A SIMPLE AND RAPID LIQUID CHROMATOGRAPHY-TANDEM MASS SPECTROMETRY METHOD FOR BETAMETHASONE MEASUREMENT IN HUMAN PLASMA VENOUS BLOOD AND UMBILICAL CORD BLOOD

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INTRODUCTION

HPLC-MS/MS is the gold standard technique for therapeutic drug monitoring (TDM)[1]. Antenatal betamethasone ((BET) therapy is recommended as a standard for fetal maturation on perinatal outcomes[2]. We developed and validated a LC-MS/MS method to quantify BET in human plasma from venous blood and umbilical cord blood.

CONCLUSION

The method was successfully developed, validated and will be applied for TDM and pharmacokinetic studies.

METHOD

SAMPLE PREPARATION

150 µL of sample
+
10 µL of 500 ng/mL IS (BET-*d5*)
+
200µL of methanolic 2 mM ZnSO4
+
200µL of pure methanol

Centrifuged 8000 rpm, 10 min

15 µL of supernatant injected

Analytical column

Hypersil Accucore C18 100 × 2.1 mm, 1.9 µm

Mobile phase at 0.35 mL/min :

[A] : $HCOONH_4$ 2 mM + 0.1% HCOOH (water)

[B]: $HCOONH_4$ 2 mM + 0.1% HCOOH (Methanol)

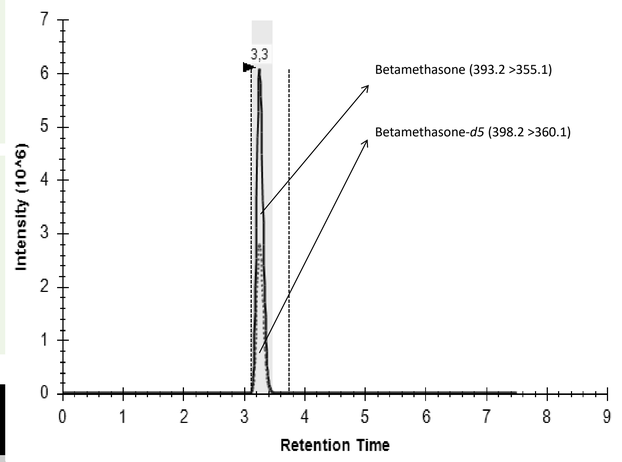
METHOD VALIDATION

FDA and (CLSI) guidelines

CLSI – EP17-A

CLSI- EP06-A

CLSI- EP15-A2



RESULTS

Parameter	Unit	Value	Parameter	Unit	Value
BET Retention time	minutes	3.18	Intra-day precision		
BET-d5 Retention time	minutes	3.11	50 ng/mL	% CV	1.68
Linearity	ng/mL	0.50-100.0	2 ng/mL	% CV	0.8
r^2	-	0.998			
LLOD	ng/mL	0.12	Inter-day precision		
LLOQ	ng/mL	0.29	70 ng/mL	% CV	1.54
Accuracy	% bias	17.7	1 ng/mL	% CV	4.97
Recovery	%	111.9			

References: **1**. Gugten, J. G. Clin. Mass Spectrom. (2019).doi:10.1016/j.clinms.2019.09.002; **2**.NIH Consensus conference: effect of corticosteroids for fetal maturation on perinatal outcomes. JAMA 1995;273:413-7

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