RIGGTEK

Dissolution Test Systems

©2025

Media Preparation

Regulatory Demands – why?

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

Following parameters are important:

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

Media Preparation

Regulatory Demands – mixing, heating, dispensing

USP:

„Place the stated volume of the dissolution medium with an ...
... accuracy of 1% in the vessels ...
... and equilibrate it to 37 +/- 0,5 °C...“

Media Preparation

Regulatory Demands – mixing, heating, dispensing

Conclusion:

1. The „Stated Volumes“ – when mixing of all components of the media - must be filled cold at „Standard Conditions“* into the vessels and then heated up.

2. In accordance with the USP e.g. 900ml dispensed into a vessel weigh 897,4g. Only the weight of a liquid is not changing when warming it! Density and volume are changing!

3. It would be wrong to measure warm media in a volumetric flask or device calibrated at 20°C.

4. It would be wrong to use the specific weight (density) for gravimetric volume measuring of the media at e.g. 37°C.

* „Standard Conditions“ for filling the vessels: USP → 25°C (USP 34), EP → 20°C and 1bar: 1 Litre of Water weighs 997,1g (USP) and 998,3g (EP)

Media Preparation

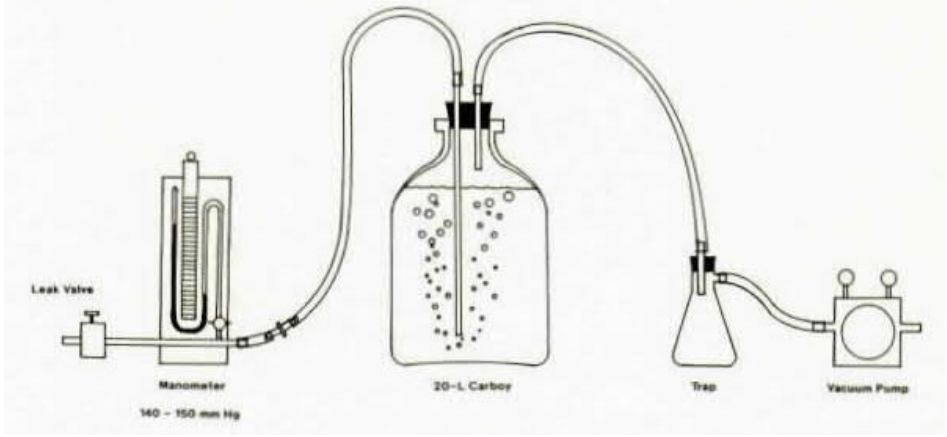
Regulatory Demands – degassing

USP:

„The USP recognizes that dissolved gases in the dissolution media may affect dissolution test results and ...
*... **recommends that gases be removed by filtering, warming and stirring under vacuum before the test is performed*.“***

FDA:

The FDA targeted the degassing more than ever as an area of concern. The recommended method refers to parameters of the USP recommendation „filtering, warming, stirring, vacuum and process time“. Stirring is realized by feeding air bubbles in the media bin. Additionally feeding air bubbles causes an Avalanche-Effect .*



*Dissoution Technologies, May 1996

Media Preparation

Regulatory Demands – degassing

Experiences:

- there were not published many and clear experience reports on the consequences of various degassing methods till now *. Usually, internal company **experiences are not pubished**.

- a high theoretical degassing efficiency of any degasing method is reduced by fast **resaturation** of dissolved air in the media. The resaturation takes place during intermediate storage, during filling, during waiting periods and in the initial phase of the dissolution test.

- under dissolution test conditions with degased media at least the dissolved air in the media may not be oversaturated, i.e. **no formation of bubbles may arise**.

- In case of water
  - with a temperature of **20°C** and an ambient air pressure of **1bar**, there are **9,08ppm** oxygen and air components dissolved.
  - In case of **37°C** there are **6,72ppm**.
  - If the temperature is increased to **100°C** and / or the air pressure is reduced against **0 bar** (full vacuum), no more air can be solved (**0,0ppm**).

*Dissoution Technologies, May 1996 / Dissoution Technologies, Feb 2004 / Dissoution Technologies, Aug 2008

Media Preparation

Regulatory Demands – degassing

Conclusion:

- The degassing is necessary at least to avoid oversaturation.
- The media can be dagassed either with the parameter „temperature“ or „vacuum“.
- The results of different degassing methods must be compared after dosage into the vessel or at the start of the dissolution test.

*Dissoution Technologies, May 1996 / Dissoution Technologies, Feb 2004 / Dissoution Technologies, Aug 2008

Media Preparation

Regulatory Demands – documentation

GLP / GMP:

The GLP / GMP rules demand a prescribed handling method SOP for the production of the media and ...
... the documentation of all working steps has to be done (traceability).

Media Preparation

User Demands

- easy handling:

  The handling must be simple and convenient. Efficiency is increased only in connection with the...
  ... full acceptance of the equipment by the laboratory staff.

- space saving:

  Nowhere in the labs is enough space available...
  ... such a unit must be compact.

- time and cost saving:

  Media filtering, heating, mixing, and degassing must be performed without user intervention in a reasonable time...
  ... for increasing throughput, avoiding manual media handling and waiting for warming the media before the start of the dissolution test. The compliance of the regulations and standards saves a lot of operational and administrative work.

- USP, EP, FDA, GLP/GMP comformity:

  There are many different requirements from regulations and standards, generating a lot of additional work...
  ... such a unit has to comply all requirements and has to save all associated operational and administrative work.

Media Preparation

Summary of demands

The following demands are important for an automated media preparation system.

Reproducibiltiy and regulatory demands:

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

Additional user demands:

6. easy operation / handling
7. space saving
8. time and cost saving with less manual handling and less manual documentation
9. conformity with USP, EP, FDA, GLP/GMP

DissoPrep X8 / X15

features (1)

1. Demand: Precise and repeatable minxing of the media

*The Dissoprep X8 / X15 is the original media preparation system which is working according the **gravimetrical principle** since 1998.*

- Precise:
  - GRAVIMETRICAL PRINCIPLE (lockout spec)
    - the weight is always measured and controlled – also for foam
    - no additional calibration necessary for each media
  - NO FLUDIC PUMP (lockout spec)
    - independent of accuracy of pumps
    - no problems with foaming media
- Repeatable:
  - always the same process of media preparation for each method
  - no individual intervention possible by the user (e.g. no additional degassing or heating after finished media preparation possible)

DissoPrep X8 / X15

features (2)

1. Demand: Precise and repeatable minxing of the media

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.

- 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)

2. Demand: warming of the media

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.
This heating process also ensures, that the warming is done reproducible, because no additional heating is possible, after the media is prepared.

DissoPrep X8 / X15

features (4)

3. Demand: Degassing of the media

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 (5)

3. Demand: Degassing of the media

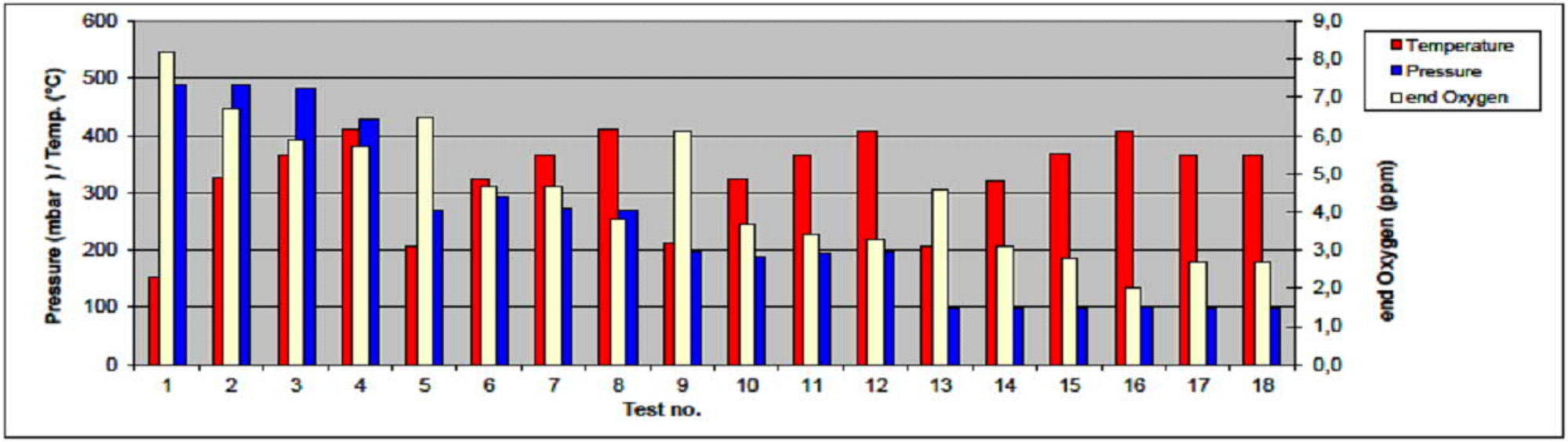
As long as the vacuum is <300mbar and the temperature is > 32°C, a sufficient degassing of typical < 5ppm will be reached

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
© 2014
www.riggtek.com
Dipl.- Ing. Hansjuergen Riggenmann

Oxymeter from WTW OXI 330
DissoPrep X8 with Firmware 8.01

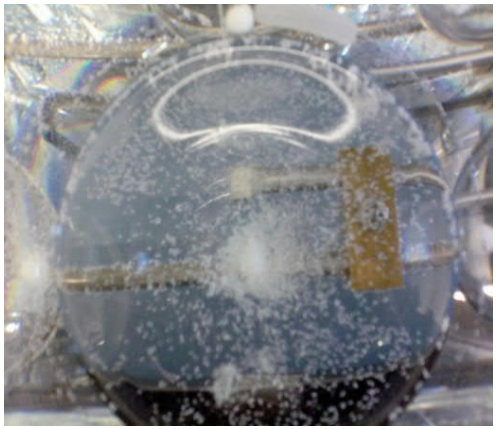
Method Parameter	Test No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Temperature set.	°C	20	32	37	42	20	32	37	42	20	32	37	42	20	32	37	42	37	37
Temperature eff.	°C/10	154	325	365	410	205	324	366	410	212	323	365	408	206	322	369	408	367	366
min. Pressure (vacuum)	mbar	489	490	484	428	269	295	274	268	197	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			



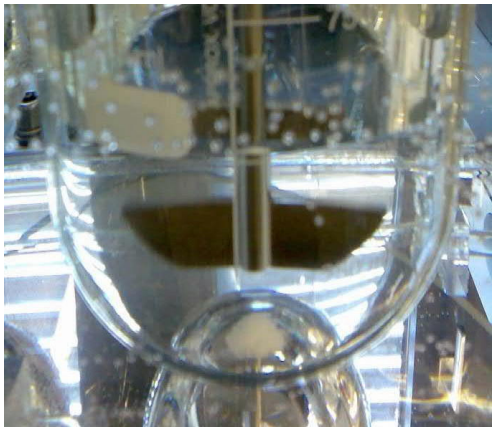
DissoPrep X8 / X15

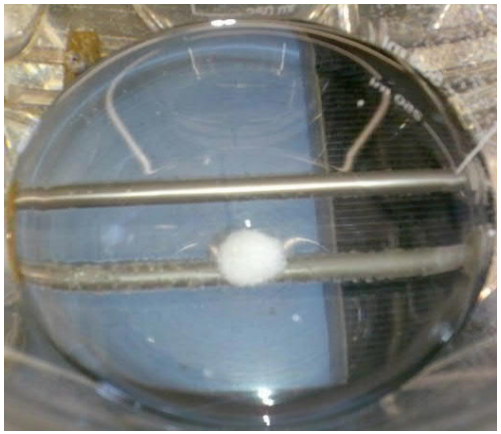
features (6)

3. Demand: Degassing of the media



Not degassed





Degassed

DissoPrep X8 / X15

features (7)

4. Demand: precise dispensing of the media in the vessels

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 per vessel can be selected between 100g and 8.000g / 15.000g (weight equivalents of mL).

DissoPrep X8 / X15

features (8)

5. Demand: 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 (9)

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

5. Demand: documentation

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

*option

DissoPrep X8 / X15

features (10)

```
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)
```

5. Demand: documentation

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

DissoPrep X8 / X15

features (11)

5. Demand: 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

3 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 (12)

6. Demand: easy operation / handling

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* and 21 CFR compliant*,
- administrate user permissions by individual user roles,
- ensures data integrity,
- audittrail review,
- data backup*,
- parent-child-coupling,
- etc.

* option

DissoPrep X8 / X15

features (13)

6. Demand: easy operation / handling

Beside the Browser-Interface, the user-interface of the DissoPrep is quite simple with only a few buttons for daily work.
The Remote Control Nozzle simplifies the direct dispensing into the vessels.
The automated process of media preparation and dispensing – especially when using acids – minimizes ***the risk to laboratory staff.***

7. Demand: 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!

DissoPrep X8 / X15

features (14)

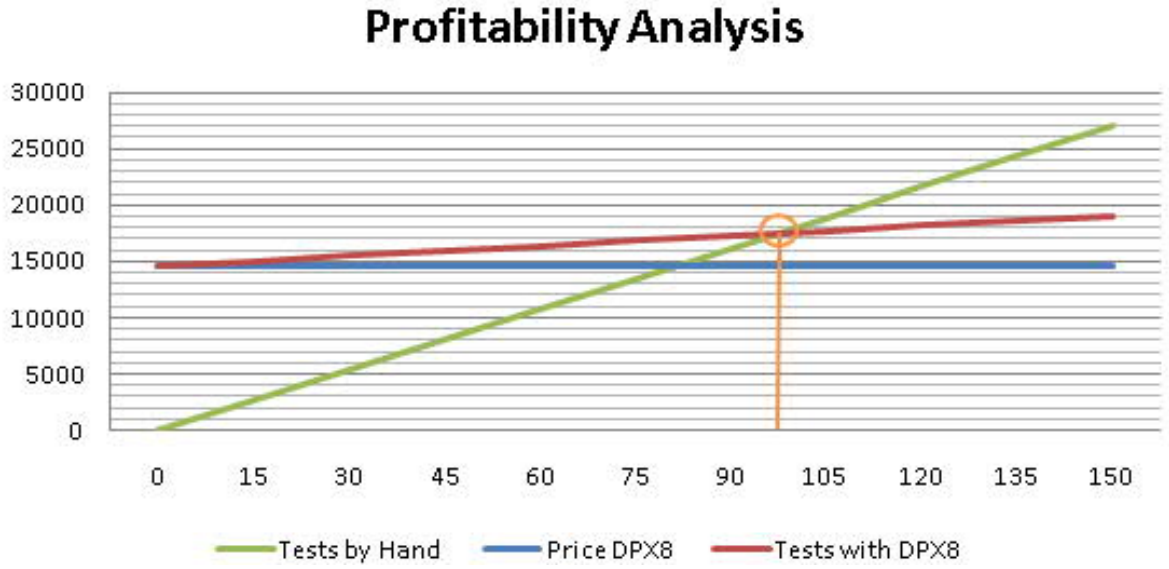
8. Demand: time and cost saving

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



DissoPrep X8 / X15

features (15)

9. Demand: 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***.

The best proof: ***The USP is using our DissoPrep!***

Media Preparation

Summary of meeting demands

to remember...

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

with the DissoPrep:

Reproducibiltiy and regulatory demands:

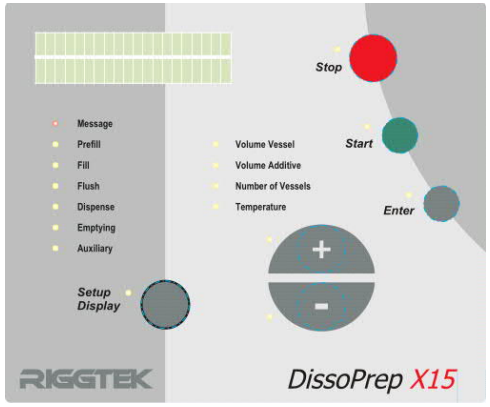
1. precise and repeatable mixing of the media ✓
2. warming of the media ✓
3. degassing of the media ✓
4. precise dispensing of the media into the vessels ✓
5. documentation of the media preparation and dispensing. ✓

Additional user demands:

6. easy operation / handling ✓
7. space saving ✓
8. time and cost saving with less manual handling and less manual documentation ✓
9. conformity with USP, EP, FDA, GLP/GMP ✓

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

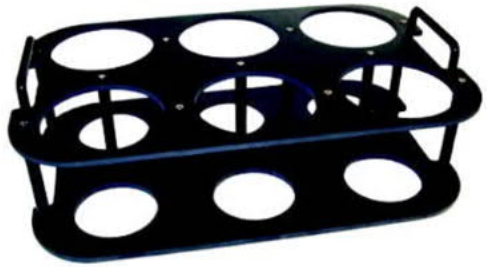
options / accessories (2)

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 network- or USB-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

please feel free to ask!

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