



RIGGTEK

Dissolution Test Systems



DissoPrep X8 / X15

features (1)



The DissoPrep is the original innovative Dissolution Media Delivery Station with gravimetric working principle without fluidic pumps - **SIMPLY SMART**

The central image shows the DissoPrep X8 / X15 Dissolution Media Delivery Station, a white and grey unit with a control panel and a dispensing nozzle. It is surrounded by various accessories including glass vessels and a power supply.

- Optional Full CFR-compliance** with individual user permissions, commenting of audit-trail and electronic signature etc. *lockout spec*
- Gravimetric high precision dispensing** of +/-0.5% into any dissolution tester *lockout spec*
- The „DissoPrep“ provides a **full report** detailing weights, mixing ratios, vacuum and temperature after each dispense cycle
- Optional automatic periodic backup** to USB or FTP *lockout spec*
- Optional connection to Dissolution Tester Dissilio** for automatic data consolidation with the Dissolution Test report
- Easy, intuitive operation and real time monitoring via your PC with the innovative „**Browser Interface**“ without any software installation
- Modern interfaces like LAN and USB, optional **Parent-Child-Functionality** for easy method and user transfer between different DissoPreps *lockout spec*
- Two versions available, which allows to prepare 8 litres (DPX8) or 15 litres (DPX15) of media, sufficient to fill all vessels of one or more dissolution testers
- Fast media preparation** in around 1.5min with high degassing efficiency by monitored vacuum and precise temperature
- Well suited for **foaming media** like SDS/SLS **Automatic-Washing** of the complete system *lockout spec*
- Various accessories available like Remote Control Nozzle, Cart for Mobile Version and **Uninterruptible Power Supply**



DissoPrep X8 / X15

features (2)



The Dissoprep X8 / X15 is filtering, mixing, warming, degassing and dispensing the media according the USP, FDA, EP, GLP / GMP.

➤ filtering:

by an **easily exchangeable Filter Cartridge**, the remaining filter capacity is checked automatically, when necessary the system prompts the user to change the filter. The Flow Through Principle prevents bacterial growth.

➤ warming:

A **special continous-flow heater warms the media** before degassing. This generates an enhanced degassing and saves considerable time when heating in the dissolution tester.

➤ Mixing:

For the **precise addition of concentrated hydrochloric acid, buffer or surfactant (SLS)** a second inlet channel is provided.

The composition of additive and water is controlled gravimetricly by a Precision Load Cell.

An **electronic stirrer mixes the components** in the storage tank and ensures a homogenous mixture concentration (functionally monitored).

The precision of the composition is very high (**deviation lower than 0,2% typ.**).

DissoPrep X8 / X15

features (3)



➤ degassing:

The media is exposed to a **high vacuum** during withdrawing the raw media.

The interaction of heating, mixing and degassing generates an **effective de-aeration of the medium e.g. for water with typically 3-5ppm O₂ (after filling into the vessel).**

The USP does not specify degassing in figures because the dissolved oxygen measurement is not robust and no traceable standards for the calibration of oxygen meters are available.

Only the physical effect parameters temperature, vacuum and duration of media exposure can be measured reliably.

DissoPrep X8 / X15

features (4)



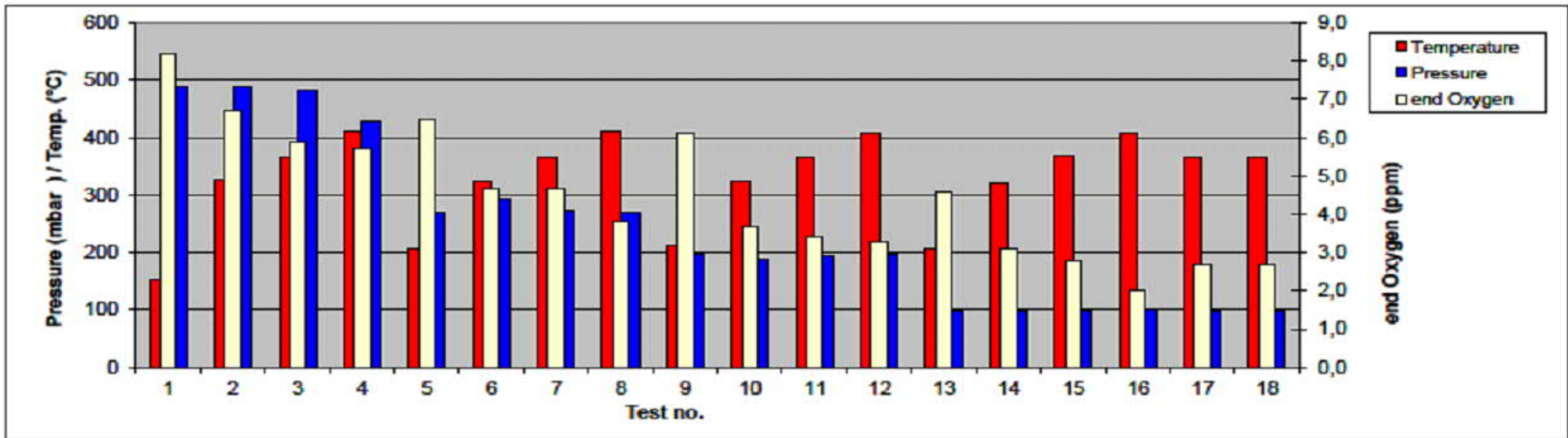
➤ degassing:

Degassing Efficiency Investigation with DissoPrep X8
 © 2014
www.rigtek.com
 Dipl.-Ing. Hansjuergen Riggemann
 Oxymeter from WTW OXI 330
 DissoPrep X8 with Firmware 8.01

As long as the vacuum is <300mbar and the temperature is > 32°C, a sufficient degassing of typical < 5ppm will be reached

The DissoPrep-Routine-Applications (vacuum <100mbar, temperature between 32°C and 37°C, additional degassing time of 120 seconds) are resulting in a fast and very good degassing result!

Method Parameter	Test No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Temperature set.	°C	20	32	37	42	20	32	37	42	20	32	37	42	20	32	37	42	37	37
Temperature eff.	°C/10	154	325	385	410	205	324	388	410	212	323	385	408	208	322	389	408	387	388
min. Pressure (vacuum)	mbar	480	400	484	428	269	295	274	288	197	190	193	197	98	99	99	100	99	98
Volume	mL	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400
add. Degas Time	sec	120	120	120	120	120	120	120	120	120	120	120	120	120	120	120	120	240	480
start Oxygen	ppm O ₂	9,1	8,3	8,1	9,2	8,4	8,4	8,9	8,9	8,8	8,1	8,5	8,2	8,6	8,2	8,4	8,4	8,6	8,5
end Oxygen	ppm O ₂	8,2	6,7	5,9	5,7	6,5	4,7	4,7	3,8	6,1	3,7	3,4	3,3	4,6	3,1	2,8	2,0	2,7	2,7
DPX8 routine application															YES	YES			

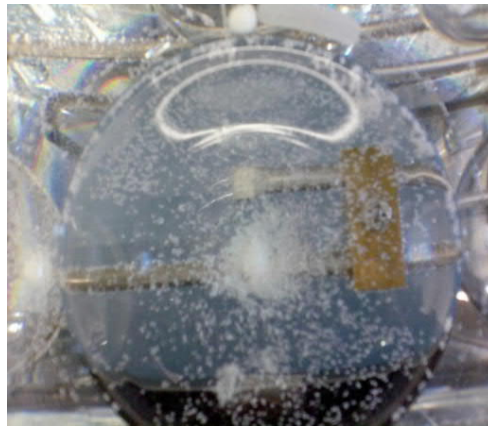


DissoPrep X8 / X15

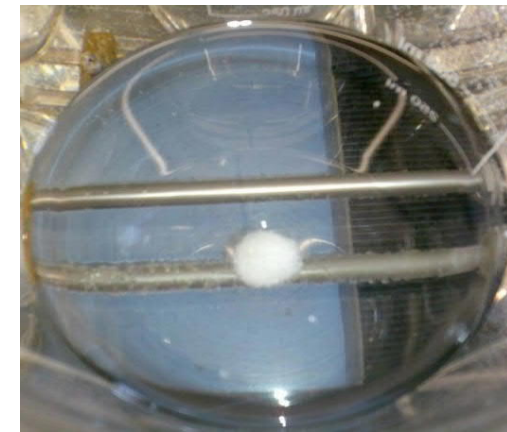
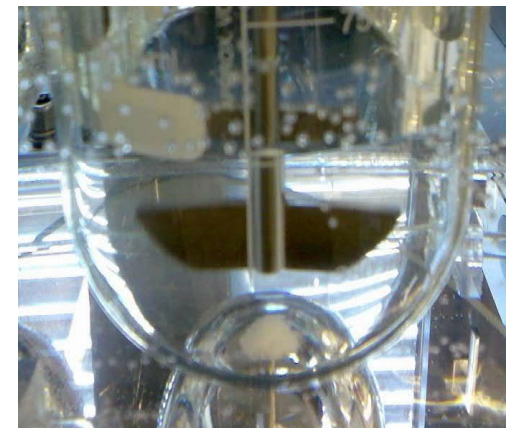
features (5)



➤ degassing:



Not degassed



Degassed

DissoPrep X8 / X15

features (6)



➤ dispensing:

The vessels in the dissolution tester are filled directly with a Dispense Tube.

The **highly precise dosage** (<1% at 500 - 8.000g / 15.000g, typ. 2g) of 900mL needs approximately **25 seconds** and is controlled by the Precision Load Cell.

The target volume can be selected between 150g and 8.000g / 15.000g (weight equivalents of mL).

Preparing and dispensing of SLS is possible with a concentration of up to 2%.

➤ documentation:

All internal dosage processes are accurately controlled and **monitored by a Precision Load Cell**.

The individual dosage processes are **documented** and can be printed on an **external printer (parallel, USB or LAN) or administrated via the (Web-)Browser of any PC** (Browser-Interface for DissoPrep – standard option).

After each DISPENSE cycle the DissoPrep provides a **DISPENSE Protocol** containing the weights, the mixing ratio, the vacuum and the temperature. Also a **CALIBRATION Protocol** is provided. **The DissoPrep can be calibrated trough a software guided procedure easily.**

DissoPrep X8 /X15

features (7)



```
MEDIA DISPENSE REPORT
No: 1

DissoPrep X8   RIGGTEK GmbH Germany

Serial Number  : R41020520
Firmware Version: 8.08

General Data:
Nominal filter capacity [l]: 5000
Remaining filter capacity [l]: 4948
Volume throughput up to now : 52

Method: 0
1000, 10.0, 6, 37.0
Method 0

Result of the dosages [g]:

          MEDIUM  ADDTV  RATIO  DEV%
Fill Nominal: 6000  60.0  0.010
Fill Actual:  6538  65.4  0.010  +0.0

          MEDIUM  DEV%  ADDTV  DEV%
Vessel No. 6: 1000  -0.0  10.0  +0.0
Vessel No. 5: 1001  +0.1  10.0  +0.0
Vessel No. 4: 1000  +0.0  10.0  +0.0
Vessel No. 3: 1000  +0.0  10.0  +0.0
Vessel No. 2: 1000  +0.0  10.0  +0.0
Vessel No. 1: 1000  +0.0  10.0  +0.0

Result (average):
          1000  0.0
Max.deviation:  1
Std.deviation:  0.3

Temperature (average): 37.1 C

MAX.VACUUM at 89 mbar abs. pressure
Overall DEGASSING TIME (mm:ss): 10:30

Date, Time: 19.05.2016, 08:01

Name:
.....

Signature:
.....
Dates/Times no verified specifications

Printed at: 2018.8.23 12:50:02 by reviewer
Submitted at: 2018.8.22 10:55:18 by usertest1
Reviewed at: 2018.8.23 12:38:16 by reviewer
Unsigned at: 2018.8.23 12:44:26 by approver
```

➤ documentation:

All parameters of a method and the instrument details are printed on the report as well as the details of the electronic signature.

DissoPrep X8 / X15

features (8)



```
MANUAL CALIBRATION PROTOCOL
No: 7
for the media dosage
with DOSAPREP X8
Serial Number : 20100056
Firmware Version: 4.25
General Data:
Nominal filter capacity [l]: 5000
Remaining filter capacity [l]: 4950
Volume throughput up to now : 50
Result of the quantity measurings [g]
      INTERN  EXTERN  DEV%
No. 8:  1003   1005   -0.2
No. 7:  1004   1004   +0.0
No. 6:  1004   1005   -0.1
No. 5:  1004   1003   +0.1
No. 4:  1003   1003   +0.0
No. 3:  1004   1003   +0.1
No. 2:  1004   1005   -0.1
No. 1:  1003   1002   +0.1
Result (average):
      1004   1004   -0.0
Result of the temperature measurings[C]
      INTERN  EXTERN  DEV
No. 8:  36.2   36.2   +0.0
No. 7:  36.3   36.3   +0.0
No. 6:  36.2   36.2   +0.0
No. 5:  36.2   36.2   +0.0
No. 4:  36.3   36.3   +0.0
No. 3:  36.3   36.3   +0.0
No. 2:  36.3   36.3   +0.0
No. 1:  36.3   36.3   +0.0
Result (average):
      36.2   36.2   +0.0
Date, Time:
.....
Name:
.....
Signature:
.....
2000-10-03 21:21:21 (UTC)
```

➤ documentation:

Calibration details are reported separately as well as performance test details.

DissoPrep X8 / X15

features (9)



➤ documentation:



RIGGTEK
Dissolution Test Systems

DissoPrep Browser Interface (S/N41010457)

Home Methods Reports Calibrations Performance Usermanager Rolemanager Setup Logout

Show 10 entries Search:

#	Status	Report	Parameter	Date	Actions
1	Approved	MEDIA DISPENSE REPORT	Method: 0	2016-05-19 08:01:27	Print Sign
2	Reviewed	MEDIA DISPENSE REPORT	Method: 0	2016-07-15 11:39:25	Print Sign
3	Unsigned	MEDIA DISPENSE REPORT	Method: 0	2016-07-15 12:11:36	Print Sign
4	Unsigned	MEDIA DISPENSE REPORT	Method: 0	2016-07-20 14:28:16	Print Sign
5	Unsigned	MEDIA DISPENSE REPORT	Method: 10	2016-07-28 11:53:15	Print Sign
6	Unsigned	MEDIA DISPENSE REPORT	Method: 9	2016-09-05 09:40:21	Print Sign
7	Unsigned	MEDIA DISPENSE REPORT	Method: 0	2016-09-19 12:37:45	Print Sign
8	Unsigned	MEDIA DISPENSE REPORT	Method: 0	2016-09-22 13:10:59	Print Sign
9	Unsigned	MEDIA DISPENSE REPORT	Method: 0	2016-09-23 11:56:35	Print Sign
10	Unsigned	MEDIA DISPENSE REPORT	Method: 0	2016-07-15 13:13:35	Print Sign

Showing 1 to 10 of 91 entries

4 5 ... 10 Next

Home Methods Reports Calibrations Performance

Show 10 entries

#	Status	Report
1	Submitted	MANUAL PRESSURE CALIBRATION REPORT
2	Unsigned	MANUAL TEMPERATURE CALIBRATION REPORT
3	Unsigned	MANUAL TEMPERATURE CALIBRATION REPORT
4	Unsigned	MANUAL QUANTITY CALIBRATION REPORT
5	Unsigned	MANUAL QUANTITY CALIBRATION REPORT
10	Unsigned	MANUAL PRESSURE CALIBRATION REPORT
11	Unsigned	MANUAL TEMPERATURE CALIBRATION REPORT
12	Unsigned	MANUAL TEMPERATURE CALIBRATION REPORT
13	Unsigned	MANUAL QUANTITY CALIBRATION REPORT
15	Unsigned	MANUAL QUANTITY CALIBRATION REPORT

Show 10 entries

#	Status	Report
6	Reviewed	MANUAL PERFORMANCE TEST REPORT
7	Unsigned	MANUAL PERFORMANCE TEST REPORT
8	Unsigned	MANUAL PERFORMANCE TEST REPORT
9	Submitted	MANUAL PERFORMANCE TEST REPORT
14	Unsigned	MANUAL PERFORMANCE TEST REPORT
21	Unsigned	MANUAL PERFORMANCE TEST REPORT
26	Unsigned	MANUAL PERFORMANCE TEST REPORT

Showing 1 to 10 of 19 entries

Showing 1 to 7 of 7 entries

DissoPrep X8 / X15

features (10)



➤ easy administration for 21CFR Compliance and data integrity:



The standard Browser-Interface for DissoPrep **BI-DPX** allows to

- connect your *DissoPrep* via LAN to your local PC or to your company network
- and to administrate your *DissoPrep* easily via your (Internet-) Browser without any further software-installation and software-validation, to
- administrate easily methods, reports incl. electronic signature,
- administrate user permissions by individual user roles,
- audittrail review,
- data backup,
- parent-child-coupling,
- etc.



DissoPrep X8 / X15

advantages (1)



➤ easy handling:

The user-interface of the DissoPrep is quite simple with only a few buttons. The Remote Control Nozzle simplifies the dispensing into the vessels.

Use of foaming media is possible because of having no fluidic pump! SLS is possible with a concentration of up to 2%.

➤ space saving:

The dimensions of the DissoPrep X8 / X15 are W 30cm x H 66cm x D 59cm quite compact to fit in every lab. Available as table or mobile device!

➤ USP, EP, FDA, GLP/GMP conformity:

DissoPrep fulfills all requirements of the media preparation according to ***the demanded rules of the USP and EP***, as well as according to the ***recommendations of the FDA and of the GLP/GMP***.



DissoPrep X8 / X15

advantages (2)



➤ Safety in the Laboratory:

By automating the process - particularly the acid preparation and media dispensing - ***the risk to laboratory personnel is minimized.***

➤ Reproducibility of the results:

Reproducibility of the test results is independently of the operators
(a result of the automation of the media preparation).

➤ Automated calibration:

The automated calibration allows an easy calibration of

- vacuum,
- weight and
- temperature.

➤ Browser-Interface: *BI-DPX*

The standard Browser-Interface for the DissoPrep allows easy administration for

- 21 CFR compliance incl. electronic signature and
- data integrity

DissoPrep X8 / X15

advantages (3)



➤ time and cost saving:

The saving of time is considerable. E.g. the DissoPrep X8 prepares up to **8L of dissolution media** automated in **less than 15 minutes** (12 minutes with prepared media). The **fast and precise dosage** by a tube into the individual vessels (~25 seconds for 900ml) saves time-consuming handling steps. The **preheated media saves up to 45 minutes** for media heating with a conventional water bath dissolution tester.

If you calculate with:

- 180€ full costs of a manual test and
- 30€ costs of a test with the DissoPrep X8,

the ROI will already be reached after 90 tests



Profitability Analysis



Media Preparation

Regulatory Demands – why?



to remember...

The correct and always repeatable media preparation has significant influence on the reproducibility of the dissolution test results

Following parameters are important:

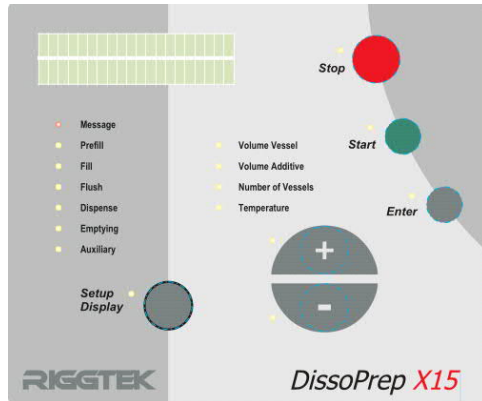
with DissoPrep:

1. precise and repeatable mixing of the media
2. precise dispensing of the media into the vessels
3. timesaving warming of the media
4. degassing of the media
5. documentation of the media preparation



DissoPrep X8 / X15

options / accessories (1)



DissoPrep X8 or X15

- X8 with 8 liter tank
- X15 with 15l tank (gross)
- same housing dimensions
- same working principle

RC-Nozzle

- comfortable remote-controlled dispensing with buttons at handle bar at tubing's end
- especially if 3m distance (tubings length) is used

Browser-Interface

- standard feature
- easy administration of methods, reports and users
- easy access with your (Internet-) Browser
- no software-installation or software-validation necessary

DissoPrep X8 / X15

options / accessories (2)



Pressure-Reducer

- for continuous, pressureless connection to DI-water tap
- installation has to be done from house technicians of customer



LabCart / mobile use

- comfortable use of DissoPrep at different places
- place for different reservoirs (available at RIGGTEK) and printer
- UPS (uninterruptable power supply)



Vessel-Rack

- safe transportation of vessels to dissolution tester
- isolation keeps vessels warm
- available for 6 or 8 vessels

DissoPrep X8 / X15

options / accessories (3)



printers

- for immediate protocol / certification printout
- suitable parallel-printer in bon-paper-size



measuring equipment

- all necessary measuring equipment for qualification of the DissoPrep is available at RIGGTEK
- special instruments with automatic communication to DissoPrep for automated qualification available

RIGGTEK

main products – customers worldwide





Thank you for your attention!
Do you have any questions?

- Visit our webpage www.riggtek.com or
- give us a call **Tel.: +49 89 2302469-0** or
- email us to support@riggtek.com

We are available!
your RIGGTEK-Team

