30th EAHP CONGRESS BARCELONA 18-19-20 MARCH 2026

Abstract number: 3PC-029

RECONSTITUTION OF ORAL POWDER MEDICATIONS: DISCREPANCIES IN FINAL VOLUME AND CONCENTRATION COMPARED WITH THE SUMMARY OF PRODUCT CHARACTERISTICS.

A. RETAMOSA ESCOLAR[1]; V. PUEBLA GARCÍA[1]; M.A. CAMPOS FERNÁNDEZ DE SEVILLA[1]; S. LÓPEZ CEDILLO[1]; L. YBÁÑEZ GARCÍA[1]; C. GONZÁLEZ PÉREZ[1]; I. MUÑOZ DELGADO[1]; M.T. BENÍTEZ GIMÉNEZ[1].

[1]Pharmacy Department, Hospital Clínico San Carlos; IdISSC, Madrid, Spain

Background and Importance

Accurate reconstitution of oral powder medications is essential to ensure the correct final drug concentration, particularly in paediatrics and for narrow therapeutic index (NTI) drugs. Discrepancies between theoretical and actual volumes may compromise treatment efficacy and safety.

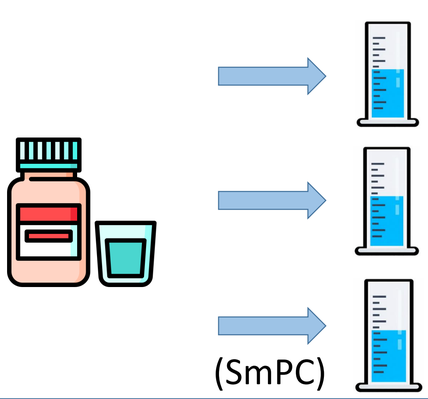
Aim and Objectives

To evaluate the concordance between final volumes obtained after reconstitution of oral powder medications and the theoretical volumes indicated in the package leaflet and Summary of Product Characteristics (SmPC).

Materials and Methods

The hospital formulary was reviewed. Selection criteria included:

- ☑ Preparations that must be compounded in the hospital pharmacy
- ☑ Drugs commonly used in paediatrics
- ☑ NTI drugs



The measured volume was compared with the theoretical value

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Drug concentration and percentage error were calculated*

*An error margin of ±10% was considered aceptable according to the European Pharmacopoeia.

Results

7/13 preparations were selected: Amoxicillin 250mg/5mL, Amoxicillin–clavulanic acid 100mg/mL–12.5mg/mL, Azithromycin 40mg/mL, Erythromycin 100mg/mL, Linezolid 100mg/5mL, Valganciclovir 50mg/mL and Mycophenolate mofetil 1g/5mL.

5/7 (71.4%) showed no significant deviation (error ≤ ±10%).

Formulation	Final volumen (mL)	Concentration (mg/mL)	Mean error (%)
Erithromycin 100 mg/mL	120.17 ± 0.76	83.22	20.17 ± 0.76
Linezolid 100mg/5mL	169.33 ± 0.76	17.72	12.89 ± 0.51

Conclusion and Relevance

The discrepancies observed highlight the importance of verifying the final volume and concentration after reconstitution, especially for paediatric and narrow therapeutic index drugs.

Errors greater than ±10% may represent a significant quality deviation, potentially compromising treatment efficacy and safety. Increasing the number of oral powder formulations analysed would help confirm the clinical significance of these findings and support the need to update leaflet and SmPC data.

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