



DISSOLUTION CALCULATION SHEET									
Issue No. : PHA-0000107		Issue Date : 18/07/18		File Version : 1.00					
Template Name : Dissolv 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				
Dissolution Information:									
Apparatus : RIGGTEK easyDiss									
Dissolution medium : DPX-15									
RPM : 35 rpm									
Temperature : 37 °C									
Time : 68.0 minutes									
Weight of Diss. Medium : 300.00 g									
Aliquot withdrawn in ml : 5.0 mL									
Aliquot replenished in ml : 3.0 mL									
VS & 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									
Dispensing : PASS									
Vacuum : PASS									
Temperature : PASS									
Sampling : PASS									
Total : PASS									
Media Preparation device : DPX-15		Nominal filter capacity (l) : 5000		No. Of Vessels : 6					
Serial Number : 16002663		Filter throughput : 4912		Fill nominal (g) : 5400.00 g					
Standard Media : SLS		Remaining filter (l) : 88 liter		Fill actual (g) : 5400.00 g					
Result of dispense (g) : Disso Media		Dev in % :		Method : Additive					
Vessel No. 6 : 900 g		0.0		Min. VACUUM Set point : 85 mBar					
Vessel No. 5 : 900 g		0.0		Max. VACUUM @ : 63 mBar					
Vessel No. 4 : 901 g		+0.1		Temperature Set point in °C : 37.0 °C					
Vessel No. 3 : 900 g		0.0		Temperature (average in °C) : 37.2 °C					
Vessel No. 2 : 899 g		-0.1		Temperature limit (+/- °C) : 1.0 °C					
Vessel No. 1 : 900 g		0.0							
Rel. Std. Dev. : 0.07 %		Max = 0.1							
		Min = -0.1							
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	6.000	6.000	6.000	6.000			
8 mins	7.000	7.000	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			
0 mins	0	0	0	0	0	0			
4 mins	183106	183111	183106	183106	183106	183106			
7 mins	245159	257366	239055	245159	245159	245176			
10 mins	306194	312237	293387	306194	306194	305177			
13 mins	367229	385540	373333	367229	367229	371298			
16 mins	428264	434368	428264	428264	428264	429281			
SD									
0 mins	0.000	0.000	0.000	0.000	0.000	0.000			
4 mins	3.489	0.00	0.00	3.489	3.489	3.489			
7 mins	6001065	2.44	238055	245176	245159	245176			
10 mins	6000.794	1.97	233887	306194	306194	305177			
13 mins	7391926	1.99	367229	367229	367229	371298			
16 mins	2491948	0.58	428264	428264	428264	429281			
% RSD									
0 mins	0	0	0	0	0	0			
4 mins	0.00	0.00	0.00	0.00	0.00	0.00			
7 mins	2.44	0.00	0.00	2.44	2.44	2.44			
10 mins	1.97	0.00	0.00	1.97	1.97	1.97			
13 mins	1.99	0.00	0.00	1.99	1.99	1.99			
16 mins	0.58	0.00	0.00	0.58	0.58	0.58			
Min.									
0 mins	0	0	0	0	0	0			
4 mins	183106	183111	183106	183106	183106	183106			
7 mins	245159	257366	239055	245159	245159	245176			
10 mins	306194	312237	293387	306194	306194	305177			
13 mins	367229	385540	373333	367229	367229	371298			
16 mins	428264	434368	428264	428264	428264	429281			
Max.									
0 mins	0	0	0	0	0	0			
4 mins	183106	183111	183106	183106	183106	183106			
7 mins	245159	257366	239055	245159	245159	245176			
10 mins	306194	312237	293387	306194	306194	305177			
13 mins	367229	385540	373333	367229	367229	371298			
16 mins	428264	434368	428264	428264	428264	429281			
Submitted By : Gordon									
Reviewed By : Ben									
Approved By : Herbert									
e-Signature		Date:		Time zone:					
Submitted By : Gordon		18/07/18 / 10:07		WEST,UTC+01:00					
Reviewed By : Ben		18/07/18 / 03:22		EST,UTC-05:00					
Approved By : Herbert		18/07/18 / 10:30		WEST,UTC+01:00					
Comments:									
File submitted									
Modifications found in cells D40; G17 & H17									
File approved, only corrections of data input									

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If there is any answer with "yes", its time to fly LabHawk

LabHawk, Features

- ☐ Regulatory compliant User Management (LDAP login, Roles, Access groups, Teams, customized policies, User defined functions)
- ☐ Tracking all activities (modification history and Audit Trail)
 - ☒ **Who did it:** The name of operator is tracked
 - ☒ **When it was done:** Date and time of changes are in the AT
 - ☒ **What has been changed:** The changed cell is changing colour, old/new values are shown in AT
 - ☒ **Why it was changed:** Each change requires a minimum comment 5 to 200 characters adjustable
- ☐ Control over versioning and printing. "Save as" & printing without saving is disabled
- ☐ Electronic Signature according 21 CFR part 11
- ☐ Ease of use Database query to retrieve the exact Excel file out of millions.
- ☐ And many more....

File Browser

Gordon Shumway - LabHawk Pilot
Logged in at: 18.03.2018 14:13:15
Time Zone: WEST/UTC+01:00

Demo Version (306 Days Left)

LabHawk

Time Zone | Home | Change Password | Logout

User Management | DSN Management | Template | Verification | File | Signature | Print / Export | History

Home > File > File Browser

Column Reorder

Current Dir. | Sub Dir. | All Dir. | Draft | Submitted | Reviewed | Approved | Unsigned

Issue No	Issued On	File Ver. No.	*Customer	*MediaInstrument	*DPX Serial No	*Media Prepare Result	*Dispensing	*Vacuum Result	*Temperature Result	*SetAdditive	*Vacuum Setpoint	*Tem
PHA-000006	28.03.2018 11:15:03	2	Fine Chemical Corp	DPK-15	2202999	PASS	PASS	PASS	PASS	0	120	37
PHA-000005	30.03.2018 14:54:48	2		DPK-15	2202999	PASS	PASS	PASS	PASS	0	95	37
PHA-000078	31.01.2018 11:14:59	2		DPK-15	2202999	FAIL	PASS	PASS	FAIL	0	120	37
PHA-000077	31.01.2018 11:06:46	1		DPK-15	2202999					0	120	37
PHA-000061	21.12.2017 14:17:20	1										
PHA-000059	21.12.2017 10:49:57	1										
PHA-000058	21.10.2017 18:52:00	2		DPK-8	17337756		PASS	PASS	PASS	80	200	37
PHA-000057	31.10.2017 13:09:00	2		DPK-15	17337756		PASS	PASS	PASS	80	220	37
PHA-000056	31.10.2017 12:48:00	3		DPK-8			PASS	FAIL	FAIL	70	210	
PHA-000055	31.10.2017 12:19:00	1		DPK-8						60		
PHA-000054	30.10.2017 19:31:00	3		DPK-8			PASS	FAIL	FAIL	34	PASS	
PHA-000053	23.10.2017 11:53:00	1		DPK-8								
PHA-000051	19.10.2017 14:25:00	2										
PHA-000050	19.10.2017 13:54:00	1										
PHA-000048	19.10.2017 13:42:00	1										
PHA-000046	19.10.2017 13:29:00	1										
PHA-000043	25.09.2017 11:49:00	2										
PHA-000041	06.09.2017 12:05:00	1										

History View

Column Reorder

	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/\$G\$17	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	

Review Open File Export Print

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