





LC-MS/MS ANALYSIS OF IMMUNOSUPPRESSIVE DRUGS in WHOLE BLOOD

Jasem® Method: Accuracy – High Speed – Simplicity in New Dimensions!

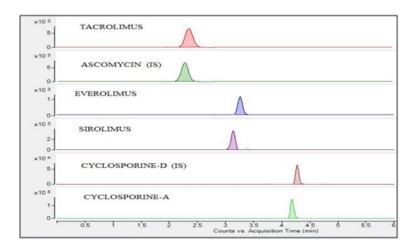
Drug Names:

Tacrolimus, Sirolimus,
Everolimus,
Cyclosporine A ,
Cyclosporine D — ISTD ,
Ascomycin - ISTD

Cyclosporine A (CsA), tacrolimus, sirolimus and everolimus are some of the immunosuppressive drugs, used in organ transplantation in order to prevent the rejection of transplanted organs and tissues. In addition, they are used in the therapy of auto-immune diseases.

Due to high pharmacokinetic variability, narrow therapeutic indexes and many potential drug-drug interactions, close monitoring of blood concentrations is required to prevent rejection and minimize toxicity

Extracted chromatogram of immunosuppressive drugs mix 20ppb spiked whole blood sample (1ppm CysA)

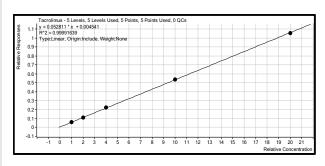


Features of Jasem® method

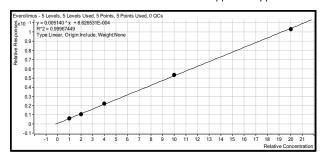
- Very easy & fast sample Preparation
- No Need for Derivatization/Evaporation step
- Much shorter run time than reference methods
- No source contamination

Benefits & Advantages of Jasem® method

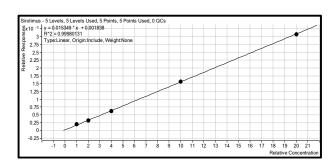
- Sample Preparation takes only 5.5 minutes
- Much lower cost than reference method



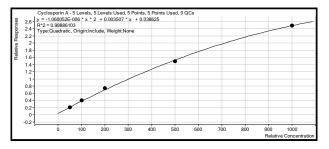
Tacrolimus calibration curve from 1 ppb to 20 ppb



Everolimus calibration curve from 1 ppb to 20 ppb



Sirolimus calibration curve from 1 ppb to 20 ppb



Cyclosporine A Calibration curve 50 ppb to 1000 ppb (quadratic curve)*

*Calibration curve linear up to 100 ppb for Cyc A

Compound	R2	LOQ(ppb)	LOD(ppb)
Tacrolimus	0.9999	0.08	0.03 (0.68)*
Sirolimus	0.9998	0.06	0.02 (0.68)*
Everolimus	0.9996	0.57	0.17 (0.68)*
Cyclosporine A	0.9988	0.06	0.02(5)*

*(values) are Reference Method values

Many immunological methods are now available for clinical chemistry analyzers which are routinely part of core laboratory instrumentation. These homogeneous methods include:

- affinity column-mediated immunoassay (ACMIA)
- · chemiluminescent microparticle immunoassay
- cloned enzyme-donor immunoassay
- · direct chemiluminescent immunoassay
- · enzyme-multiplied immunoassay
- microparticle enzyme immunoassay (MEIA)*.

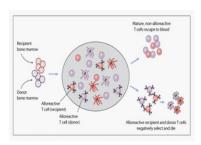
Note:

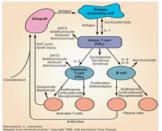
The Microparticle Enzyme Immunoassay (MEIA) method is widely used **Present Reference Method:** Microparticle enzyme immunoassay (MEIA) method and other methods are widely used as reference method and sample preparation – including at least 8 different steps –which will take> 1 hour.

Jasem ®Method: 4 sample prep steps only and done within 5,5 minutes!



What happens in the human body after Organ Transplantation?







Why is global medical interest in Immunosuppressants so rapidly growing?

In today's world, organ transplantations are more executed than ever before.

Due to high pharmacokinetic variability, narrow therapeutic indexes and many potential drug-drug interactions, close monitoring of blood concentrations is required to prevent rejection of transplanted organs and minimize toxicity.

Immunological methods are largely used in routine laboratories for quantification of immunosuppressive drugs. The disadvantage is that cross-reactions can occur with some metabolites, resulting in an overestimation of the measured drug concentrations with unacceptable biases

Note

Regulatory Label
Consideration



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