4°C, protected from light	77
	PVC infusion bags	NaCl 0.9%	10 mg/mL	8 days at 25°C or 4°C, protected from light	78
Inotuzumab ozogamicin				Follow SPC	
Irinotecan	PVC infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 0.4–2.8 mg/mL	28 days at room temperature or 2–8°C, protected from light	79
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 1 mg/mL	84 days at 4°C, protected from light	29
Ipilimumab	Vials with a Spike device	-	5 mg/mL	28 days, protected from light, at 4°C or 25°C	80,81
A 0.22-μm in-line filter has to be used	PO infusion bags	NaCl 0.9%	2 mg/mL	30 days, protected from light at 22°C or 4°C	
Isatuximab				Follow SPC	
A 0.22 μm in-line filter has to be used					
Levofolinate calcium	PE infusion bags	Dextrose 5%	Diluted in administration vehicle: 1.6 mg/mL	95 days at -20°C and 30 days at 2–8°C	82
	PO infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 1.7 mg/mL	14 days at 4°C, protected from light	83
	PP syringes	WFI	10 mg/mL	14 days at 4°C, protected from light	
Lurbinectedin	Glass vials	WFI	Reconstituted: 500 μg/mL	14 days at 4°C, protected from light	84
	Glass vials	NaCl 0.9% or Dextrose 5%	15–70 μg/mL	14 days at 4°C, protected from light	
	PO infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration: 30 μg/mL	14 days at 4°C, protected from light	
Melphalan	PVC infusion bags	NaCl 3%	Diluted in administration vehicle: 0.2 mg/mL	48 hours at 4°C, protected from light and 3 hours at 26°C, in the light	85
Dextrose 5% must not be used					
The degradation of melphalan increases with the temperature	PVC, PE infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.06 mg/mL	24 hours at 4°C and 1 hour at room temperature, protected from light	34
	PP infusion bags	NaCl 0.9% at 4°C	Diluted in administration vehicle: 2 mg/mL	4 hours at 4°C, followed by 90 min at room temperature	86
Methotrexate	PP syringes	NaCl 0.9%	Diluted in administration vehicle: 2.5 mg/mL	7 days at room temperature and at 4°C, protected from light	87
	PO infusion bags	NaCl 0.9% or dextrose 5%	Diluted administration vehicle: 20 mg/mL	28 days at 23–27°C, protected from light	88
	PO infusion bags	NaCl 0.9%	Diluted administration vehicle: 0.2 mg/mL	28 days at 23–27°C, protected from light	
	PVC infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.225–24 mg/mL	30 days at 4°C, protected from light	89
Mitomycin	PP syringes	NaCl 0.9%	Diluted in administration: 1–2 mg/mL	5 hours at 37°C	90
		WFI	1 mg/mL	8 hours at 25°C, protected from light	91,92
		WFI	2 mg/mL	8 hours at 25°C or 2–8°C, protected from light	
		NaCl 0.9%	0.4 mg/mL	6 hours at 25°C, protected from light 2 days at 2–8°C, protected from light	
		NaCl 0.9%	0.2 mg/mL	10 hours at 25°C, protected from light 5 days at 2–8°C, protected from light	
Mitoxantrone	Glass vials	Ready-to-use solution	2 mg/mL	42 days at 4°C and at 23°C	93
	PVC infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 0.04–0.4 mg/mL	7 days at 4°C and at 23°C, protected from light	94
Nelarabine	EVA infusion bags	None	5 mg/mL	28 days at 2–8°C, protected from light or at 25°C in presence of light	95
Nivolumab			Dilution in administration vehicle	Follow SPC	
A 0.22-μm in-line filter has to be used	Vials with a Spike device		10 mg/mL	28 days at 2–8°C	96
Obinutuzumab				Follow SPC	
Omacetaxine	Glass vials	NaCl 0.9%	3.5 mg/mL	14 days at 2–8°C and 24 hours at 25°C, not protected from light	97

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Table 1 (*continued*)

Product	Container	Vehicle	Concentration	Recommendation for Storage Conditions	References
	Polycarbonate syringes	NaCl 0.9%	3.5 mg/mL	14 days at 2–8°C	
Oxaliplatin	PO infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.25 mg/mL	90 days at 4°C, protected from light or at room temperature with or without protection from light	98
	PO infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.2–1 mg/mL	28 days at 22°C or 2–8°C, protected from light	99
	PO infusion bags	Dextrose 5%	Diluted in administration vehicle: 0.7 mg/mL	30 days at room temperature or 3–7°C, protected from light	100
Paclitaxel				Follow SPC	
Exclude PVC containing DEHP					
Paclitaxel is less stable at increasing concentration or temperature due to increased risk of precipitation					
A 0.22-μm in-line filter has to be used					
Paclitaxel albumin	Glass vials	NaCl 0.9%	5 mg/mL	7 days at 2–8°C	101
	EVA infusion bags	NaCl 0.9%	5 mg/mL	7 days at 2–8°C and 4 days at 25°C	
Panitumumab				Follow SPC	
A 0.22-μm in-line filter has to be used					
Pegaspargase				Follow SPC	
Pembrolizumab	PO infusion bags	NaCl 0.9%	1 and 4 mg/mL	14 days at 4°C or 7 days at room temperature	102,103
A in-line filter has to be used					
Pemetrexed disodium	PP syringes	NaCl 0.9%	Diluted in administration vehicle: 25 mg/mL	2 days at room temperature, not protected from light and 31 days at 4°C, protected from light	39,104
If stored at 4°C (microparticles might form), a 0.22-μm in-line filter has to be used	PE, PO infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 2.5–7.5–12.5 mg/mL	14 days at 2–8°C and 2 days at room temperature, protected from light	
Pemetrexed disodium pentahydrate				Follow SPC	
Pemetrexed diarginine	PO infusion bags	NaCl 0.9% or Dextrose 5%	Diluted in administration vehicle: 3–12 mg/mL	7 days at 20–25°C, not protected from light 28 days at 2–8°C, not protected from light	105
	Vials with a Spike device	—	Reconstituted: 25 mg/mL	7 days at 2–8°C, protected from light and 4 days at 25°C, not protected from light	
Pentostatin	Glass vials	NaCl 0.9%	Reconstituted: 2 mg/mL	3 days at 23°C	106
	PVC infusion bags, glass vials	NaCl 0.9%	Diluted in administration vehicle: 0.002–0.02 mg/mL	48 hours at 23°C	
Pertuzumab				Follow SPC	
Pevonedistat	Vials with a Spike device	NaCl 0.9%	10 mg/mL	7 days at 2–8°C, protected from light	107
	Glass vials	NaCl 0.9%	50 and 200 μg/mL	14 days at 2–8°C, protected from light	
	PO infusion bags	NaCl 0.9%	100 μg/mL	14 days at 2–8°C, protected from light	
Pixantrone				Follow SPC	
Raltitrexed				Follow SPC	
Ramucirumab				Follow SPC	
A 0.22 μm in-line filter has to be used					
Rituximab	Vials with a Spike device		10 mg/mL	15 days at 25°C and 28 days at 2–4°C	108,109
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 1 mg/mL	180 days at 4°C	
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 1 and 4 mg/mL	28 days at 2–8°C and 15 days at room temperature	
Romidepsine				Follow SPC	
Streptozocin				Follow SPC	
Tafasitamab				Follow SPC	
Teclistamab				Follow SPC	
Temozolomide				Follow SPC	
Temsirolimus	PP infusion bags	NaCl 0.9%	0.1 mg/mL	3 days at 20°C, protected from light and 4 days at 2–8°C	110
Exposure to light can lead to a degradation of tempsirolimus					
A in-line filter has to be used					

(*continued on next page*)

Table 1 (*continued*)

Product	Container	Vehicle	Concentration	Recommendation for Storage Conditions	References
Thiotepa	PO infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 1-2–3 mg/mL	14 days at 2–8°C	111
A 0.22-μm in-line filter has to be used		NaCl 0.9%	Diluted in administration vehicle: 1 and 3 mg/mL	1 day at 25°C	
		Dextrose 5%	Diluted in administration vehicle: 1 mg/mL	3 days at 25°C	
		Dextrose 5%	Diluted in administration vehicle: 2 mg/mL	5 days at 25°C	
		Dextrose 5%	Diluted in administration vehicle: 3 mg/mL	7 days at 25°C	
Topotecan	PVC infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.01 > 0.05 mg/mL	28 days at 4°C and at room temperature, protected from light	112
	Elastomere	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.01 and 0.05 mg/mL	28 days at 25°C or 2–8°C, not protected from light	
Trabectedin	Glass vials	WFI	Reconstituted: 0.05 mg/mL	21 days at 4°C protected from light	113
			Diluted in administration	Follow SPC	
Trastuzumab	Vials with a Spike device	WFI	Reconstituted solution: 21 mg/mL	90 days at 4°C	114–116
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.8 >> 4 mg/mL	76 days at 4°C	
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.8–2.4 mg/mL	180 days at 4°C or 18–22°C	
Trastuzumab emtansine				Follow SPC	
A 0.22 μm in-line filter has to be used					
Trastuzumab deruxetan				Follow SPC	
A 0.22 μm in-line filter has to be used					
Treosulfan				Follow SPC	
Vinblastine	Glass vials	WFI	Reconstituted: 1 mg/mL	21 days at 4°C, protected from light	117,118
	PP infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.02 mg/mL	21 days at 4°C and at 25°C, protected from light	
	PVC infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.1 mg/mL	7 days at 4°C, protected from light	
Vincristine	PP infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.02 mg/mL	21 days at 4°C and at 25°C, protected from light	117,119
	PP infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.025–0.1 mg/mL	84 days at 2–8°C or at 25°C, protected from light	
	PO infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.05 mg/mL	84 days at 2–8°C, protected from light or at 25°C	
Vindesine	Glass vials	WFI	Reconstituted: 1 mg/mL	21 days at 4°C, protected from light	117
	PP infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.02 mg/mL	21 days at 4°C and at 25°C, protected from light	
Vinflunine				Follow SPC	
Vinorelbine	PVC, PE infusion bags	NaCl 0.9%	Diluted in administration vehicle: 0.385 mg/mL	7 days at 23°C, protected from light	34,120
	PVC infusion bags	NaCl 0.9% or dextrose 5%	Diluted in administration vehicle: 0.5–2 mg/mL	5 days at room temperature, not protected from light	

vedotin, cabazitaxel, carfilzomib, cemiplimab, cetuximab, crisantaspase, daratumumab, daunorubicin/cytarabin liposomal, durvalumab, gemtuzumab ozogamycin, glofitamab, inotuzumab ozogamicin, ipilimumab, isatuximab, lurbinectedin, nivolumab, obinutuzumab, omacetaxine, paclitaxel albumin, panitumumab, pegaspargase, pembrolizumab, pemetrexed diarginine, pemetrexed disodium pentahydrate, pertuzumab, pevonedistat, pixantrone, raltitrexed, ramucirumab, romidepsine, tafasitamab, temozolomide, teclistamab, trabectedin, trastuzumab emtansine, trastuzumab deruxetan, treosulfan, vinflunine).

Among these 46 drugs, there are 15 monoclonal antibodies, 5 monoclonal antibody-drug conjugates, and 3 bispecific monoclonal antibodies showing that research at present is mainly oriented toward targeted therapies.

3.2. The advice "Follow SmPC"

For 33 medicines, our advice is to "Follow the SmPC" because for most of the medicines in this category, no publication has been found or the literature data do not provide any additional information compared with laboratory recommendations (as for asparaginase or carmustine). For four drugs (daratumumab, durvalumab, nivolumab, and trabectedin), relevant stability data are available in the literature and in the SmPC. Among these 33 drugs, it is interesting to point out that certain stability data are extended beyond 24 or 48 hours, a duration widely reported in the recommendations of pharmaceutical laboratories. This development is mainly explained by the need to promote the use of the product or to fight against competition from a product used in the same therapeutic area and already having an extended period of stability. These data concern arsenic trioxide (30 days), blinatumomab (10 days), durvalumab (30 days), glofitamab (72 hours), nivolumab (30 days), and pertuzumab (30 days).

3.3. Hospital or academic stability studies

For 16 drugs, publications allow greater stability than that of SmPC or show stability data in specific conditions. This highlights the interest of stability studies performed in hospital settings or universities. These data allow production in advance, reuse of nonadministered preparations, and product savings. These stabilities concern the following products: 14 days for aflibercept,[3] 90 days for atezolizumab,[4] 28 days for cabazitaxel,[25,26] 28 days for carfilzomib,[31] 90 days for cetuximab,[35] 28 days for daratumumab administered subcutaneously,[48] 28 days for a durvalumab vial with a Spike device,[58] 30 days for ipilimumab,[80,81] 14 days for lurbinectedin,[84] 10 days for a nivolumab vial with a Spike device,[96] 14 days for omacetaxin,[97] 7 days for paclitaxel albumin,[101] 14 days for pembrolizumab,[102,103] 28 days for pemetrexed diarginine,[105] 14 days for pevonedistat,[107] and 21 days for trabectedin in a glass vial.[113]

3.4. Stability studies of partially used vials

For 11 drugs (bevacizumab, cabazitaxel, cetuximab, durvalumab, ipilimumab, nivolumab, paclitaxel albumin, pemetrexed diarginine, pevonedistat, rituximab, trastuzumab), stability data for vials equipped with a Spike device are available in the literature. These data mean that leftover vials can be reused over several days, rather than discarded at the end of the activity.

3.5. New information for drugs present in the second edition

Some drugs received new information (azacitidine, bleomycin, busulfan, cisplatin, cytarabine, daunorubicine, dexrazoxane, epirubicine, etoposide, idarubicine, irinotecan, methotrexate, trastuzumab).

This new information concern the following:

- Stability in a new container
  - Polyolefin infusion bags: 28 days for cisplatin,[29] 14 days for daunorubicine,[51] 84 days for irinotecan,[29] 28 days for methotrexate,[88] and 76 days for trastuzumab.[115]
  - Polypropylene syringes: 30 hours for busulfan[24] and 5–28 days depending on the concentration for cytarabine.[44]
- Stability at high concentration for chemoembolization: epirubicine at 8.33 mg/mL[60] and idarubicine at 4 mg/mL.[76]
- Stability at lower concentration than SmPC: 1 mg/mL for dexrazoxane.[53]
- Stability at higher concentration than SmPC to allow smaller volumes of infusions for etoposide.[64]

4. Conclusion

As previously stated in the previous update, these new recommendations have to be taken into consideration only if the preparation is made according to the Good Manufacturing Practices in classified rooms. Biological safety cabinets or isolators have to be used for production, and the preparation process has to be validated to prove the sterility of the syringes or infusions.

These new stability will allow an optimization of preparation conditions, facilitate the preparation in advance of standardized doses and the savings savings of medicine.

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REFERENCES

1. SFPO stability group. SFPO and ESOP recommendations for the practical stability of anticancer drugs. EJOP 2010;4(3):7–10.
2. Vigneron J, Astier A, Trittler R, et al. SFPO and ESOP recommendations for the practical stability of anticancer drugs: an update. Ann Pharm Fr 2013;71:376–389.
3. Hermosilla J, Pérez-Robles R, Salmerón-García A, et al. Stability study over time of clinical solutions of ziv-aflibercept prepared in infusion bags using a proper combination of physicochemical and functional strategies. J Pharm Biomed Anal 2021;203:114209.
4. Hui A, Yin J, Liu W, et al. Prolonged In-use Stability of Diluted Atezolizumab in Commercial Intravenous Bags. Int J Pharm Compound 2021;25(3):246–257.
5. Balouzet C, Chanat C, Jobard M, et al. Stability of 25 mg/mL 5-azacitidine suspension kept in fridge after freezing. Pharm Technol Hosp Pharm 2017;2(1):11–16.
6. Trambloy Q, Vigneron J, Clarot I, et al. Physicochemical stability of azacitidine suspensions at 25 mg/mL in polypropylene syringes stored under different conditions of storage. Pharm Technol Hosp Pharm 2022; 7(1):20220003.
7. Iudicello A, Genovese F, Strusi V, et al. Development and validation of a new storage procedure to extend the in-use stability of azacitidine in pharmaceutical formulations. Pharmaceuticals 2021;14:943.
8. Vieillard V, Appudurai O, Voytenko S, et al. Stabilité physico-chimique de la suspension d'azacitidine (25 mg/mL) conservée à 4°C. Poster presented SFPO Congress, France; 2011. Available on: www.stabilis.org.
9. Khalili H, Sharma G, Froome A, et al. Storage stability of bevacizumab in polycarbonate and polypropylene syringes. Eye 2015;29(6):820–827.

10. Seckute J, Castellanos I, Bane S. Physicochemical stability of the bevacizumab biosimilar, ABP 215, after preparation and storage in intravenous bags. GaBI Journal 2020;9(4):155–162.
11. Park D, Kim J, Yun J, et al. Evaluation of the physico-chemical and biological stability of SB8 (Aybintio), a proposed biosimilar to bevacizumab, under ambient and in-use conditions. Adv Ther 2020; 37:4308–4324.
12. Paul M, Vieillard V, Roumi E, et al. Long-term stability of bevacizumab repackaged in 1 mL polypropylene syringes for intravitreal administration. Ann Pharm Fr 2012;70(3):139–154.
13. Vieillard V, Paul M. Physicochemical stability study of a biosimilar of Bevacizumab in vials and after dilution in 0.9% NaCl in polyolefin intravenous bags. Pharm Technol Hosp Pharm 2023;8(1):20220007.
14. Morand K, Paul M, Lahlou A, et al. Stabilité de solutions diluées de bévacizumab en fonction de la température. Poster presented at SFPO Congress, France; 2009. Available on: www.stabilis.org.
15. Weiser S, Burns C, Zartler E. Physicochemical stability of PF-06439535 (bevacizumab-bvzr; Zirabev®), a bevacizumab biosimilar, under extended in-use conditions. J Oncol Pharm Practice 2022;29(5):1032–1043.
16. El Kateb N, Chaussard M, Bellenger P, et al. Stability of an extemporaneously prepared bleomycin-lidocaine-epinephrine intradermal admixture used in dermatology. J Oncol Pharm Pratice 2014;21(3):178–187.
17. Law S, Charbonneau L, Iazetta J, et al. Stability of generic formulations of bortezomib 1.0 and 2.5 mg/mL in vials and syringes stored 4°C and room temperature (23°C). Can J Hosp Pharm 2021;74(1):57–69.
18. Bosch-Ojeda C, Sanchez-Rojas MF, Espinosa-Bosch M. Chemical stability of bortezomib solutions in original manufacturer vials. Int J Pharm Bio Sci 2012;2(3):344–350.
19. Berruezo garcia J, Espinosa Bosch M, Sanchez Rojas F, et al. Chemical stability of bortezomib solutions in original manufacturer vial at room temperature and in syringe at 4°C. Int J Pharm Bio Sci 2013;3(1): 449–458.
20. Karstens A, Krämer I. Untersuchungen zur Stabilität der Busulfan-Stammlösung (Busilvex®, Busulfex™) in B/Braun Injekt® Einmalspritzen. Pharmazie 2006;61:845–850.
21. Xu QA, Zhang YP, Trissel LA, et al. Stability of busulfan injection admixtures in 5% dextrose injection and 0.9% sodium chloride injection. J Oncol Pharm Practice 1996;2:101–105.
22. Karstens A, Krämer I. Chemical and physical stability of diluted busulfan infusion solutions. EJHP Science 2007;13(2):40–47.
23. Loboda C, Lider P, Vigneron J. Incompatibility of busulfan with 1 ml Luer-Lock syringes. J Oncol Pharm Practice 2016;22:571–572.
24. Guichard N, Bonnabry P, Rudaz S, et al. Stability of busulfan solutions in polypropylene syringes and infusion bags as determined with an original assay. Am J Health Syst Pharm 2017;74(22):1887–1894.
25. Lazzarini R, Salvadori S, Trapella C, et al. Physicochemical stability of cabazitaxel and docetaxel solutions. Eur J Hosp Pharm 2014;22: 150–155.
26. D'Huart E, Sacrez M, Vigneron J, et al. Physicochemical stability of Cabazitaxel Zentiva® solution in vials after opening and diluted-solutions in three infusion bags. Pharm Technol Hosp Pharm 2023; 8(1):20220009.
27. Kaestner S, Sewell G. A sequential temperature cycling study for the investigation of carboplatin infusion stability to facilitate 'dose-banding. J Oncol Pharm Pract 2007;13:119–126.
28. Prat J, Pujol M, Girona V, et al. Stability of carboplatin in 5% dextrose solutions in glass, polyethylene and polypropylene containers. J Pharm Biomed Anal 1994;12(1):81–84.
29. Sewell G, Massimini M. Studies on the stability and compatibility of cytotoxic drug infusion with the Tevadaptor system. EJOP 2014;8(3): 26–30.
30. Diaz Amador F, Sevilla Azzati E, Herreros de Tajeda y Lopez-Coterilla A. Stability of carboplatin in polyvinyl chloride bags. Am J Health System 1998;55:602–604.
31. Kim S.H, Krämer I. Physicochemical stability of carfilzomib (Kyprolis®) containing solutions in glass vials, ready-to-administer plastic syringes and infusion bags over a 28-day storage period. J Oncol Pharm Practice 2017;25(2):339–350.
32. Knoll L, Kraemer I, Thiesen J. Physicochemical stability of carmustine-containing medicinal products after reconstitution and after dilution to ready-to-administer infusion solutions stored refrigerated or at room temperature. Eur J Hosp Pharm 2023;30(1):1–16.
33. Favier M, De Cazanove F, Coste A, et al. Stability of carmustine in polyvinyl chloride bags and polyethylene-lined trilayer plastic containers. Am J Health-Syst Pharm 2001;58(3):238–241.
34. Beitz C, Bertsch T, Hannak D, et al. Compatibility of plastics with cytotoxic drug solutions-comparison of polyethylene with other container materials. Int J Pharma 1999;185(1):113–121.
35. Vieillard V, Le Guyader G, Jallades A, et al. Extended physicochemical stability of cetuximab in opened vials and infusion bags when stored at 4°C and 25°C. J Oncol Pharm Practice 2023;30(1):142–150.
36. Benaji B, Dine T, Luyckx M, et al. Stability and compatibility of cisplatin and carboplatin with PVC infusion bags. J Clin Pharm Ther 1994;19(2):95–100.
37. Rochard E, Barthes D, Courtois P. Stability of cisplatin in ethylene vinylacetate portable infusion-pump reservoirs. J Clin Pharm Ther 1992; 17(5):315–318.
38. Sewell G. Physical and chemical stability of cisplatin infusions in PVC containers. EJOP 2010;4(3):11–13.
39. Patel T, Sewell G. Short report: extended stability studies on bortezomib injection and infusions of cisplatin and pemetrexed (all Accord Healthcare). Newsletter Stabilis 2018;41:2–6.
40. Daouphars M, Vigneron J, Perrin A, et al. Stability of cladribine in either polyethylene containers or polyvinyl chloride bags. Eur J Hosp Pharm Prac 1997;3(4):154–156.
41. Kaiser J, Krämer I. Long-term stability study of clofarabine injection concentrate and diluted clofarabine infusion solutions. J Oncol Pharm Pract 2012;18(2):218–221.
42. Mittner A, Vincze Z, Jemnitz K. Stability of cyclophosphamide containing infusions. Pharmazie 1999;54:224–225.
43. Beijnen JH, Van Gijn R, Challa EE, et al. Chemical stability of two sterile, parenteral formulations of cyclophosphamide (Endoxan) after reconstitution and diluted in commonly used infusion fluids. J Parenter Sci Technol 1992;46(4):111–116.
44. Ben Ayed W, Drira C, Ali SM, et al. Physical and chemical stability of cytarabine in polypropylene syringes. J Oncol Pharm Practice 2020; 27(4):827–833.
45. Rochard E, Chapelle G, Bouquet S, et al. Stability of fluorouracil and cytarabine in ethylvinylacetate containers. J Pharm Clin 1989;9:31–35.
46. El Aatmani M, Poujol S, Astre C, et al. Stability of dacarbazine in amber glass vials and polyvinyl chloride bags. Am J Health Syst Pharm 2002; 59(14):1351–1356.
47. Benvenuto JA, Anderson RW, Kerkof K, et al. Stability and compatibility of antitumor agents in glass and plastic containers. Am J Hosp Pharm 1981;38(12):1914–1918.
48. Knoll L, Thiesen J, Klassen D, et al. In-use stability of ready-to-administer daratumumab subcutaneous injection solution in plastic syringes. European Journal of Hospital Pharmacy Published Online First: 25 October 2023. doi: 10.1136/ejhpharm-2023-003928.
49. Wood MJ, Irwin WJ, Scott DK. Stability of doxorubicin, daunorubicin, and epirubicin in plastic syringes and minibags. J Clin Pharm Ther 1990; 15(14):279–289.
50. Wood MJ, Irwin WJ, Scott DK. Photodegradation of doxorubicin, daunorubicin and epirubicin measured by high-performance liquid chromatography. J Clin Pharm Ther 1990;15(4):291–300.
51. Respaud R, Quenum L, Plichon C, et al. A stability-indicating, ion-pairing, reversed-phase liquid chromatography method for studies of daunorubicin degradation in i.v. infusion fluids. J Pharm Biomed Anal 2013;83:164–170.
52. Kaiser JD, Vigneron J, Zenier H, et al. Chemical and physical stability of dexrazoxane diluted with Ringer's lactate solution, in polyvinyl and polyethylene containers. Eur J Hosp Pharm Prac 2007;13(3):55–59.
53. Zhang Y-P, Myers AL, Trinh VA, et al. Physical and chemical stability of reconstituted and diluted dexrazoxane infusion solutions. J Oncol Pharm Practice 2014;20(1):58–64.
54. Thiesen J, Krämer I. Physico-chemical stability of docetaxel premix solution and docetaxel infusion solutions in PVC bags and polyolefine containers. Pharm World Sci 1999;21(3):137–141.
55. MacLeod S, Sewell G. Physical and chemical stability of docetaxel infusions. Eur J Hosp Pharm 2011;17(2):39–43.
56. Hart MC, Ahmed W. Taxotere 1-vial (docetaxel 20 mg/ml) physical and chemical stability over 28 days in infusion bags containing 0.9% saline solution and 5% glucose solution. EJOP 2011;5(1):24–27.
57. Walker SE, Lau DWC, DeAngelis C, et al. Doxorubicin stability in syringes and glass vials and evaluation of chemical contamination. Can J Hosp Pharm 1991;44:71–88.
58. Almasi K, Thiesen J, Krämer I. Physicochemical stability of durvalumab (Imfinzi®) concentrate for solution in original vials after first opening. Pharm Technol Hosp Pharm 2023;8(1):20230008.
59. Walker SE, Lau DWC, DeAngelis C, et al. Epirubicin stability in syringes and glass vials and evaluation of chemical contamination. Can J Hosp Pharm 1990;43:265–272.

60. Bennis Y, Savry A, Correard F, et al. Stability of a highly concentrated solution of epirubicin for conventional transcatheter arterial chemoembolization. Int J Pharm 2015;495(2):956–962.
61. Poujol S, Dell'ova M, Bekhtari K, et al. Stability of the ready-to-use solutions of eribulin for intravenous infusion. Ann Pharm Fr 2012;70: 249–255.
62. Spindeldreier K, Thiesen J, Lipp H.P, et al. Physico-chemical stability of eribulin mesylate containing concentrate and ready-to-administer solutions. J Oncol Pharm Practice 2014;20:183–189.
63. Sadou Yayé H, Hassani L, Secrétan PH, et al. Physical and chemical stability of a generic etoposide formulation as an alternative to etoposide phosphate. J Pharm Biomed Anal 2020;178:112896.
64. D'Huart E, Vigneron J, Lider P, et al. Physicochemical stability of etoposide diluted at range concentrations between 0.38 and 1.75 mg/mL in polyolefin bags. Eur J Hosp Pharm 2020;27(1):43–48.
65. Zhang Y, Trissel LA. Physical and chemical stability of etoposide phosphate solutions. J Am Pharm Assoc 1999;39(2):146–150.
66. Trittler R. New stability studies for fludarabine according to the European Pharmacopoeia 7.0. EJOP 2012;6(1):1–2.
67. Biondi L, Nairm C. Stability of 5-FU and fluorocytosine in parenteral solutions. Can J Hosp Pharm 1986;39(3):60–66.
68. Closset M, Onorati S, Colsoul M-L, et al. Long-term physicochemical stability of 5-fluorouracil at selected standardised rounded doses in polyolefin bags. J Oncol Pharm Pratice 2023;29(8):1878–1883.
69. Roberts S, Sewell GJ. Stability and compatibility of 5-fluorouracil infusions in the Braun Easypump®. J Oncol Pharm Pratice 2003;9: 109–112.
70. Closset M, Onorati S, Colsoul M.L, et al. Long-term physico-chemical stability of 5-fluorouracile at standardised rounded doses (SRD) in MyFuser® portable infusion pump. J Chemotherapy 2021;33(7): 486–491.
71. Lecompte D, Bousselet M, Gayrard D, et al. Stability study of reconstituted and dilute solutions of calcium folinate. Pharm Ind 1991; 53(1):90–94.
72. Cadrobbi J, Hecq JD, Vanbeckbergen D, et al. Effect of freezing, long-term storage and microwave thawing on the stability of sodium folinate. EJHP Science 2009;15(1):15–19.
73. Dine T, Khalfi T, Gressier B, et al. Stability study of fotemustine in PVC infusion bags and sets under various conditions using a stability-indicating high-performance liquid chromatographic assay. J Pharm Biomed Anal. 1998;18(3):373–381.
74. Xu Q, Zhang Y, Trissel LA. Physical and chemical stability of gemcitabine solutions. J Am Pharm Assoc 1999;39(4):509–513.
75. Beijnen JH, Rosing H, de Vries PA, et al. Stability of anthracycline antitumor agents in infusions fluids. J Parenter Sci Technol 1985;39(6): 220–222.
76. Bourcier B, Lagarce R, Lebreton V. Stability of a high-concentrated aqueous solution of idarubicin stored in a polypropylene syringe for transarterial chemoembolization. J Pharm Biomed Anal 2022;210: 114543.
77. Dine T, Lebegue S, Benaji B, et al. Stability and compatibility studies of four cytostatic agents (fluorouracil, dacarbazine, cyclophosphamide and ifosfamide) with PVC infusion bags. Pharm Sci Com 1994;4:97–101.
78. Munoz M, Girona V, Pujol M, et al. Stability of ifosfamide in 0.9% sodium chloride solution or water for injection in a portable IV pump cassette. Am J Health System 1992;49:1137–1139.
79. Thiesen J, Krämer I. Physicochemical stability of irinotecan injection concentrate and diluted infusion solutions in PVC bags. J Oncol Pharm Pract 2000;6(3):115–121.
80. Bardo-Brouard P, Vieillard V, Shekarian T, et al. Stability of ipilimumab in its original vial after opening allows its use for at least 4 weeks and facilitates pooling of residues. Eur J Cancer 2016;58:8–16.
81. Bardo P, Vieillard V, Astier A, et al. Stabilité physicochimique de solutions diluées d'ipilimumab: résultats préliminaires à 1 mois. Poster presented at SFPO Congress, France; 2013. Available: www.stabilis.org.
82. Lebitasy M, Hecq J.D, Athanassopoulos A, et al. Effect of freeze-thawing on the long-term stability of calcium levofolinate in 5% dextrose stored on polyolefin infusion bags. J Clin Pharm Ther 2009;34(4):423–428.
83. Sanogo S, Silimbani P, Gaggeri R, et al. Stability of calcium levofolinate reconstituted in syringes and diluted in NaCl 0.9% and glucose 5% polyolefin/polyamide infusion bags. J Oncol Pharm Practice 2021;27(2): 288–296.
84. Loeuille G, Vigneron J, D'Huart E, et al. Physicochemical stability of lurbinectedin reconstituted at 500 μg/mL and diluted at 15, 30, and 70 μg/mL in 0.9% sodium chloride and 5% dextrose. EJOP 2021;4(3): e03.
85. Pinguet F, Martel P, Rouanet P, et al. Effect of sodium chloride concentration and temperature on melphalan stability during storage and use. Am J Hosp Pharm 1994;51(21):2701–2704.
86. Vigneron J, Zenier H, May I, et al. Stabilité du melphalan à 2 mg/mL dans le chlorure de sodium 0,9% dans des conditions pratiques d'utilisation. Poster presented at the ECOP Congress, Pologne; 2014. Available: www.stabilis.org.
87. Jacolot A, Arnaud P, Lecompte D. Stability and compatibility of 2.5 mg/ml methotrexate solution in plastic syringes with 7 days. Int J Pharm 1996;128:283–286.
88. Nissen KB, Jorgensen LB, Berg DL, et al. Stability study of methotrexate in 0.9% sodium chloride injection and 5% dextrose injection with limit tests for impurities. Am J Health-Syst Pharm 2017;74(9):211–223.
89. Benaji B, Dine T, Goudaliez F, et al. Compatibility study of methotrexate with PVC bags after repackaging into two types of infusions admixtures. Int J Pharm 1994;105:83–87.
90. Myers A-L, Zhang Y-P, Kawedia J-D, et al. Solubilization and Stability of Mitomycin C Solutions Prepared for Intravesical Administration. Drugs R D 2017;17(2):297–304.
91. Briot T, Truffaut C, Le Quay L, et al. Stability of reconstituted and diluted mitomycin C solutions in polypropylene syringes and glass vials. Pharm Technol Hosp Pharm 2016;1(2):83–89.
92. Almasi J, Erdnuss F, Thiesen J, et al. Physicochemical stability of urea-containing Mitomycin C preparations in glass vials (1.0 mg/mL) and plastic syringes (2.0, 0.4, 0.2 mg/mL). Pharm Technol Hosp Pharm 2023; 8(1):20230003.
93. Walker SE, Lau DWC, DeAngelis C, et al. Mitoxantrone stability in syringes and glass vials and evaluation of chemical contamination. Can J Hosp Pharm 1991;44:143–151.
94. Lecompte D, Bousselet M, Magnam J. Stabilité des solutions diluées de mitoxantrone (Novantrone®) en poches de PVC pour perfusions. J Pharm Clin. 1990;9(3):159–165.
95. Kaiser J, Krämer I. Physico-chemical stability of nelarabine infusion solutions in EVA infusion bags. EJHP Science 2011;17(1):7–12.
96. Le GG, Vieillard V, Mouraud S, et al. Stability of nivolumab in its original vials after opening and handing in normal saline bag for intravenous infusion. Eur J Cancer 2020;135:192–202.
97. Parikh A, Van de Rijn J, Melville C, et al. Storage and transport of reconstituted omacetaxine mepesuccinate: Considerations for home administration. J Oncol Pharm Pract 2018;24(3):201–208.
98. Junker A, Roy S, Desroches MC, et al. Stability of Oxaliplatin Solution. Ann Pharmacother 2009;43(2):390–391.
99. Krämer I, Sarakbi I, Thiesen J. Physikalisch-chemische Stabilität von Oxaliplatin-beta-Infusionslösungskonzentrat und Infusionslösungen in 5 % Glucose in Polyolefin-Infusionsbeuteln. Krankenhauspharmazie 2017;38(7):334–340.
100. André P, Cisternino S, Roy AL, et al. Stability of oxaliplatin in infusion bags containing 5% dextrose injection. Am J Health Syst Pharm 2007; 64(18):1950–1954.
101. Linxweiler H, Thiesen J, Krämer I. Physicochemical stability of nanoparticle albumin-bound paclitaxel (Pazenir®) infusion dispersion in original glass vials and EVA infusion bags. Poster presented at the GERPAC Congress, France; 2023.
102. Avrillon K, Le Guyader G, Doillet H, et al. Etude de stabilité physicochimique de solutions diluées de pembrolizumab à 1 et 4 mg/mL conservées dans des poches en polyoléfine de NaCl 0.9. Poster presented at the SFPO Congress, France; 2021. Available: www.stabilis.org.
103. Sundaramurthi P, Sean Chadwick S, Narasimhan C. Physicochemical stability of pembrolizumab admixture solution in normal saline intravenous infusion bag. J Oncol Pharm Pratice 2020;26(3):641–646.
104. Zhang Y, Trissel LA. Physical and chemical stability of pemetrexed solutions in plastic syringes. Ann Pharmacother 2005;39(12): 2026–2028.
105. Nisse Y-E, Sobalak N, Vigneron J, et al. Physicochemical stability of pemetrexed diarginine at 25 mg/mL in partially-used vials and at 3 and 12 mg/mL diluted in dextrose 5% or in sodium chloride 0.9% in polyolefin bags. EJOP 2022;5(2):e00037.
106. Al-Razzak LA, Benedetti AE, Waugh WN, et al. Chemical stability of pentostatin (NSC-218321) a cytotoxic and immunosuppressant agent. Pharm Res 1990;7(5):452–460.
107. Doncheva R, d'Huart E, Vigneron J, et al. Etude de stabilité physico-chimique du pévonédistat à 50, 100 et 200 μg/mL dans du NaCl 0,9% et à 10 mg/mL dans des flacons partiellement utilisés avec un SPIKE. EJHP 2024.
108. Paul M, Vieillard V, Jaccoulet E, et al. Long-term stability of diluted solutions of the monoclonal antibody rituximab. Int J Pharm 2012;436: 282–290.

109. Vieillard V, Paul M, Ibrahim T, et al. Extended stability of the rituximab biosimilar CT-P10 in its opened vials and after dilution and storage in polyolefin bag. Ann Pharm Fr 2017;75(6):420–435.
110. Poujol S, Bressolle F, Solassol I, et al. Stability of ready-to-use temsirolimus infusion solution (100 mg/L) in polypropylene containers under different storage conditions. Ann Pharm Fr 2012;70(3):155–162.
111. Linxweiler H, Thiesen J, Krämer I. Physicochemical Stability of Generic Thiotepa Concentrate and Ready-to-Administer Infusion Solutions for Conditioning Treatment. Pharmaceutics 2023;15:309.
112. Krämer I, Thiesen J. Stability of topotecan infusion solutions in polyvinylchloride bags and elastomeric portable infusion devices. J Oncol Pharm Pratice 1999;5:75–82.
113. Lipp H-P, Gfrörer W. Physikalisch-chemische Stabilität von rekonstituierten Trabectedin-haltigen Lösungen. Krankenhauspharmazie 2017;38(7):423–429.
114. Vieillard V, Astier A, Paul M. Extended stability of a biosimilar of trastuzumab (CT-P6) after reconstitution in vials, dilution in polyolefin bags and storage at various temperatures. GaBI Journal 2018;7(3):101–110.
115. Davies L, Milligan K, Corris M, et al. Extended stability of the trastuzumab biosimilar ABP 980 (KANJINTI™) in polyolefin bags and elastomeric devices. Gabi Journal 2021;10:4.
116. Paul M, Vieillard V, Da Silva Lemos R, et al. Long-term physico-chemical stability of diluted trastuzumab. Int J Pharm 2013;448: 101–104.
117. Beijnen JH, Vendrig DE, Underberg WJ. Stability of vinca alkaloid anticancer drugs in three commonly used infusion fluids. J Parenter Sci Technol 1989;43(2):84–87.
118. Dine T, Luyckx M, Cazin JC, et al. Stability and compatibility studies of vinblastine, vincristine, vindesine and vinorelbine with PVC infusion bags. Int J Pharm 1991;77(2-3):279–285.
119. Trittler R, Sewell G. Stability of vincristine (TEVA) in original vials after re-use in dilute infusions in polyolefin bags and in polypropylene syringes. EJOP 2011;5(1):10–14.
120. Lieu CL, Chin A, Gill MA. Five-day stability of vinorelbine in 5% dextrose injection and in 0.9% sodium chloride injection at room temperature. Int J Pharm Compound 1999;3:67–68.