



INTERNATIONAL  
ASSOCIATION OF

THERAPEUTIC DRUG  
MONITORING AND  
CLINICAL TOXICOLOGY

**APPLICATION FOR SUPPLY OF MATERIALS  
TERMS OF MATERIALS TRANSFER**

**THIS IS AN APPLICATION REQUESTING THE INTERNATIONAL ASSOCIATION OF THERAPEUTIC DRUG MONITORING AND CLINICAL TOXICOLOGY (IATDMCT) TO SUPPLY THE MATERIALS SHOWN BELOW. IATDMCT IS UNDER NO OBLIGATION AT ANY TIME TO SUPPLY OR TO CONTINUE SUPPLYING THE MATERIALS. IATDMCT HAS APPOINTED ANALYTICAL SERVICES INTERNATIONAL LTD (ASI LTD) TO DISTRIBUTE THE MATERIALS.**

Applicant's Contact Details	
Name	
Position	
Tel.	
Fax	
E mail	

Applicant (Name of Organisation)	
Delivery Address (PO Box not accepted)	
Location (eg Dept)	
Building	
Street	
City	
Post/ Zip Code	
Country	

**Material required ("Materials"):**

Deuterated Ciclosporin A (d12), up to 5mg

please tick

Deuterated Everolimus RAD001 [ $^{13}\text{C}_2\text{D}_4$ ], up to 0.3mg

The Materials have been made available to IATDMCT as a gift of Novartis Pharma AG, Basel, Switzerland. Only shipping costs apply. The Materials will be used as internal standards in analytical methods to measure ciclosporin or everolimus. The methods will be applied to therapeutic drug monitoring ("TDM") of these drugs.

**Representations and Undertakings of the Applicant:**

The Applicant represents as follows and acknowledges that if IATDMCT agrees to supply the Materials to the Applicant, such representations shall become the terms of the contract with IATDMCT:

1. The Applicant is regularly engaged in conducting laboratory studies or therapeutic drug monitoring, and has all the required authorizations, approvals, registrations, licenses, and permits and is entitled to perform such work at the place of investigation. In particular, the Applicant is entitled under all applicable laws, rules, and regulations to perform TDM.
2. The Materials will be used in accordance with the laws and regulations of the country and locality where the TDM is to be performed, and in accordance with all applicable guidelines and ethical principles.
3. The Materials will be used solely for investigations under suitable containment conditions and will under no circumstances be administered to humans.
4. The Materials will not be used, analyzed or modified other than necessary for the purpose of the TDM.
5. Upon completion of the TDM, any unused Materials and derivatives thereof will be either returned to IATDMCT or disposed of under the Applicant's supervision in accordance with the applicable laws and regulations governing the Applicant.
6. All data obtained in the course of the TDM with the Materials and derivatives thereof will be submitted to IATDMCT if requested by IATDMCT. These data may be used by IATDMCT without restriction.
7. The TDM will be conducted under the Applicant's exclusive responsibility and IATDMCT will not be liable for any consequences thereof. The Materials are to be used and handled with caution and prudence in any work. IATDMCT shall not be liable for any damages resulting from the use, application, storage, or disposal/destruction of the Materials by Applicant or any third party, except to the extent such damage result directly from the gross negligence of IATDMCT or willful misconduct. Applicant will indemnify, hold harmless and defend IATDMCT, its Affiliates and their respective officers, directors, employees and agents against any and all claims, actions, demands, suits or causes of action for damages arising out of or relating to Applicant's use, application, storage, destruction or disposal of the Material (collectively, "Claims").

- 8. THE MATERIALS ARE BEING SUPPLIED TO APPLICANT WITH NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE. IN PARTICULAR, IATDMCT DOES NOT REPRESENT OR WARRANT THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR PROPRIETARY RIGHTS OF THIRD PARTIES.
- 9. The Applicant, or a representative of a Company applying for Material, will be a member of IATDMCT in good standing.
- 10. IATDMCT is a not-for-profit Corporation, incorporated in Ohio, USA. IATDMCT's Business Office is located at 4 Cataragui Street, Suite 310, Kingston Ontario K7K 1Z7 Canada. This Agreement is governed by, and construed in accordance with the laws of Ohio, USA, except as they relate to the conflict of laws. Any disputes between the parties are to be resolved by the ordinary courts in Ohio, USA, without restricting any right of appeal.
- 11. The Applicant agrees to bear all administration and shipping costs

**Acceptance of Representations and Undertakings**

Authorised Signatory of Applicant

PRINT FULL NAME:.....

SIGN.....DATE.....

Please complete, sign and return this form by mail to: info@bioanalytics.co.uk and you will be contacted regarding shipping costs.

Any queries please either e mail info@bioanalytics.co.uk or contact ASI Ltd:

Tel: +44 (0)20 8725 2845

Fax: +44 (0)20 8767 9687

Analytical Services International  
St George's, University of London  
Cranmer Terrace  
London  
SW17 0RE  
UNITED KINGDOM

**Acceptance of Application and Authorization to ship Materials:**

**ASI Ltd**

***To be left blank by Investigator***

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Name:

Title: