CQS

Consultancy Quality Solutions…we draw the line

LabHawk

让Microsoft® Excel®符合法规

System Cal
Bicarb Cal 1
Bicarb Cal 2
HDL Cal
Salicylate Cal
Paracetamol Cal
Alcohol Cal
Bilirubin Cal
Bile Acid Cal
Randox 1 QC
Lactate / Vnc
Ammonia QC
Randox 1 QC For Glucose
Urine QC 1

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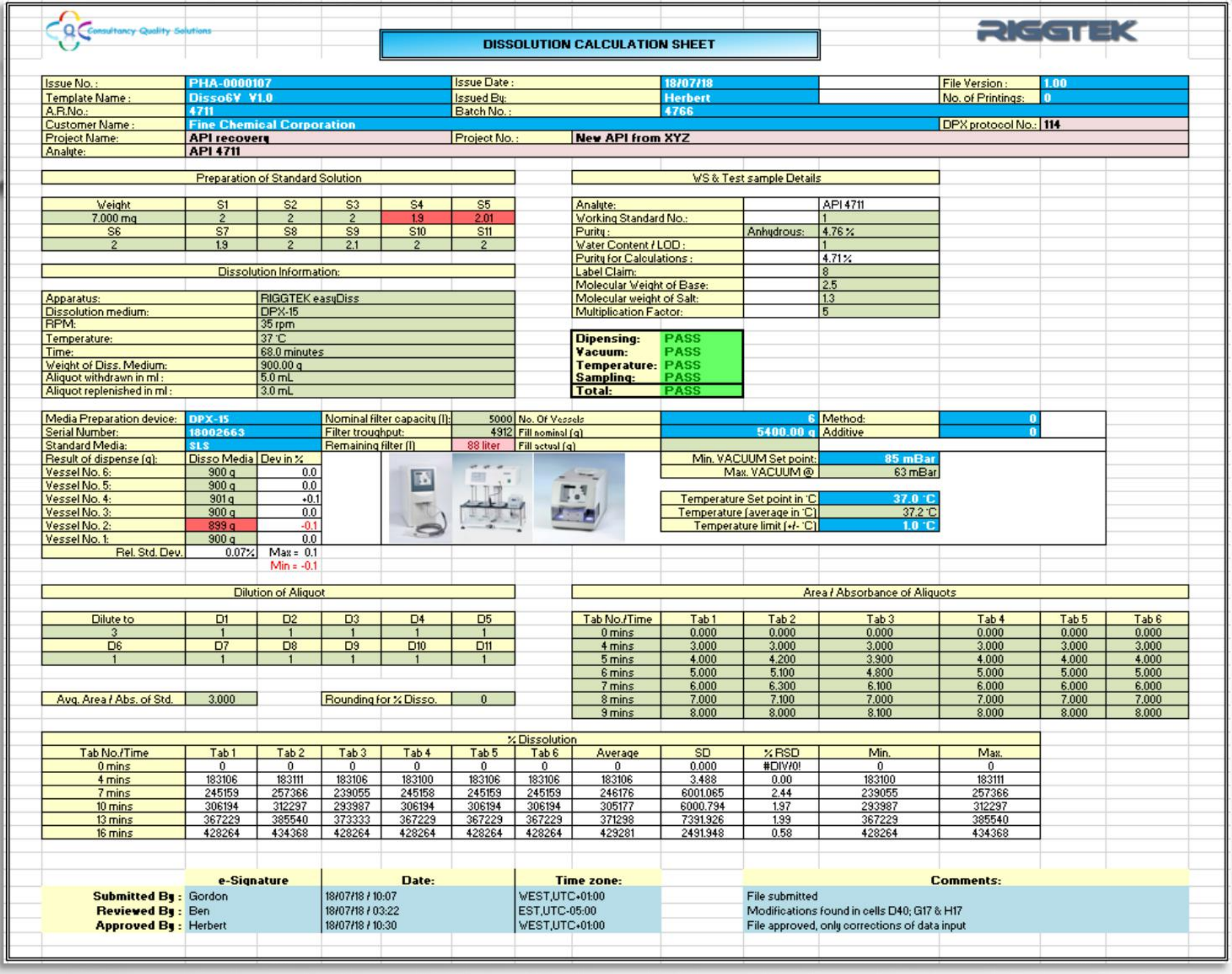
让Microsoft® Excel®符合法规



DISSOLUTION CALCULATION SHEET

Issue No. :	PHA-0000107	Issue Date :	18/07/18	File Version :	1.00
Template Name :	Disso6V V1.0	Issued By:	Herbert	No. of Printings:	0
A.R.No.:	4711	Batch No. :	4766		
Customer Name :	Fine Chemical Corporation			DPX protocol No.:	114
Project Name:	API recovery	Project No. :	New API from XYZ		
Analyte:	API 4711				

Preparation of Standard Solution

Weight	S1	S2	S3	S4	S5
7.000 mg	2	2	2	1.9	2.01
S6	S7	S8	S9	S10	S11
2	1.9	2	2.1	2	2

WS & Test sample Details

Analyte:		API 4711
Working Standard No.:		1
Purity :	Anhydrous:	4.76 %
Water Content / LOD :		1
Purity for Calculations :		4.71 %
Label Claim:		8
Molecular Weight of Base:		2.5
Molecular weight of Salt:		1.3
Multiplication Factor:		5

Dissolution Information:

Apparatus:	RIGGTEK easyDiss
Dissolution medium:	DPX-15
RPM:	35 rpm
Temperature:	37 °C
Time:	68.0 minutes
Weight of Diss. Medium:	900.00 g
Aliquot withdrawn in ml :	5.0 mL
Aliquot replenished in ml :	3.0 mL

Dipensing:	PASS
Vacuum:	PASS
Temperature:	PASS
Sampling:	PASS
Total:	PASS

Media Preparation device:	DPX-15	Nominal filter capacity (l):	5000	No. Of Vessels	6	Method:	0
Serial Number:	18002663	Filter troughput:	4912	Fill nominal (g)	5400.00 g	Additive	0
Standard Media:	SLS	Remaining filter (l)	88 liter	Fill actual (g)			

Result of dispense (g):	Disso Media	Dev in %
Vessel No. 6:	900 g	0.0
Vessel No. 5:	900 g	0.0
Vessel No. 4:	901 g	+0.1
Vessel No. 3:	900 g	0.0
Vessel No. 2:	899 g	-0.1
Vessel No. 1:	900 g	0.0
Rel. Std. Dev.	0.07%	Max = 0.1 Min = -0.1

Min. VACUUM Set point:	85 mBar
Max. VACUUM @	63 mBar
Temperature Set point in °C	37.0 °C
Temperature (average in °C)	37.2 °C
Temperature limit (+/- °C)	1.0 °C

Dilution of Aliquot

Dilute to	D1	D2	D3	D4	D5
3	1	1	1	1	1
D6	D7	D8	D9	D10	D11
1	1	1	1	1	1

Avg. Area / Abs. of Std.	3.000	Rounding for % Disso.	0

Area / Absorbance of Aliquots

Tab No./Time	Tab 1	Tab 2	Tab 3	Tab 4	Tab 5	Tab 6
0 mins	0.000	0.000	0.000	0.000	0.000	0.000
4 mins	3.000	3.000	3.000	3.000	3.000	3.000
5 mins	4.000	4.200	3.900	4.000	4.000	4.000
6 mins	5.000	5.100	4.800	5.000	5.000	5.000
7 mins	6.000	6.300	6.100	6.000	6.000	6.000
8 mins	7.000	7.100	7.000	7.000	7.000	7.000
9 mins	8.000	8.000	8.100	8.000	8.000	8.000

% Dissolution

Tab No./Time	Tab 1	Tab 2	Tab 3	Tab 4	Tab 5	Tab 6	Average	SD	% RSD	Min.	Max.
0 mins	0	0	0	0	0	0	0	0.000	#DIV/0!	0	0
4 mins	183106	183111	183106	183100	183106	183106	183106	3.488	0.00	183100	183111
7 mins	245159	257366	239055	245158	245159	245159	246176	6001.065	2.44	239055	257366
10 mins	306194	312297	293987	306194	306194	306194	305177	6000.794	1.97	293987	312297
13 mins	367229	385540	373333	367229	367229	367229	371298	7391.926	1.99	367229	385540
16 mins	428264	434368	428264	428264	428264	428264	429281	2491.948	0.58	428264	434368

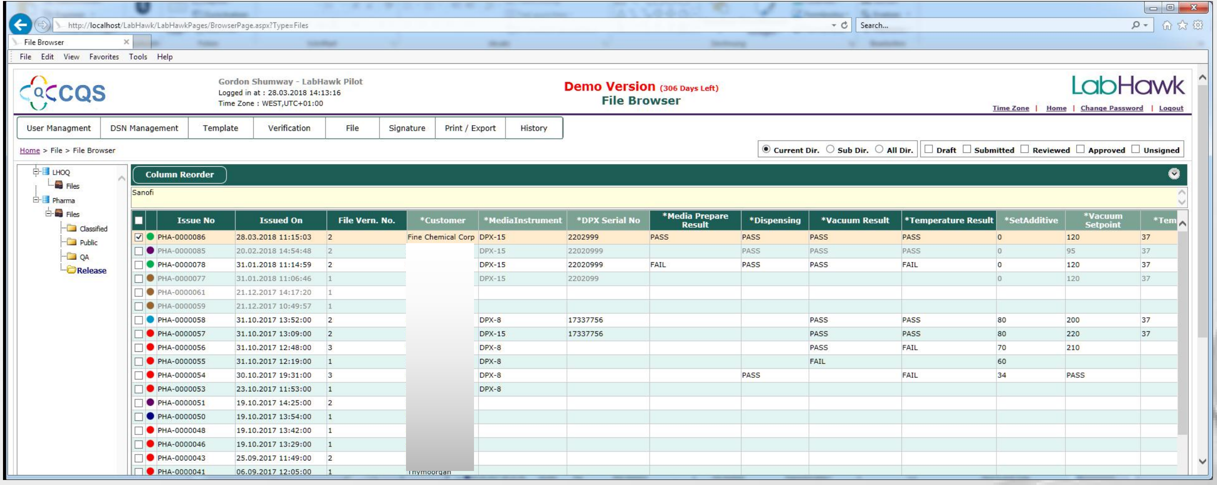
	e-Signature	Date:	Time zone:	Comments:
Submitted By :	Gordon	18/07/18 / 10:07	WEST,UTC+01:00	File submitted
Reviewed By :	Ben	18/07/18 / 03:22	EST,UTC-05:00	Modifications found in cells D40; G17 & H17
Approved By :	Herbert	18/07/18 / 10:30	WEST,UTC+01:00	File approved, only corrections of data input

- 您需要把重要的数据和结果输入到已验证的Microsoft Excel®数据表格中吗？
- 您希望他们仍然保持被验证的状态吗？
- 您想提交已验证的Microsoft Excel®数据表到监管环境中吗?
- 您想让Microsoft Excel®符合21CFR part11的法规要求吗？
- 是否有一个简单的方法可以在在数以万计的Microsoft Excel®数据表格中快速搜索到您想要的文件？

如果您的答案是“yes”，那么是时候选择LabHawk了

LabHawk给您带来

- ❑ 符合法规的用户管理（LDAP登陆，角色，访问组，团队，自定义策略，用户定义功能）
- ❑ 追踪所有的活动（修改记录和审计追踪）
  - ☑ **谁做的：**操作者的名字被追踪
  - ☑ **什么时候做的：**审计追踪中记录更改的时间和日期
  - ☑ **更改了什么：**更改过的单元格会变颜色，新老数据显示在审计追踪中
  - ☑ **为什么更改：**每个更改都需至少5到200个可调节字符的注释
- ❑ 版本和打印控制，“另存为”和不保存打印都是禁止的
- ❑ 符合21 CFR part 11的电子签名
- ❑ 简便的数据库查询，可从数百万的Excel文件中找到需要的文件
- ❑ 还有更多....


File Browser
File Edit View Favorites Tools Help
Search...
CQS
LabHawk
Time Zone | Home | Change Password | Logout
User Managment
DSN Management
Template
Verification
File
Signature
Print / Export
History
LHOQ
Files
Pharma
Files
Classified
Public
QA
Release
Column Reorder

http://localhost/LabHawk/LabHawkPages/BrowserPage.aspx?Type=Files

Gordon Shumway - LabHawk Pilot
Logged in at : 28.03.2018 14:13:16
Time Zone : WEST,UTC+01:00

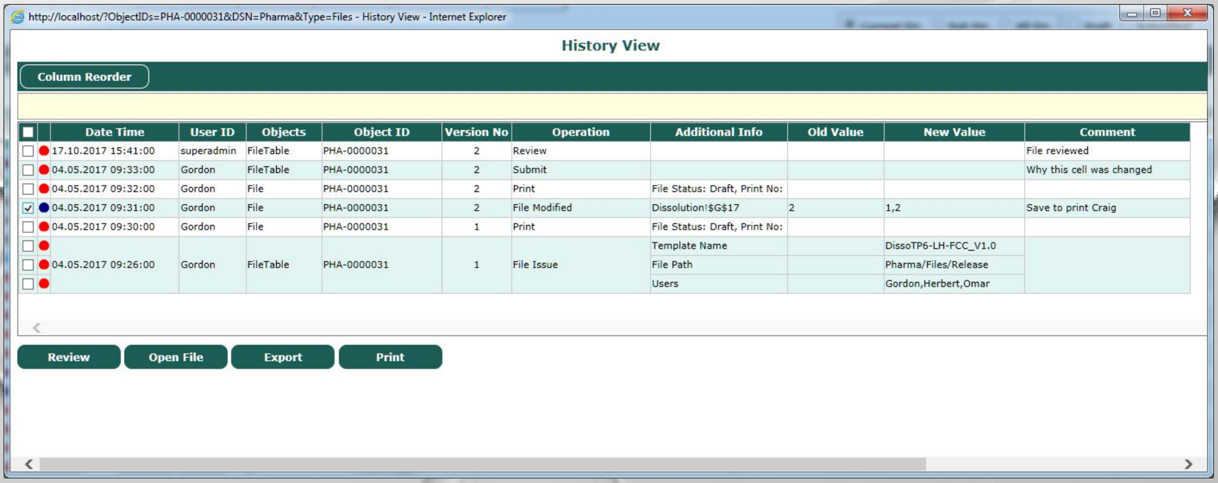
Demo Version (306 Days Left)
File Browser

Home > File > File Browser

● Current Dir. ○ Sub Dir. ○ All Dir. ☐ Draft ☐ Submitted ☐ Reviewed ☐ Approved ☐ Unsigned

Sanofi

☐		Issue No	Issued On	File Vern. No.	*Customer	*MediaInstrument	*DPX Serial No	*Media Prepare Result	*Dispensing	*Vacuum Result	*Temperature Result	*SetAdditive	*Vacuum Setpoint	*Tem
☑	●	PHA-0000086	28.03.2018 11:15:03	2	Fine Chemical Corp	DPX-15	2202999	PASS	PASS	PASS	PASS	0	120	37
☐	●	PHA-0000085	20.02.2018 14:54:48	2	[redacted]	DPX-15	22020999		PASS	PASS	PASS	0	95	37
☐	●	PHA-0000078	31.01.2018 11:14:59	2	[redacted]	DPX-15	22020999	FAIL	PASS	PASS	FAIL	0	120	37
☐	●	PHA-0000077	31.01.2018 11:06:46	1	[redacted]	DPX-15	2202099					0	120	37
☐	●	PHA-0000061	21.12.2017 14:17:20	1	[redacted]									
☐	●	PHA-0000059	21.12.2017 10:49:57	1	[redacted]									
☐	●	PHA-0000058	31.10.2017 13:52:00	2	[redacted]	DPX-8	17337756			PASS	PASS	80	200	37
☐	●	PHA-0000057	31.10.2017 13:09:00	2	[redacted]	DPX-15	17337756			PASS	PASS	80	220	37
☐	●	PHA-0000056	31.10.2017 12:48:00	3	[redacted]	DPX-8				PASS	FAIL	70	210	
☐	●	PHA-0000055	31.10.2017 12:19:00	1	[redacted]	DPX-8				FAIL		60		
☐	●	PHA-0000054	30.10.2017 19:31:00	3	[redacted]	DPX-8			PASS		FAIL	34	PASS	
☐	●	PHA-0000053	23.10.2017 11:53:00	1	[redacted]	DPX-8								
☐	●	PHA-0000051	19.10.2017 14:25:00	2	[redacted]									
☐	●	PHA-0000050	19.10.2017 13:54:00	1	[redacted]									
☐	●	PHA-0000048	19.10.2017 13:42:00	1	[redacted]									
☐	●	PHA-0000046	19.10.2017 13:29:00	1	[redacted]									
☐	●	PHA-0000043	25.09.2017 11:49:00	2	[redacted]									
☐	●	PHA-0000041	06.09.2017 12:05:00	1	[redacted]									


Column Reorder
Review
Open File
Export
Print

http://localhost/?ObjectIDs=PHA-0000031&DSN=Pharma&Type=Files - History View - Internet Explorer

History View

☐		Date Time	User ID	Objects	Object ID	Version No	Operation	Additional Info	Old Value	New Value	Comment
☐	●	17.10.2017 15:41:00	superadmin	FileTable	PHA-0000031	2	Review				File reviewed
☐	●	04.05.2017 09:33:00	Gordon	FileTable	PHA-0000031	2	Submit				Why this cell was changed
☐	●	04.05.2017 09:32:00	Gordon	File	PHA-0000031	2	Print	File Status: Draft, Print No:			
☑	●	04.05.2017 09:31:00	Gordon	File	PHA-0000031	2	File Modified	Dissolution!G17	2	1,2	Save to print Craig
☐	●	04.05.2017 09:30:00	Gordon	File	PHA-0000031	1	Print	File Status: Draft, Print No:			
☐	●	04.05.2017 09:26:00	Gordon	FileTable	PHA-0000031	1	File Issue	Template Name		DissoTP6-LH-FCC_V1.0	
☐	●							File Path		Pharma/Files/Release	
☐	●							Users		Gordon,Herbert,Omar	

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