



GERPAC
EUROPEAN SOCIETY OF HOSPITAL
PHARMACEUTICAL TECHNOLOGIES



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Gabapentin is commonly used in pediatrics to treat epilepsy and manage neuropathic pain.¹ In Canada, gabapentin is not approved for any of these indications in patients under 18 years old. In the absence of a child-friendly formulation on the market, the off-label use of this drug mainly relies on pharmaceutical compounding.

Objectives

The purpose of this study was to assess the stability of two 100-mg/mL gabapentin oral formulations compounded either from USP bulk powder or 300-mg capsules (Apotex) in a low-osmolality (~100 mOsm/kg), pH 4.5-buffered suspension vehicle free from potentially harmful excipients in neonates (KIDs List).²

Stability was evaluated at room temperature and, additionally, after simulated temperature excursions to support stability over transportation or patient daily use.

Materials and Methods

Three batches of each preparation in the suspension vehicle, composed of deionized water, natural flavors, sodium citrate dihydrate, citric acid monohydrate, xanthan gum, potassium sorbate, carboxy-methylcellulose sodium and sucralose, were studied at 25°C/60% relative humidity (RH) in amber polyethylene terephthalate (PET) bottles and amber polypropylene (PP) oral syringes for 90 and 30 days, respectively.

To support stability over temperature excursions, all preparations stored in bottles at 25°C/60% RH for 30 days were subjected to three 24-hours cycles either at -20°C or 40°C/75% RH, before returning at 25°C/60% RH until the end of the study.

References

¹ W. Branstetter J, Mantione J, Deangelo A, A. Branstetter L. (2024) Safety and Efficacy of Gabapentin for Pain in Pediatric Patients: A Systematic Review. *Hosp Pediatr.* 14 (1): e57–e65.

² McPherson C, Meyers RS, Thackray J, et al. (2025) Pediatric Pharmacy Association 2025 KIDS List of Key Potentially Inappropriate Drugs in Pediatrics. *J Pediatr Pharmacol Ther.* 30(4):422-439.

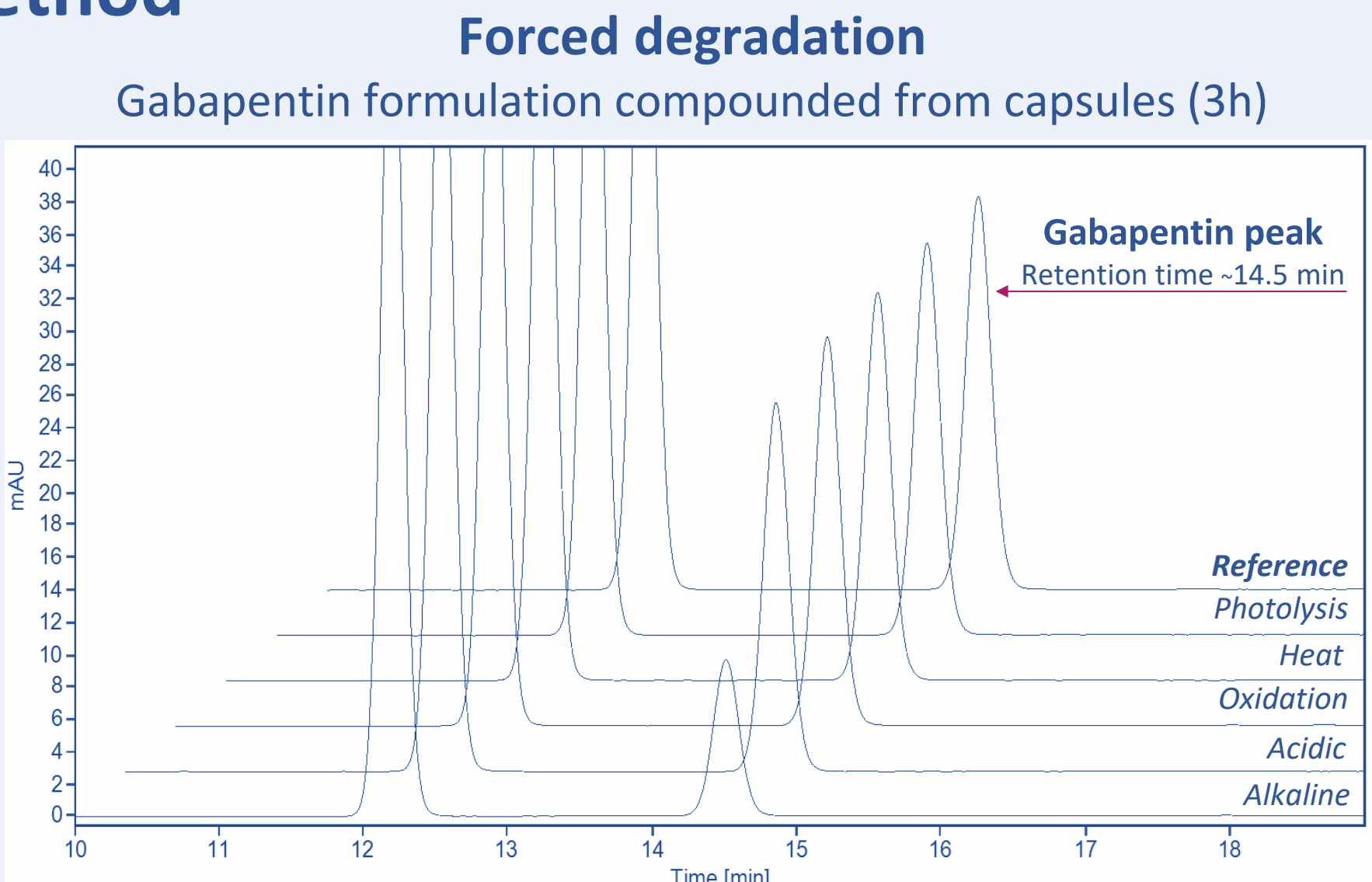
Materials and Methods

Stability tests and specifications

Stability	Test	Specification	
Chemical	Gabapentin assay using a validated stability-indicating HPLC-UV method	± 10.0% from initial assay	
	Formulation pH	± 1.0 unit from initial pH	
Physical	Appearance and organoleptic properties	No notable change from initial (visual evaluation in a clear container)	
Microbiological	USP <51> Antimicrobial Effectiveness Test	Bacteria	At day 14, NLT 1.0 log reduction from initial. At day 28, no increase from day 14
		Yeast and molds	At day 14 and 28, no increase from initial

Validated stability-indicating HPLC-UV method

HPLC Column	InfinityLab Poroshell 120 EC-C18 4.6 x 150 mm, 2.7 µm	
Mobile phase	A	B
	Water pH 3.0 with phosphoric acid	Acetonitrile
	50 %	50%
Flow rate	1 mL/min	
Column temperature	40°C	
Runtime	25 min	
Wavelength	264 nm	
Injection volume	10 µL	



Chemical derivatization with fluorenylmethoxycarbonyl chloride (FMOC-Cl) was used to improve the retention and detection of gabapentin.

Results

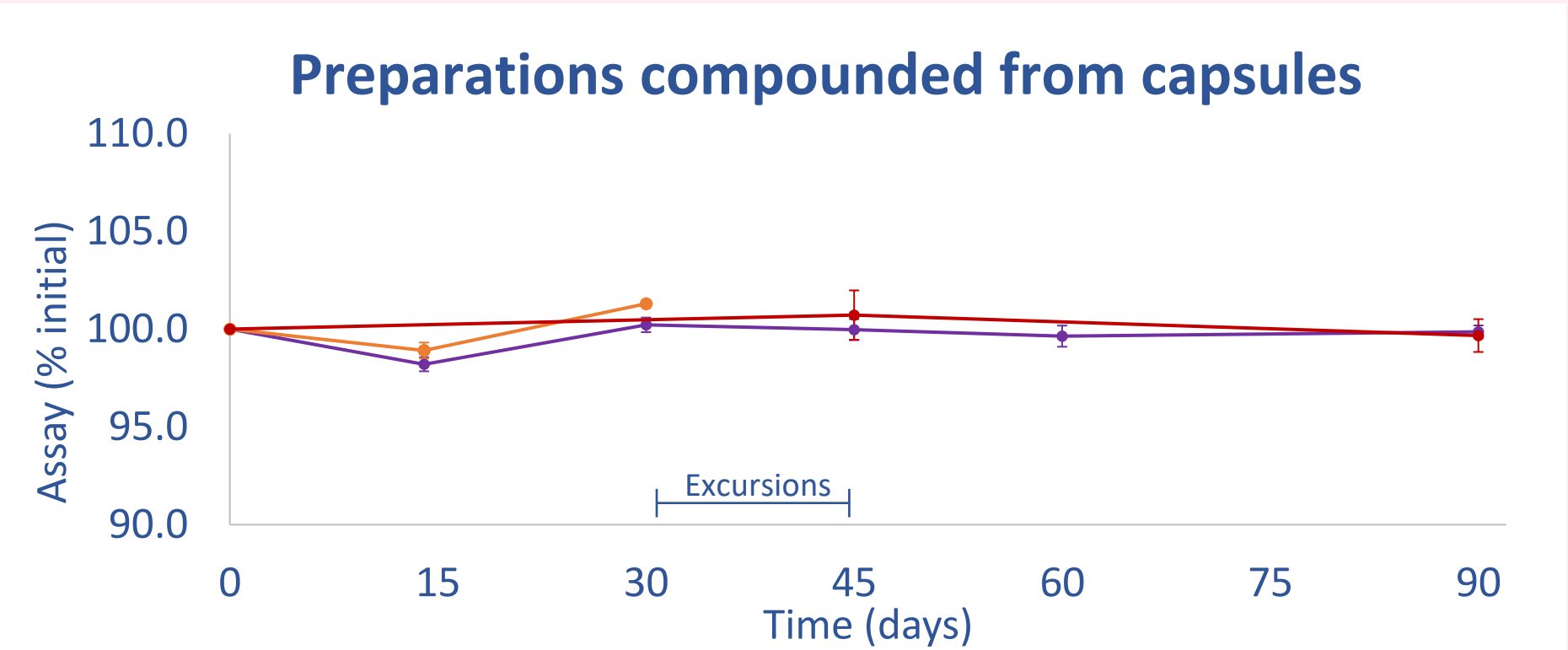
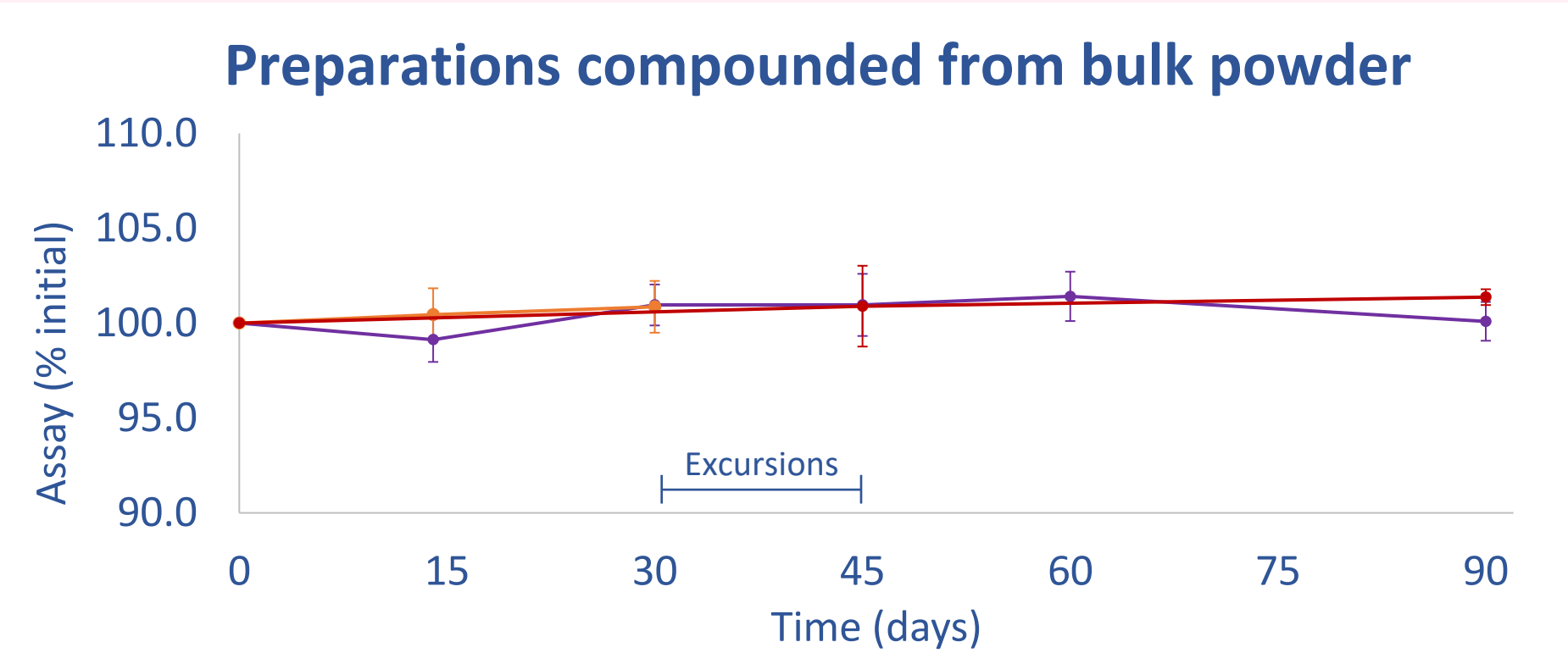
Physical stability

Formulations prepared from bulk powder and capsules were both translucent colorless to yellowish viscous solutions; gabapentin was totally soluble in the suspension vehicle. Note that a slight increase in yellowness was observed over time, without any further significant impact on overall stability of the formulations.

The only significant physical instability observed throughout the stability study was the precipitation and crystallization of gabapentin in formulations exposed to -20°C temperature excursion cycles. This instability persisted even after extensive manual shaking which could lead to high risk of dose non-uniformity.

All other preparations remained physically stable and maintained a pleasant tropical fruit aroma until the end of the study.

Results



Legend :

- 25°C/60% RH in amber PET bottles (n=3)
- 25°C/60% RH in amber PP oral syringes (n=3)
- Excursions at 40°C/75% RH in amber PET bottles (n=3)

Chemical stability (assay)

Gabapentin concentration remained above 98% of its initial concentration at each time point for all preparations (bulk powder and capsules)

Chemical stability (pH)

Initial pH for gabapentin formulations prepared from powder was 5.6 while those prepared from capsules was 5.7. The pH of all preparations remained at ± 0.1 pH unit from the initial over the entire stability study.

Microbiological stability

AET tested strains : *C. albicans*, *A. brasiliensis*, *E. coli*, *P. aeruginosa* and *S. aureus*

Gabapentin preparation	Timepoint	Result
Bulk powder	Initial	Conforms to specification
	After 90 days at 25°C/60% RH	Conforms to specification
Capsules	Initial	Conforms to specification
	After 90 days at 25°C/60% RH	Conforms to specification

Conclusion

Chemical, physical, and microbiological stability results support the assignment of a BUD of 90 days when stored in amber PET bottles and 30 days in amber PP oral syringes for gabapentin 100-mg/mL oral preparations compounded from capsules or bulk powder in a new low-osmolality suspension vehicle free from potentially harmful excipients.

Temperature excursions evaluated in this study, simulating potential fluctuations during transportation or daily patient use, demonstrated if freezing occurs, formulations should be discarded

This study provides healthcare clinicians with a safe and versatile alternative in epilepsy and neuropathic pain management when no commercial options are available.

Disclosures : All authors – Galenova