Ø Labels 6 Create Update bata Treatment Create 6 an Dose Dilut 44 Stock Solutions Ba Batches Edit н ч н н > Urine Faeces Cage Wash Trap 2 Trap 1 Barcass Kidney Liver G.I. Tract 8h 24h 48h 72h

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6.3.7.201

Real time

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2M 3M 4M Gp2 1M Gp2 2M

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26.57376 a

Conc. SD

0.77864

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0.9250 g 0.9417 g 0.9258 g 0.9475 g 0.9357 g 0.9874 g

11.70624 µgEq./g

0.34301

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The world's leading metabolism Laboratory Information Management System

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Sampling

Pooling

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Pools & Solid

Debra is a purpose built LIMS designed specifically to manage the entire life cycle of a range of drug and environmental metabolism studies within a FDA/GLP regulated environment.

Continuous development over 30 years has resulted in a system that is the industry standard and is used by many of the world's leading Pharmaceutical, Agrochemical and Contract Research Organisations.

Whatever the scope of your study, Debra allows you to take complete control of the process, improving efficiency, whilst meeting the requirements of regulatory compliance at every step.



Dosing

Improved efficiency

By managing data electronically, Debra significantly improves workflow efficiency in the following areas:

- Direct capture from equipment, thus eliminating transcription errors.
- Easy to use batch worksheets to organise data capture.
- Automatic calculations of dosing requirements.
- Immediate generation of raw data and summary reports.
- Easy label generation for all samples.
- Direct links with the industry standard Laura radiochromatography and Seescan WBA software.
- Automatic calculation of results
- Audit Trail.

protocol

Treatment

ebra

Metabolism LIMS Software

- Security Access in accordance with regulatory requirements.
- Electronic signatures; no more missing manual signatures.

Improved compliance

Debra is a closed system that ensures compliance with regulatory demands.

- User access is managed via a unique login ID and password that is linked to users' training and skill set.
- Electronic signatures and audit trails are fully configurable and in line with the FDA 21 CFR part 11 requirements.
- Debra has full auditing capabilities to ensure that any changes are fully tracked and easily reportable.

LabLogic have decades of experience creating systems within highly regulated environments. We are confident that our systems will improve compliance within your facility.

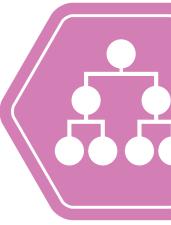
www.**lablogic**.com



Direct data capture

To achieve the goals of productivity and GLP confidence, Debra avoids transcription errors by capturing raw data either directly from the instrument or via sample result data files from analytical instrumentation systems.

- No transcription necessary.
- Seamless communication to and from the instrument.
- A wide variety of models and versions of balances, LSC's and WBA are handled with instrument specific interfaces.







etch number 3 Batch game	Batch 3	Subject balance g balano		nod el pipette 4dp	
		Syringe balance g balance	e - 4 dp		
abiert	Dose time	Treatment	Action	Value	
Adject 021M (Group 1)	0 m	Man 1	Subject weight	200.0000-9	0
021M (Group 1) 031F (Group 1)	0 m	Man 1	Subject weight	210.0000 g	8
	0 m	Man 1	Subject weight	205.0000 g	
3041F [Group 1]	0m	Man 1	Dose required	1.6667 g 1.6667 ml	
0021M [Group 1]	0m	Man 1	Full syringe	11.4512 g	
0021M [Group 1]	0 m	Man 1	Empty syringe	9.7745 g	0 0
0021M [Group 1]	0 m	Mar 1	Seven	Review	
0021M (Group 1)		Mar 1	Dose required	1.7500 g 1.7500 mil	
0031F [Group 1]	0 m	Man 1	Full mingt	NA	
0031F (Group 1)	0 m	Man 1	Empty syringe	N/A	
0031F [Group 1]	0 m		Review	Review	
0031F (Group 1)	0 m	Man 1	Dose required	1.7083 g 1.7083 ml	
0041F (Group 1)	0 m	Man 1	C.R.a.date		
ADATA I Case of 12	A.u.	111			
Results		dam received	72227400.00 dpm		
Subject 0021M			167,6700 µCi		
Subject weight 200.0	g 0000	Activity received			
	I512 9	üominal dose level	53.0000 mg/kg		
On springe more		Actual dose level	50.3010 mg/kg		
tmpty syringe weight 9.7	745 9	Dase error	0.60 %		
Dose administered 1.4	1767 9	Date enve			
	0602 =9	Loss dpm	0 dpm		
Actual dose time					
Actual door only					

Dosing

- Automatically perform dose calculations based on treatment data and nominal dose rate.
- Design dosing schedule ahead of time.
- Directly capture subject and dose weights either separately or as a single process.
- Allows multi-dose studies.
- Capture the actual time of dosing to calculate real-time sampling for PK studies.

Sampling

Pooling

Dosing

Laura

• Immediate calculation of compound and activity administered.

Treatment

Treatment

Debra

Calcs

- Design, prepare and analyse dose preparations, dose vehicles and stock solutions.
- Manually enter existing treatment data or interactively create new treatments.
- Automatically calculate dose compound requirements accounting for compound properties.
- Directly capture preparation weights and analysis data.
- Automatically calculate treatment concentration and specific activity.



Sampling

Pooling

- Eliminate transcription errors; no manual entry or data checking required.
- Directly capture weight data from balances.
- Interface with LSCs to import dpm data.
- Design and print sample labels.
- Create scheduled or barcoded batches for data capture.
- Automatic detection of manual data entry, with full audit trail.
- Immediately generate reports following data capture.

• Pool samples across subjects or timepoints to create new samples for analysis.

• Specify percentage of original sample to split, or use a fixed amount.

• Automatically specify samples to be pooled based on dose recovery.

• Optionally capture pooled sample data, or use calculated values.

protocol • Easily configure sampling schedules. Reports

Protocol

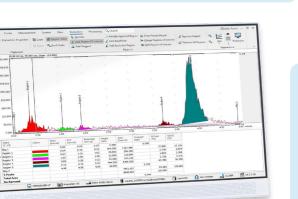
- Summary tables for • final recovery and concentration reporting. Instant graphical data to track .
- Tissue grouping.
- •
- •
- •

- Variability rules.
- LOD / LOQ settings.
- Tolerances.
- Normalisation settings.

www.lablogic.com

.aura

Radiochromatography Data Collection and Analysis Software





Analysis

- Direct link to our industry standard radiochromatography software, Laura.
- Create HPLC batches within Debra ready • to run your analyses in Laura.
- View chromatography data in Debra for each sample; calculate and report metabolite concentrations and dose recovery.
- Link security between the two systems.

Calculations

Calculate recoveries and concentrations taking into account parameters such as:

REPORTS

• Multi-dose settings.

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- Create simple or complex protocols to suit your needs.
- Easily add subjects and apply naming masks.
- Group subjects by species, sex, dose level, dose rate.
- Configure single or multi dosing schedules per project, group or subject.
- Assign users to the study based on their access rights.

Go from raw data to final results in minutes. A wide range of reports is available, covering all functional areas of the system.

- Raw data reports.

 - sample recovery and concentration.
 - Configurable decimal
 - and significant figures.
- Statistical analysis.
 - Normalisation of data.
 - LOD and LOQ reporting rules.
- Include/exclude subjects,
 - tissues and timepoints.

Sample	Terrepoint	Male 1M	Male 2M	Male 3M	Male 4M	Male Mean	Male 5D	Mean	50	
Unine		5.0	4.9			5.3	0.4	5.3	0.4	
Urine	8h-24h	623.6	3.7	35	- 55	158.7	305.9	158.7	329.5	
UNITED		0.0		0.7	0.9	0.6	0.4	0.6	0.4	
Utrine	72h-96h	N.C.	0.5	0.4	0.7	0.5	0.2	0.5	0.2	
	96-h - 120-h			0.3	0.5	0.4	01		0.1	
									1.0	
Faeces						1.0	0.2			
Faeces		0.2	0.2	0.3	0.2	0.2	0.1	0.2	0.1	
		3.8								
Cape Wash	48h-72h	0.1	0.0	0.3	0.3	0.1	0.1	0.1	0.1	
Cape Wash	72h-96h				0.1	0.1	0.1	0.1	0.1	
Cope Wash	196.5 - 120.5	0.0	0.0	0.0	0.0	6.0	- 40	0.0	0.8	
	0-85									
	81-241	0.1	0.3	0.1	0.1	0.2	0.1	0.2	0.1	
Trap 2		0.1	1.4	0.6	0.2	0.6	0.6	0.6	0.6	
	72h-96h	0.2	0.7	0.6	0.1	0.4	0.3	0.4		
1 sp 2	96h-120h	0.3	0.6	0.5		0.4		0.4	0.2	
	10.01									
	82-265	10.2	7.0	7.2	7.8	8.1	1.5	8.1	1.5	
Trap 1	24h-48h	4.8	2.3	2.9		4.3	0.9	4.3	0.9	
Trap 1	48h-72h	3.4	1.0	23	- 53	2.7	- 14	2.7	- 14	
1mp1	96h-120h	1.2	1.0	1.0	2.3	1.4	0.6	1.4	0.6	
Suborod		40.7	26.4	29.7	40.5	34.2	- 2.3	34.2	7.3	
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Regulatory Compliance

Regulatory Compliance is an essential feature of Debra, built to meet GLP, and 21 CFR part 11 requirements.

Electronic Signatures

- Fully configurable for all tasks.
- Options for: Single signatures. Double signatures for peer approval. Silent signatures where no action is required by the user to apply the signature. Disabled signatures.

Signature Types Meanings Notifica	tion Message			
Name	Requirement	Meaning		Edit
Batch Weight Capture	One Signature	Authorship		
Batch Weight Create	Silent	Authorship		
Batch Weight Delete	Two Signatures	Authorship	1	
Batch Weight Update	Two Signatures	Authorship		
Dose Accept Per Animal	Disabled	Authorship		
Dose Accept Per Session	Disabled	Authorship		
Dose Loss Applied	Disabled	Authorship		
Dose Vehicle Design Accept	Disabled	Authorship		
Dose Vehicle Prepare Accept	Disabled	Authorship		
Edit Dosing Data	One Signature	Authorship		
Edit Project Data	Two Signatures	Authorship		
Edit Sampling Data	One Signature	Authorship		

Debra's electronic signatures are in line with regulatory guidance to ensure that relevant details are captured:

- Printed name of the signer.
- Date and time that the signature was executed.
- The meaning associated with the signature (e.g. authorship, review, approval etc).



Audit Trail

Debra provides full auditing facilities. This ensures that changes to date are tracked with reference to the new and previous value, the operator and date / time.



User Settings

• Quickly and simply configure user access and rights.

• Configure hierarchical levels of access.

within Debra based on access level.





Screen Controls

Access Levels

• Fully configure access to every control

Labelling



- Generate project specific labels based on data entered into the system with just a few clicks.
- Highly configurable user-defined formats.
- Predefined label formats can be created to cover the corporate standard.
- Barcoded labels allow the user to take advantage of barcoding options for data collection to speed up processes within the laboratory and reduce the risk of user error.



Document Management System

Debra's reporting package provides convenience and flexibility. Using the comprehensive range of reports in conjunction with the Document Management System to allow management of your reports in a secure environment.



- Save and track reports within the database.
- Seamlessly integrate tables, graphs and text into final reports through an automated link to Microsoft® Word.
- Quickly and accurately create final reports using standard templates linked to study-specific information.
- Record document history, highlighting changes between versions of the document.
- Define columns, print order, assign macros, add free text, size the table and its position and even specify the decimal precision of the data.





EXPERIENCE & EXPERTISE

	Subject: 1M Urine S h * Pot/Sample	Subject:11M Urine 🍄 8 h 🍄 Aliquot 1	Subject 1M Unine 8 h 🍄 Aliquot 2	Subject 1M Urine 🍄 24 h 🍄 Pot/Sample	Subject: 1M Utine 24 h 😤 Aliquot 1	Subject 1M Urine 24 h Aliquot 2
	Subject: 11M Faxoos 24 h Pot/Sample	Subject: 1M Faeces 24 h Aliquet 1	Subject 1M Facos &	Subject 1M Faeces 24 h Alquot 3	Sublect: 1M Urine * 43 h Pot/Semple	Subject 1M Urine 48 h Aliquot 1
	Subject: 1M Urine 48 h Aliquot 2	Subject: 1M Recors 48 h Pot/Sample	Sublect 1M Factors 48 h Aliquot 1	Subject: 1M Faeces Alquor 2	Subject: 1M Facos Aliquot 3	Subject 1M Urine 72 h Pot/Semple
	Subject: 1M Urine 72 h * Aliquot 1	Subject 1M Urine Zh Miquot 2	Sublect 11M Faicais Pot/Sample	Subject: 11M Fascas Aliquot: 1	Subject: 1M Fasces 72 h Aliquot 2	Subject 1M Fasces 72 h
	Subject: 1M Urine 90 h Pot/Sample	Subject: 1M Urine 90 h	Subject: 11M Urime 90 h 😭 Aliquot 2	Subject 1M Facons 90 h Pot/Sample	Subject: 1M Facon 90 h Alquot 1	Subject 1M Faeces 90 h Aliquot 2
	Subject: 1M Facos 96 h Aliquot 3	Subject: 1M Urine 120 h Pot/Sample	Subject: 1M Urina 120 h Aliquot 1	Subject 1M Urine 120 h Aliquet 2	Subject: 1M Faces 120 h Pot/Semple	Subject 1M Faelos 120 h Aliquot 1
bje	ct: 1M	Subject: 11M Feeces 120 h Aliquot 3	Sublect 2M Urine 8 h Pot/Sample	Subject 2M Urine 8 h 😤 Alquot 1	Subject: 2M Utile 8 h &	Subject 2M Urine 24 h Pot/Sample
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quo	ot 1		1			
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Subject: 11 Urine 8 h Aliquot 2 - 🛠





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Extraction Trees



- Isolate metabolites and residues.Further analyse or characterise
- existing samples.
 Create on-the-fly extraction pathways, displayed as a tree structure, adding extracts and samples as you go.
- Pool and concentrate samples, monitoring recovery and concentration at each stage.
- View and report all extraction data.
- Extraction trees can optionally be created as a stand-alone study.
- View all calculations.
- Can be used for any sample in any study, or as a stand-alone study.







Study Types Debra allows the user to undertake of

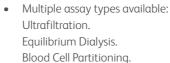
Debra allows the user to undertake a range of study types including ADME, Protein Binding Environmental Metabolism, and Topical Application.



ADME

- ADME study types include: mass balance, tissue distribution, blood : plasma ratio, pharmacokinetics.
- Easily configure complex protocols.
 Multiple dose routes, species, dose rates.
 Define sampling schedules.
- Design prepare and analyse dose solutions and dose vehicles.
- Create and perform dilutions on stock solutions.
- Interactively weigh subjects and administer dose.
- Capture sampling data directly from balances and LSCs.
- Full reporting at all stages with automatic generation of final summary tables.





- Set up studies with single or multiple species.
- Select multiple concentrations and number of replicates.
- Options to perform non-specific binding and time to equilibrium assays prior to the main study.
- Define spiking schedule and analyse the spiked samples.
- Create serial dilutions of stock solutions.
- Free/bound and other associated calculations automatically performed and reported.



Environmental Metabolism

- Perform rate of degradation studies including: Aerobic soil / anaerobic soil. Aqueous sediment. Adsorption / Desorption.
- Define soils with water holding capacity details.
- Determine soil moisture content.
- Calculation of target equivalent dry weight of dispensed soil.
- Maintain moisture content.
- Dose rate calculations from field rates.
- Quickly apply known dose amount to all flasks.
- Adsorption / Desorption extraction trees.

Topical Application

- Specify application area (ha / m² / cm²).
- Specify dose rate per area.
- Specify default areas.



WBA

- Direct links to Seescan WBA software.
- Use Debra's core features to facilitate QWBA studies.
- Create batch worksheets to import WBA data from a variety of sources.
- Perform QWBA work as part of a larger ADME study or as a discrete project.
- Use Debra's reporting tools for consistent and seamless reporting in a secure environment.





A full range of services are available from LabLogic to maximise investments in Debra

At LabLogic we do not underestimate the need for a comprehensive set of services to ensure successful implementation of Debra. Years of experience and unrivalled expertise in providing these services, are what make our systems so successful.

Quality Assurance

Quality of service and product is of paramount importance to LabLogic and this is reflected in our systems. Our continued efforts in this area have resulted in ISO 9001 accreditation for: Design, development and supply of scientific instrumentation, laboratory information management systems (LIMS) and applications software with on-going maintenance support, including, installation, validation and training of systems for pharmaceutical, agrochemical, nuclear medicine and contract research organisations.

Validation

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan suited to your needs. Our Validation Specialists incorporate years of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet your company's requirements.

Support

Supporting our systems and products has always been our priority and what our reputation has been built on.

Our support team are experienced in not only deciphering coding problems, but also in the use of the system. Our Debra team include ex-scientists and users of Debra who can relate directly to any problems or questions that you may have.

Training

We can provide tailored training to suit your needs, from one-onone sessions to full classroom based training. This can also be split between systems managers training and user training to enable each group of people to get the most out of the system.



Bespoke Development

Debra's direction has always been dictated by the customer's needs – all functionality in the system has been as a result of a customer request.

LabLogic will work closely with you to understand your processes. We have product and industry specialists with experience in many types of metabolism studies who can work with you to ensure successful and timely implementation of your functionality.



Service and Support

Users of our systems can benefit from our comprehensive, fully inclusive service and support.

We can give reassurance that if things go wrong or you need expert advice, help is only an e-mail or phone call away.

Validation Services

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan, suited to your needs. Our Validation Specialists who have many years' of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.

Training

LabLogic can provide a variety of training courses and workshops to help you get the most out of your instrument and software.

All training is performed by our expert Product and Support Specialists who have many years experience in the development and use of the instruments and software.

Certificates can be provided to complement your internal GLP training records.



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