

Inhalytix™

Flexible and fully validated inhaler testing data analysis software

2021 EDITION

Inhaler



USP Chapter <601> and Ph.Eur. Chapter 2.9.18 and draft USP Chapter <1604> specify various types of multi-stage cascade impactor that can be used for measuring the drug-specific aerodynamic particle size distribution (APSD) of orally inhaled and nasal drug products (OINDPs).

This process involves quantitative recovery and chemical analysis of the size-fractionated aerosol, typically by High Pressure Liquid Chromatography (HPLC). From the resulting assay a number of important

SP Induction Port

metrics can be derived that are used to characterise the APSD, in accordance with pharmacopoeial specifications and various FDA and EMA guidance.



Inhalytix[™] data analysis software is a flexible and fully validated solution for the entry, analysis and reporting of the APSD of drug output from all OINDPs. It also serves as a database for laboratory-based cascade impactor inventory and provides for the setting up and running of detailed test methods. User-configurable,

the software will accept data from standard and customised cascade impactors, including the Andersen Cascade Impactor (ACI), Next Generation Impactor (NGI), Fast Screening Impactor (FSI), Fast Screening Andersen (FSA), Glass Twin Impinger (GTI) and Multi-Stage Liquid Impinger (MSLI).

Licensing

Inhalytix[™] is available as a three user licence software package, based on named users that can be added or removed by the system administrator. The software is available via PC, server and cloud-based installations, with digital licence keys supplied by email. Additional packages of three users are available and can be added to the system at any time.

System Characteristics



System Operation (Configure > Test > Report)

Dashboard: On entering the software the user is presented with a dashboard providing useful information about how the software is being used. This contains information such as the number of analysts and supervisors set up on the system, as well as the total number of tests prepared, executed and completed. It also summarises the number of tests, equipment and report configurations, as well as details of the equipment inventory, databased by type.

Equipment Types

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Quick and easy to install, Inhalytix™ is 21 CFR part 11 compliant, enabling the creation of users, assignment of multiple roles (typically admin, supervisor and analyst) and access to audit logs, assisting in data monitoring and ensuring data integrity. The software will operate on Windows 7, 8 and 10 operating systems.

Dehboard	Dashboard statistics And Reports							
) Teats	Admin Count Of Users	1	Analyst Count Of Users	c	Count Of Users			
Equipment Inventory	Tests Summary			Configuration				
Administration >	Total Tests All Tests Have Beet-Created		4	Active Test Methods Count Of Active Test Metho	dis.			4
	Prepared Tests A Test Has Been Created But Not Executed		1	Equipments Count Of Equipments				5
	Executed Tests Text Data Has Book Created		2	Report Templates Count Of Report Templates				2
	Completed Tests Duta Has liven Analysed And Reports Generated		1	Summary Report Temple Count Of Summary Report				2
				Detailed Reports Templa Court Of Detailed Report 5				0
	Equipment Inventory			Equipment Types (Deta	lled)			
	Impactors/Impingers Assets Total Impactors/Impingers Assets		3	Impoctors/Impingers		Components		
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	Total Component Assets			ADI		Devices	3	
	Assets With Mensuration Data Total Assets With Mensuration Data		1	PSA	4	External Filter Holders	1	
	Total Pastera men Persolation Data			FS	23	Gass Expansion Chambers	3	

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The software is pre-populated with the most commonly used impactor types for immediate use. However, it is not uncommon for custom versions of cascade impactors to be used in some laboratories. In these circumstances, users can generate bespoke impactor types that can then be stored and recalled for use later. This function may, for example, allow a user to add or remove certain stages from an impactor or add special components to the software, such as modified induction ports.

Equipment Inventory

Keeping track of equipment inventory and associating it with the corresponding inhaler testing data can be a burden. For this reason, the **Inhalytix™** equipment asset library allows users to keep their equipment databased and include equipment-specific data in their testing reports. Not only does this allow users to keep track of equipment, it ensures full traceability by keeping comprehensive records of which specific pieces of equipment were used for each test. Furthermore, the software provides the user with the option to enter impactor-specific mensuration data, allowing the precise calculation of stage cut-off diameters, thereby enhancing the precision and accuracy of test results. The software will also notify users if an impactor is due for stage mensuration.

					Add Equipment	
Detrobund Tests Configuration Co)	Impactor/Impinger ACI 28.3 L/m Impactor/Impinger	iscade Impactor (ACI) Template	
	Stages					
	for this impact mensuration c + Add mensuration	rove the accuracy of the cor/impinger, the Effective entificate can be entered uration data	Diameters (EDs) fro			
		ECD @ 28.3 L/min*	ECD @ 60 L/min*	ECD @ 90 L/min*	Stage Serial Number	
	Stage 0	ECD @ 28.3 L/min*	ECD @ 60 L/min*	ECD @ 90 L/min*	Stage Serial Number	
	Stage 0 Stage 1		ECD @ 60 L/min* - 4.4	ECD @ 90 L/min*	Stage Serial Number	

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Dashboard

Tests

Configuration

🚊 Methods

📚 Equipment

Reports

Configuration

Testing of different drug products requires different methods to be in place, different equipment to be used and different metrics to be calculated. This configuration takes place in three easy steps:

Reports • Equipment • Methods

1. Reports

The Reports configuration screen allows users to create tailored report templates, which are then stored and can be paired with different test methods, allowing data to be reported as required.

COPLEY Inhalytix ^m			Create Report Template	🗱 English 🗸 🝳
 Dashboard Tests Configuration Equipment Inventory Equipment Types Administration 	2	Report Header Image: Completed By Autopopulated from username Completed Date Autopopulated from date test completed Report Date Autopopulated from date test generated Equipment Configuration	Complete One Official Complete One Completed One Official Complete One <td>EXAMPLE 1010/2019 [Emple Repet]] [Configuration] NGI [Example Serial Number]</td>	EXAMPLE 1010/2019 [Emple Repet]] [Configuration] NGI [Example Serial Number]
	(Report Template List		Cancel Save Report Template

		Stage
FDA		Stage Ef
USP		Impactor
		Large Pa
		Small Par
		LPM/SPN
		СРМ
		FPM
		EPM
IMAD)		Graphs
		Log-Prob
		Drug Mas
		Cumulati
	USP	USP

2. Equipment

The equipment configuration screen allows users to generate specific combinations of impactor/impinger and components to match the equipment configuration described in the testing protocol. Users simply drag and drop the impactor and components of their choice into the equipment configurator. This, for example, could see the combination of an NGI, with external filter holder, NGI preseparator, NGI induction port, mouthpiece adapter and inhaler. The software automatically sorts the components into the correct order and ensures that only viable combinations can be created.





lective Cut-off Diameter (ECD)

ticle Mass (LPM

ive Drug Distributi

	Review equipment configuration:	
	Inhaler	
0	Mouthpiece Adapter	
P	NGI Induction Port	
0	NGI Preseperator	
	\frown	
	External Filter Holder	





The software allows a high degree of customisation, including both a "Summary" or "Detailed" report template and toggles to turn on or off the reporting of a broad range of metrics. Company logos can be added to the report header if required.

3. Methods

Delivered Dose Drug Substance Delivery Rate

Regression Coefficient, R** 😡

	COPLEY.								
Balamert Configuration Stellar te auforent configuration *	 Dashboard Tests 								+ Create Test M
	Contouration -	Test Mathed	Equipment Configuration	impactor/Impinger	Components	Esports	Created	Multiple	
Product Information	Methods © Equipment	Volidation 4 - Custom ACI	ACI 80.0 L/min without Stage 5 and 6	ACI 50.0 L/min without 55 and 55	inholer , Aduit Alberta Idealised Throat , ACI 60 IJmin Preseparator	Validation Report	odimin odimin December 7, 2019 (0.3) Abr	odimin odimin Oscambar 7, 2018 10:31 aar	
Product Carter	 Reports Equipment Inventory 	Validation 4 - MSU	Validation 1 - MBU	MSU	Nosal Spray . Adult Alberta idealised Throat	Validation Report	admin admin December 7, 309 8:57 AM	oximin oximin Oscember 7, 205 E-07 AM	
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Additional Info + Add additional Telef		Validation 4 - NOI	Validation 5 - NGI	NOI	inholer . Adult Alberto idealised Throat . NGI Preseperator	Validation Report	admin admin December 7, 399 7:37 AM	odmin odmin December 7, 209 7, 49 AM	
Report Forman* - A dat report format Via Nas									

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Dashboard

Tests

Configuration

A Equipment Inventory

Equipment Types

Creating a test method allows the user to combine detailed product information, such as drug components and device details, with equipment and report configurations. Users have the opportunity to define for example stage groupings and fine particle dose (FPD) specifications and to select whether delivered dose (when testing MDIs, DPIs, ADIs etc.) or drug substance delivery rate (when testing nebulisers) is recorded. Configuring the product specific method is the final step before a user can run a test and analyse their results.

Prepare Execute Analyse

Select test method * 🚱

Validation 2 - NGI

Test Method

Tests

Once the necessary report, equipment and test method configurations are in place, the user is ready to enter the data and complete the analysis. This function can be found under the 'Tests' tab. Tests are completed in three steps:

Prepare • Execute • Analyse

COPLEY Inhalycix ^{ee}	۲			
2 Dashboard		Search		
Tests		♥ Show advanced filters		
Configuration				
8 Equipment Inventory				
Equipment Types		Test Name	Test Method	Equipment Configuration
Administration		DAL Test Prepared	test DAL	DAL 601/min - 56 BS
		Anna Test 1 Prepared	test DAL	DAL 601/min - S6 BS
		Anna Test	test DAL	DAL 601/min -S6 BS

All tests are databased and their current status can be monitored to see if they are at the prepared stage, whether results have been entered or whether they are complete.

1. Prepare

To prepare for a test, users are required to recall the test method relating to the product to be tested. During this step, users will have the opportunity to enter test specific information, including the number of runs to be performed.

COPLEY Inhalytix*			Test
DashboardTests	Pr	repare Execute Analyse	
Configuration C		Test Method Select test method*	\$
Administration >		(Inhaler	Saujament ID Not selected *
		Adult Alberta Idealised Throat	aupment ID Auto selected Control Contr
		Norimal Flow Rate	Not selected *
		Report Formats Validation Report + Add report format Test Runs	

2. Execute

The user then executes the test by entering the number of doses actuated and drug deposition values for each stage of the impactor, as well as any additional components included in the equipment configuration. This process is then repeated for all additional runs. Alternatively, data can be automatically imported from a CSV or XLSX file.

All values are easily displayed in a scrollable table and can be edited at any point prior to analysis, for example when importing data from HPLC software or exporting data for report writing.

OPLE

e Execute	Analyse				
1 Import Results	😧 🖹 Downi	oad xisx template	Download csv 1	emplate	
position Data Tabl	e				
Run No.	Dose No.	Stage 1	Stage 2	Stage 3	Stage 4
✓ 1	1	0.00000	0.00000	0.00000	0.00024
✓ 2	2	0.00000	0.00000	0.00099	0.15309
√ 3	3	0.12065	0.72588	2.10530	6.56490
✓ 3 ✓ 4	3	0.12065	0.72588	0.00388	6.56490
✓ 4	4	0.00000	0.00000	0.00388	2.66574
✓ 4✓ 5	4	0.00000	0.00000	0.00388	2.66574 10.03756

		NGI Copleyhaler ﷺ English ✓
文 Dashboard		Prepare Execute Analyse
Tests		🖽 Results Summary 🛱 Group Results 📶 Graphs 🕹 Reports
Configuration	>	View Graph Drug Distribution per Discharge for Impactor Only
Equipment Inventory		Probit
Equipment Types	>	Deposition (All Components)
Administration	>	Cumulative 5
		Deposition (Impactor Only) Cumulative You can compare up to three test runs Compare Test Runs (Maximum 3 Test Runs)
		✓ Test Run Number 1 Stage 1 Stage 2 Stage 3 Stage 4 Stage 5 Stage 6 Stage 7 MOC
		Test Run Number 3
		€ Tests Cancel Save ✓ Completion

3. Analyse

Once all data has been entered or imported the software analyses the data and presents it to the user in the form of:

- **Results Summary** provides all the key metrics for all test runs in a scrollable table for immediate review.
- **Groups Results** (where used) displays the drug fractions for each stage or size grouping defined in the method.
- **Graphs** allows viewing of log-probit plot, drug deposition (by impactor stage/component) and cumulative drug distribution for each run. Also allows the comparison of up to 3 runs from the same test or other tests, so long as the same equipment configuration and data analysis specifications have been set previously.
- **Reports** allows viewing and printing of standard and customised reports.

Summary of Key Features

- Standardised approach to the analysis of impactor data
- Ph. Eur. 2.9.18 and draft USP <1604> compliant
- 21 CFR Part 11 compliant
- Fully validated with in-built auto-validation protocols
- Supports PC, server and cloud-based installations
- Equipment inventory and test-related database
- Impactor-specific mensuration data log
- Bespoke configurations, methods and reports
- Data import and export capability for use with HPLC software
- Quick 3-step results analysis: Prepare Execute Analyse
- Runs and/or Tests comparison capabilities

Inhalytix

Cat. No.	Description
8260C	Inhalytix Data Analysis Software
	(3 user licences) - Cloud
8260P	Inhalytix Data Analysis Software
	(1 user licence) - PC
8260S	Inhalytix Data Analysis Software
	(3 user licences) - Server
8261	Additional 3 User Licences for Inhalytix
	(Cloud & Server)
8263	Annual Support and Upgrade
	Package (per user)



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