RIGGTEK

Dissolution Test Systems

DissoPrep X8 / X15

features (1)

The Dissoprep X8 / X15 is the original media preparation system which is working according the gravimetrical principle for more than 14 years and so fulfills the USP, FDA, EP, GLP / GMP.

- GRAVIMETRICAL PRINCIPLE (lockout spec)
- NO FLUDIC PUMP (lockout spec)
- mixing of acid or buffer
- high dispensing accuracy
- complete printout / documentation
- high degassing efficiency
- 8 or 15 liter tank
- fast economic amortisation

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 O_2 (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 paramaters temperature, vacuum and duration of media exposure can be measured reliably.

DissoPrep X8 / X15

features (4)

- degassing:

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!

Degassing Efficiency Investigation with DissoPrep X8

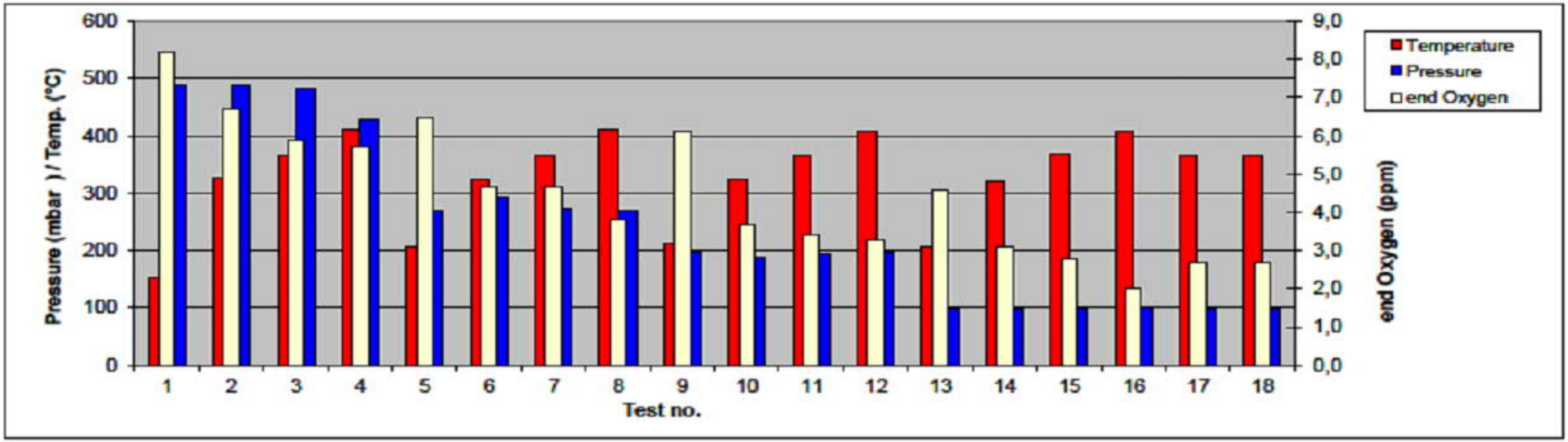
www.riggtek.com

Dipl.- Ing. Hansjuergen Riggenmann

Oxymeter from WTW OXI 330

DissoPrep X8 with Firmware 8.01

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	365	410	205	324	366	410	212	323	365	408	206	322	369	408	367	366
min. Pressure (vacuum)	mbar	489	490	484	428	269	295	274	268	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	8,6	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			

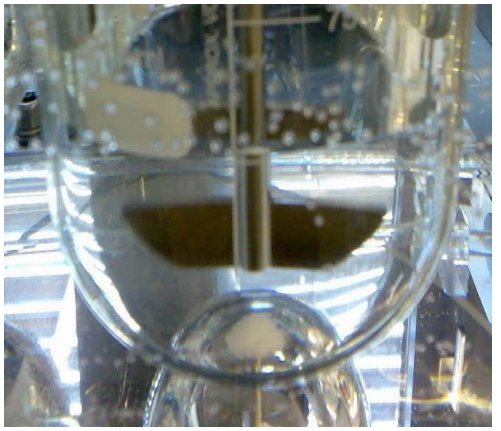


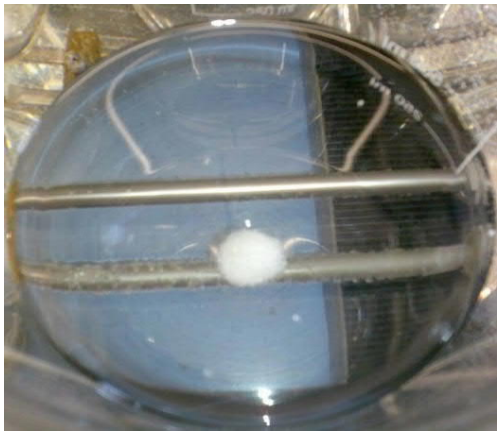
DissoPrep X8 / X15

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).

- 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 *BI-DPX* – 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
Submited 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 separetely 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 en

4 5 … 10 Next

Home | Methods | Reports | Calibrations | Performance

Show 10 entries

#	Status	Report
1	Submited	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

Showing 1 to 10 of 19 entries

Show 10 entries

#	Status	Report
6	Reviewed	MANUAL PERFORMANCE TEST REPORT
7	Unsigned	MANUAL PERFORMANCE TEST REPORT
8	Unsigned	MANUAL PERFORMANCE TEST REPORT
9	Submited	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 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 simplify the dispensing into the vessels.

➢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 comformity:

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)

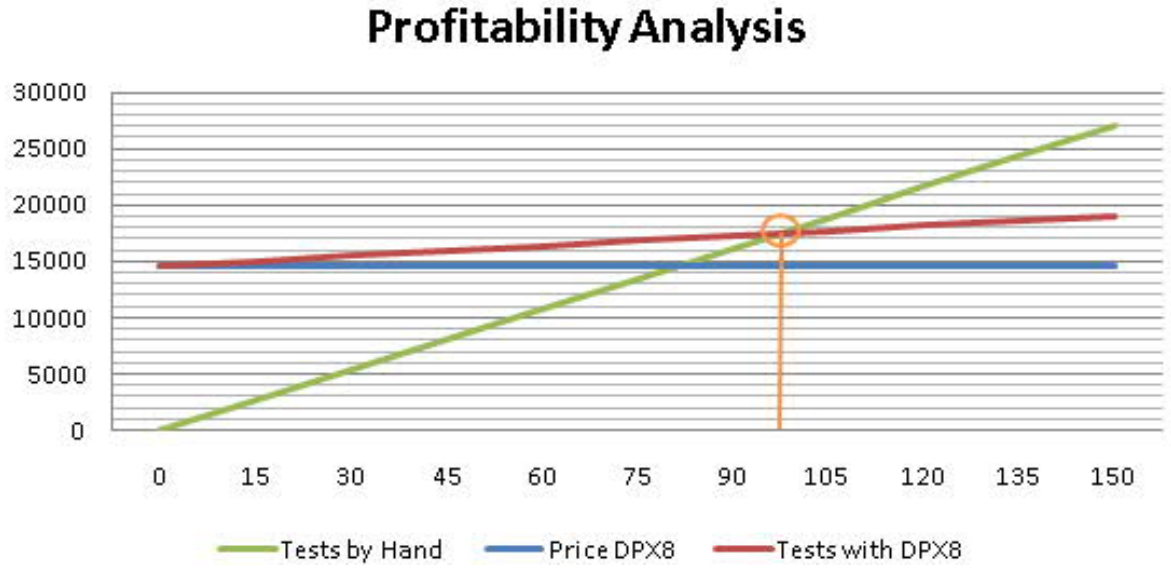
➢time and cost saving:

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



Media Preparation

Regulatory Demands – why?

to remember...

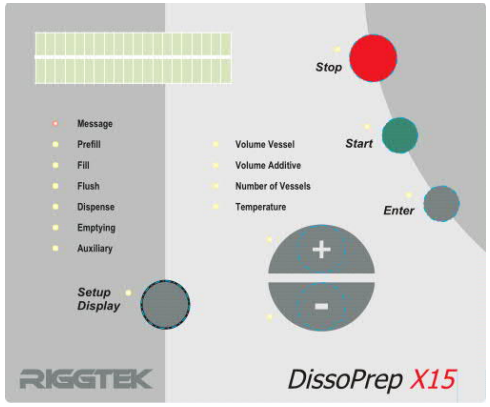
The correct and always repeatable media preparation has significant influence on the reproducibilty of the dissolution test results

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-controled 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 continous, pressureless contection to DI-water tap
- installation has to be done from house technicans of customer

LabCart / mobile use

- comfortable use of DissoPrep at different places
- place for different reservoirs (available at RIGGTEK), printer and vessel-rack
- UPS (uninterruptable power supply)
- second more slim version available soon!

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-printers in DINA4- or 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

DPX

EDS

SX 8

acino, BAYER, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi-Sankyo, Dr. Pfleger, élan, EXCELLA PHARMA SOURCE, Johnson & Johnson, LOSAN PHARMA, MERCK, NOVARTIS, NYCOMED, Pfizer, PHAST quality standards, ratiopharm, SANDOZ, sanofi aventis, SCHERING making medicine wo, Takeda, TEVA

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