ELECTROLAB NEWS

Advancing the science of physical testing

Newsletters

Advancing the science of physical testing

Head Office : 401, Tirupati Udyog, I. B. Patel road, Off. Western Express highway, Goregaon (East), Mumbai - 400 063, India.
Tel : +91 - 22 - 4041 3131 • E-mail : sales@electrolabgroup.com
Factory : EL 23/24, T. T. C., Electronic Zone, M. I. D. C, Mahape, Navi Mumbai - 400 710, India.
Tel : +91 - 22 - 4161 3122 • Website : www.electrolabgroup.com

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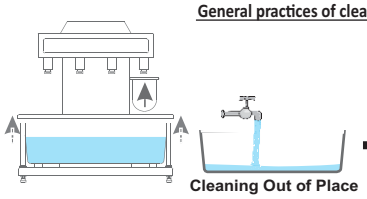
Frequent Waterbath Maintenance? ⇨ Get ClearView™

US FDA form 483 excerpt (2017)

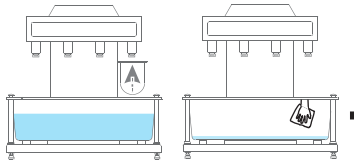
....Your analyst recorded the water in water bath for *** dissolution tester as clear. I observed the water in the water bath was not clear as required in your written procedure for operation and calibration of the **** dissolution tester. I also observed unidentified whitish **** floating in the water bath.

Waterbath Temperature + Circulation → Promotes growth of microorganisms in waterbath → Demands frequent waterbath cleaning

General practices of cleaning of water bath



Cleaning Out of Place → Mechanical Qualification could be affected



Cleaning In Place → Breakdown due to microorganism deposition in tubings and pump

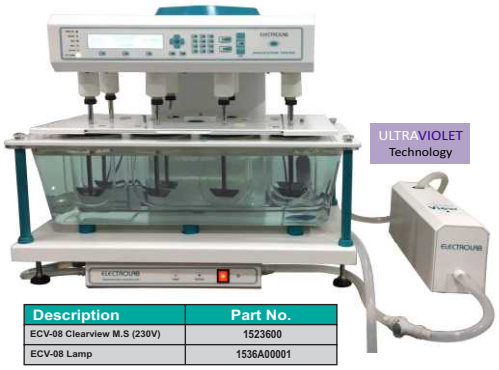
Alternative methods to maintain clean a water bath for a longer period of time

Chemical Agents → **Limited Effectiveness** When used independently

Ultraviolet Sterilization → **Broad Effectiveness**

ELECTROLAB Solution

ClearView™ (ECV-08): Retrofittable to most brands of dissolution testers.



Description	Part No.
ECV-08 Clearview M.S (230V)	1523600
ECV-08 Lamp	1536A00001

Within weeks of routine use

After several months of integration with ClearView™

Features:

- Chemical Free
- Efficient Reduction of Microorganisms
- Rugged Construction
- Smaller Footprint
- 8 & 14 Dissolution Tester
- USP Apparatus 1-7 Compatibility
- Rotating Bottle Apparatus

Note:

- To enhance the efficiency, use ClearView™ in combination with deconex® 12 BASIC.
- Efficiency of ClearView™ depends on the source water microorganism load.

Advantages:

- Unaffected MQ
- Enhances Visual Observation
- Reduces Breakdown
- Reduces Consumables
- Reduces Water Consumption
- Reduces Labour Time

ELECTROLAB Cares

- Use of de-mineralized water in water bath is recommended to enhance the efficiency of ClearView™.
- To be more effective, ClearView™ should be used on water that is clean from the beginning as dead microorganisms already present in the water cannot be removed.
- To achieve optimum kill rate, ClearView™ should be kept on continuously.
- Replace the UV lamp after every 12 months of continuous use.
- Ensure that there is no leak or air bubble entrapped in the waterbath tubings.

Contact Us

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✉ . : sales@electrolabgroup.com

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Rotating Bottle Apparatus

Introduction

- In 1970s, Professor Beckett and many workers used the rotating bottle apparatus in order to assess the dissolution profiles of extended-release products especially those in the pellet form.
- At present, the rotating bottle apparatus is used in release-rate testing of many dosage forms.
- In this apparatus, bottles are clipped on a rotating shaft which is immersed in a water bath and the shaft is rotated at a desired speed.

What does USP state about rotating bottle apparatus?

USP 39-NF 34 <1092> The Dissolution Procedure: Development and Validation states:

A rotating bottle or dialysis tubes may have utility for microspheres and implants...

Methodology

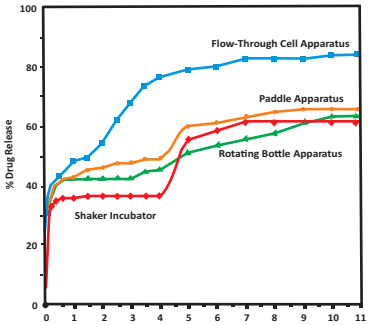
1. Add the dosage form and extracting fluid to the standard test bottles.
2. Close the caps of the test bottles and snap the bottles on the rack.
3. Carefully place the rack into the water bath and close the lid. Turn on the rotating bottle apparatus.
4. At appropriate sampling intervals, the apparatus stops automatically. Remove the rack assembly and withdraw the desired volume of sample.
5. Replenish the volume of sample withdrawn with fresh media, if required.
6. In case of media changeover, decant the previous media using a suitable tool and replace it with new media.

Advantages

Rotating bottle apparatus presents important advantages over the basket and paddle apparatuses, especially with regards to hydrodynamics and the possibility of using pH gradient. The advantages of rotating bottle apparatus are as follows:

- Provides a sound hydrodynamic system i.e. the dosage form moves freely through the dissolution medium as the bottle is rotated.
- This is in contrast to the movement of media relative to the dosage form in USP apparatus 1 and 2, wherein various portions of the bulk medium move at different rates.
- Facilitates pH profiling.
- Small volume dissolution environment.
- Offers higher reproducibility.
- Prevents evaporative loss.

Comparative studies on drug release testing from microparticulate drug delivery systems using different dissolution techniques.



(Ref: Conti B. et al., 1995.)

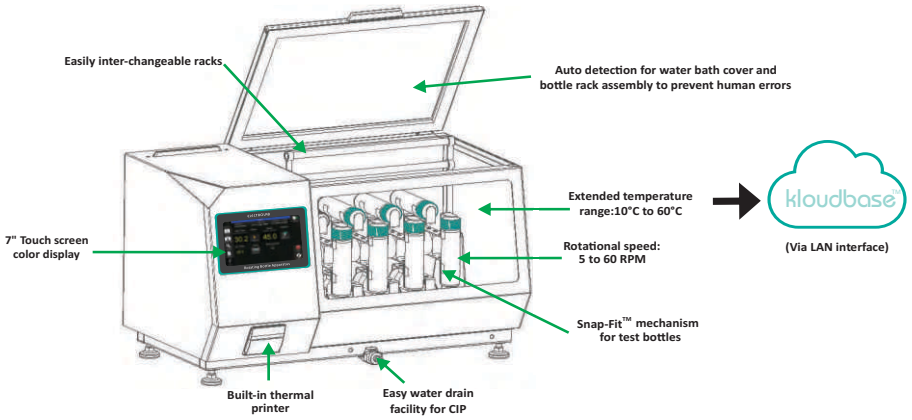
Applications

•Tablets and capsules	•Microspheres	•Implants
• Coated pellets	•Nanoparticulates	•Stents
•Suppository	•Liposomes	•Milk-clotting activity

Note: FDA recommends the use of rotating bottle apparatus for drug release testing of Naltrexone (extended release suspension) and Risperidone (injectable).

ELECTROLAB Solution

Rotating Bottle Apparatus (ERB-Wu)



Note: Test bottle capacity - 10 mL, 100 mL, 200 mL and 250 mL

- integrOS™ — Integrity Operating System
- Multi-Level Security
- 10 User Programmable Roles
- 100 Users
- RPM & Temp. — Excursion Report
- 1000 Protocols 100 Reports — Non-Volatile Memory
- User Defined Report Templates
- Report Printout
- D'light™ — Technology

ELECTROLAB Cares

- Ensure the cap of the test bottle is closed tightly to prevent leakage.
- Ensure the bottles are secured firmly onto the rack assembly.
- Weigh the dosage form accurately before loading it into the test bottles.
- As a safety precaution, wear gloves to remove the rack assembly from the water bath.
- Clean the water bath regularly using mild detergent like deconex 12 BASIC to prevent algal growth.

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Virtually Eliminate Waste Volume in Autosampling

USP 38-NF 33 <1092>

The Dissolution Procedure: Development and Validation, states ...

- Comparison of manual and automated procedures should be performed to evaluate the interchangeability of the procedures.
- Autosampling is a useful alternative to manual sampling, especially if the test includes several time points.

USP-PF 40 (1) In Process Revision: <1092>

The Dissolution Procedure: Development and Validation, states ...

- Automated methods offer opportunities for increased precision and reproducibility; however, bias may be introduced.
- A recirculated sampling alignment can be operated either by "**Discharging the tubing contents into the vessel after each sampling** or by allowing the tubing to remain filled with solution in the intervals between sampling points. In the latter case, the dead volume and carryover effects are important considerations".

Advantages of Auto Sampling

Accuracy ↑
Precision ↑
Productivity ↑
Human Intervention ↓

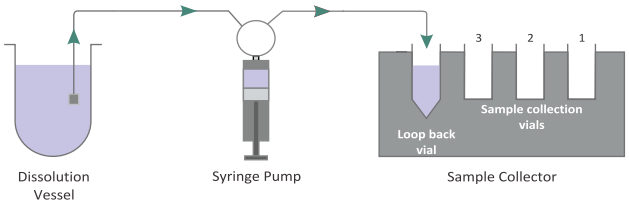
ELECTROLAB Solution

Loop-Back™ technology in Dx sample collector (ESC-8Dx/12Dx)

Schematic of Loop-Back™ Technology

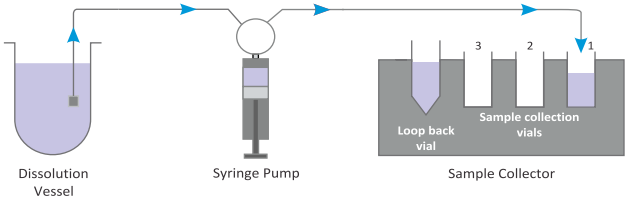
Step 1 : Split-Rinse™ — **57 % Reduction in rinse volume**

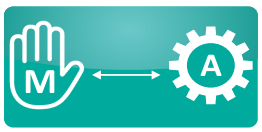
1.5 ml x 2 = 3 ml



Step 2 : Sampling

10 ml

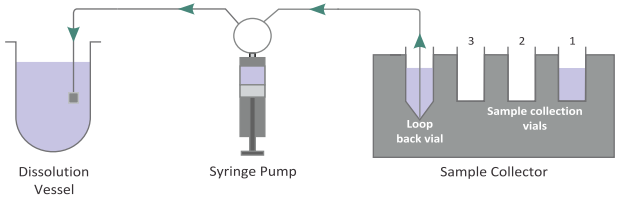




Seamless method transfer from manual to automated method that leads to equivalency of accuracy and precision between manual and auto-sampling

Step 3 : Loop-Back™

~ 3 ml




Loop-Back


Mechanical Mixing of Aliquot & Diluent


Adaptability to different types of vials

Technology

Example

Media Consumption	Manual	With Loop-Back™	Without Loop-Back™
Number of samples	5	5	5
Sample volume	10	10	10
Rinse volume for each sample	0	Rinse volume - Loop-Back volume (3 m - ~ 3 ml) = ~ 0 ml	3
Total volume withdrawn from vessel	50 ✓	~ 50	~ 65 ml

ELECTROLAB Cares

- Electrolab offers complimentary phone support to enable smooth functioning of Loop-Back™ technology
- With your existing Dx sample collector the Loop-Back™ feature can be activated in the dissolution tester by menu:
  Menu >> Configure >> Sampling >> Auto >> Syringe >> 10 ml (Syringe Capacity) >> Rinse by Loopback.

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150 ml dissolution apparatus now compendial in United States Pharmacopeia (USP)

What

- When the conditions present at the actual site of application are not suitable for the conventional dissolution method to provide relevant data, a smaller dissolution vessel is preferred

Why

- Small volume dissolution is a useful technique when dosage contains very small amount of active ingredient, or for ER tablets where small amount of drug is released and may be difficult to detect using HPLC or UV-Vis spectrophotometer
- Smaller media volume increases the concentration of the sample and allows proper detection

How

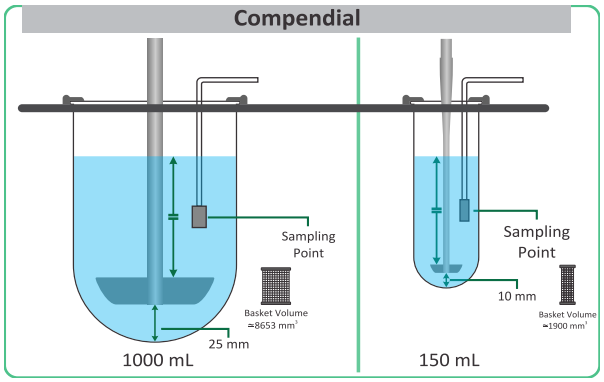
- Smaller dissolution vessels with special baskets and paddles have been designed to overcome these challenges
- The lowest volume that can be used in a 150 mL vessel is about 40 mL

What did USP state about small volume dissolution?

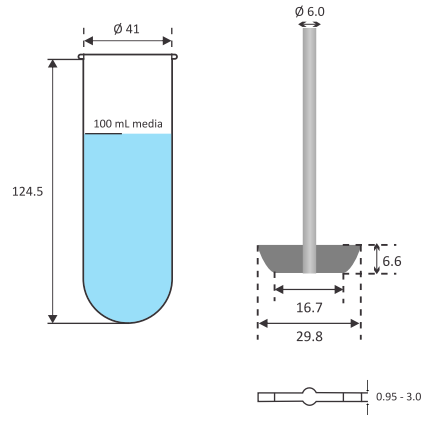
- Till 2014, small volume dissolution was not compendial in USP, although; a 250 mL vessel was detailed in the Chinese Pharmacopoeia, but was not widely used
- As the dimensions for the smaller dissolution vessels, baskets and paddles were not specified in the pharmacopeia, specification variations between different apparatus manufacturers were observed

Addition in USP about small volume dissolution

- In 2014, a small volume dissolution apparatus using 150 mL or 200 mL vessel has been discussed in USP forum - Chapter 40 (6) In-Process Revision: Doxercalciferol Capsules
- The development and regulatory submission of the vessel and paddle assembly for Doxercalciferol Capsules was a result of joint efforts by Cipla Ltd. and Electrolab.



Dimensions of mini vessel and paddle



*All measuring unit in mm

ELECTROLAB Solutions

150 mL Dissolution Apparatus vessel and paddle

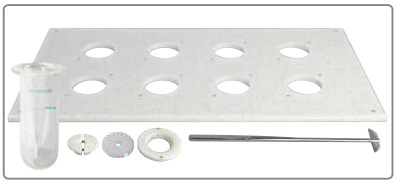
Features :

- Compatible with current USP 1 and USP 2 dissolution testers
- Easy Snap-fit™ shaft locking mechanism for positive engagement and wobble free operation
- Authenticity of vessels and paddles with ELECTROLAB hologram and laser marking
- Clear and amber colored vessels available

Accessories available:

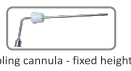
- **Standard:** Composite top plate, 150 mL glass vessels, jarlocks and jarlids
- **Optional:** Validation kit - depth gauge, centering device, dial gauge etc

150 mL Conversion kit for 8 Station Dissolution Tester



Part no. 0104A00303

Basket 40 mesh for 150 mL vessel
Part no. 0104A00300



Sampling cannula - fixed height for 150 ml vessel
Part no. 0104A00295

Conversion Kit for 14 Station Dissolution Tester also available

ELECTROLAB Cares

- Clean the vessels with mild detergent /soap or cleansing agents
- Specially designed, washable and stackable basket & paddle tray

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Effective Deaeration → Reduces Variability

Recommend your friend or colleague

What

Removal of dissolved air/gases from the dissolution media

Why

Non - deaerated media may lead to dissolution failures as dissolved **air/gases (bubbles) tend to change:**

- **Fluid flow characteristics**
- **pH of an unbuffered solution**
- **Nature of the active ingredient**
- **Dispersion characteristics of particles and aggregates**
- **Wetting pattern and cause the dosage form to become buoyant**

< 6 ppm is USP recommended **Dissolved Oxygen**(DO) level

Effective deaeration reduces variability in results by :

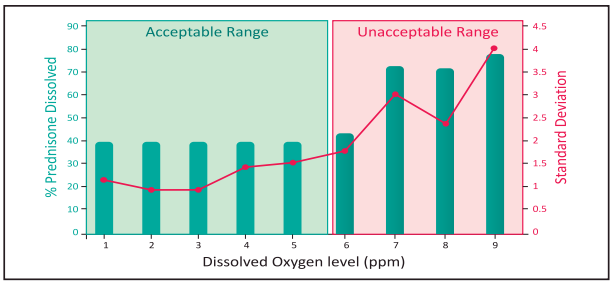
- 52.3% of mean percent dissolved
- 11.8% of standard deviation

(Ref : Eaton J. et al., 2007)

- Different deaeration procedures are permissible, but they should be demonstrated to be equivalent to the USP procedure. Verification can be done using a dissolved gas meter.

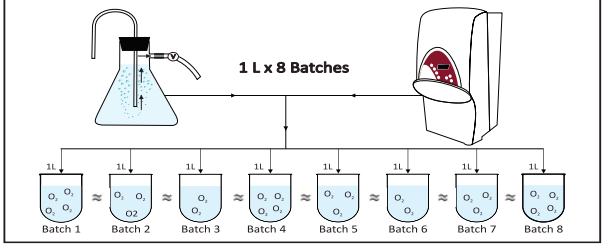
(Ref : Dissolution toolkit version 2.0, 2010)

Variability is significantly higher when DO level is > 6 ppm :



(Ref : Nithyanandan P. et al., 2006)

Smaller batches of deaeration may lead to greater variability in DO level

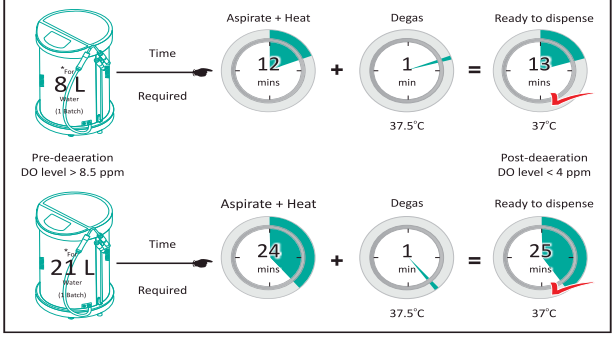


ELECTROLAB Solutions

Dissolution Media Preparator (EMP 21-DO)

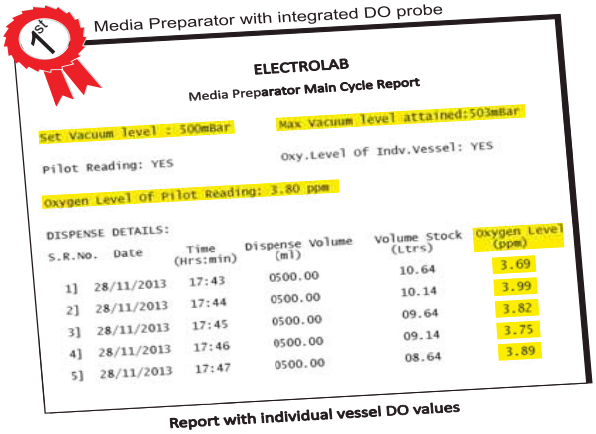
Batch Capacity | Rugged-SS Construction | Dead Volume | Dearates Surfactants like SLS | Temperature Accuracy | Volume Change Increment | Memory | DO Level

Single batch deaeration reduces process time and ensures inter-vessel consistency in DO level



*Data on file

Media Preparator with integrated DO probe



ELECTROLAB
Media Preparator Main Cycle Report

Set Vacuum level : 500mBar
Max Vacuum level attained:503mBar
Pilot Reading: YES
Oxy.Level Of Indv.Vessel: YES
Oxygen Level Of Pilot Reading: 3.80 ppm

DISPENSE DETAILS:

S.R.No.	Date	Time (Hrs:min)	Dispense Volume (ml)	Volume Stock (Ltrs)	Oxygen Level (ppm)
1]	28/11/2013	17:43	0500.00	10.64	3.69
2]	28/11/2013	17:44	0500.00	10.14	3.99
3]	28/11/2013	17:45	0500.00	09.64	3.82
4]	28/11/2013	17:46	0500.00	09.14	3.75
5]	28/11/2013	17:47	0500.00	08.64	3.89

Report with individual vessel DO values

ELECTROLAB Cares

- EMP-21 DO can hold the media under vacuum, without electrical power for several hours. It is recommended that the dissolution test is started promptly after deaeration.
- Media for all the vessels in the dissolution tester should be deaerated in a single batch to ensure consistency.
- Cleaning cycle should be run after deaeration of every media.
- All tubes and pipes should be kept away from sharp edges.

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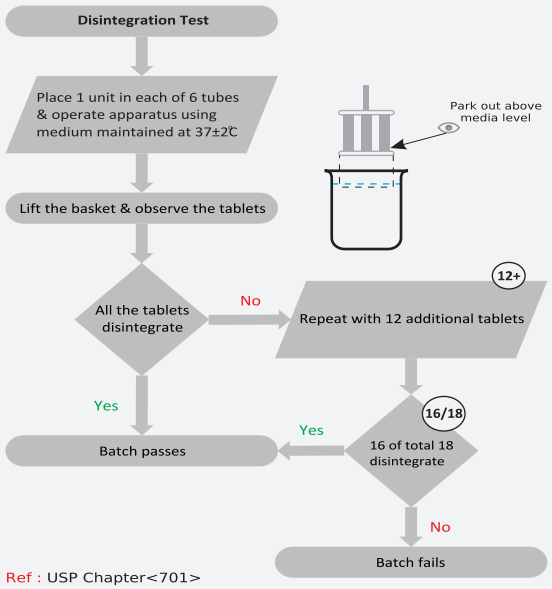
Disintegration Test - Procedure and Specifications

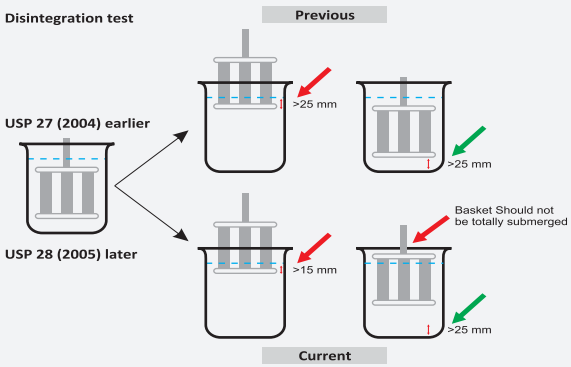
Recommend your friend or colleague

USP procedure for Disintegration Test



Ref : USP Chapter<701>

Changed USP specifications for Disintegration Test



The USP requirements for volume of immersion medium should be followed correctly as the volume plays the most crucial part to obtain correct and reproducible test results

Ref : Schmid K. et al. Influence of the Changed USP Specifications on Disintegration Test Performance. Dissolution Technologies;6-10

Note : Beaker should be USP compliant (ID = 97-115 mm) as the measurement of the immersion medium volume is directly related to the size of the beaker

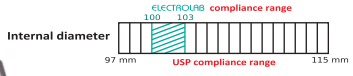
ELECTROLAB Solutions

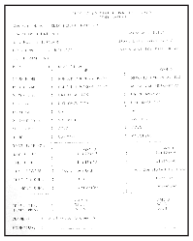
2 Station Semi Automatic Park Out (EDI-2SA)

Maintenance Free | Security | Park Out | Report Print | Temperature Range (40℃ to 15℃)

- Complies with USP, IP, BP and Ph. Eur. specifications
- Bathless heating saves: • Time • Electricity • Water
- Quick heating of media attains media temperature 30% faster as compared to disintegration tester with bath
- Offers disintegration time registration for individual tablets
- Green illumination from bottom for active arm offers better visibility of disintegration process
- Ergonomically designed and magnetically coupled basket for easy loading

Narrower tolerance for ELECTROLAB beakers





Test Report

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- Thorough cleaning of the basket is recommended for accurate and reliable results
- The entire basket assembly can be disassembled without using any special tool
- During the cleaning process, the rubber retainer will prevent the tubes from falling
- The use of online visual verification of stroke amplitude may assure the user of compliance with regulatory standards

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Machine Verification replaces human verification in Blue Dye Leak Test method

What

- A 'Leak Test' is a method that detects the presence of a defect in a package; the defect is capable of permitting loss of product contents or critical head space gases, and/or capable of permitting entry of liquids, reactive gases, microorganisms or nonviable particulate (Ref. USP 40 (5) <1207>).

Why

- Any sort of physical breach in the packaging structure, such as weak seals, capillaries, pin holes or micro cracks can result in product integrity and safety being compromised. Hence, evaluating the integrity of packaging in the pharmaceutical and food industries is essential.
- It is not only critical in terms of preserving the product shelf-life and efficacy, but is also a FDA regulatory requirement as specified in cGMP 21 CFR 211.166 for finished pharmaceuticals.

How

- A number of methods exist to detect leaks and various media are used as tracing agents depending upon the method used.
- A vast majority of pharmaceutical companies are exclusively using the dye ingress test (Tracer Liquid Test) to assess the integrity of the blister packs, with varying degrees of success.

USP (USP 40 (5) <1207.2>)

"Tracer liquid test requires the use of either analytical detection through instrumentation or visual inspection aids" that may reduce significant human dependency.
"Analytical detection offers the advantage of minimizing the human error that is inherent in visual discernment of low dye concentrations".

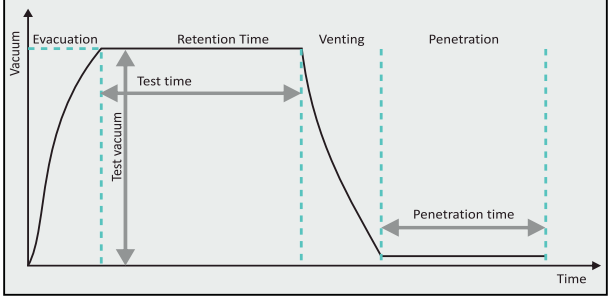
Tracer Liquid Test

This is the simplest and the oldest method used for integrity testing of blister packs. In this method, the package is placed in a bath of methylene blue dye within a desiccator and a set vacuum is drawn on the package. This technique involves the following phases:

- **Evacuation:** During this phase, the instrument attempts to draw air out of the package cavity.
- **Retention Time (Vacuum Hold Time):** Following evacuation, the submerged test samples are subjected to vacuum at a predetermined vacuum level for a predetermined time.
- **Venting:** During venting, vacuum is released from the test chamber and the next phase begins.
- **Penetration:** Following vacuum release, test samples remain submerged in the dye for a predetermined time.

If the package cavity has a leak, it will have a negative pressure during evacuation, drawing the methylene blue dye inside the cavity. The lab operator inspects the package for any blue dye ingress following the completion of the test.

Graphical Representation of Tracer Liquid Test Procedure



Advantages

- Well established method
- Quick and economical method
- Method provides precise leak detection data

Disadvantages

- Significant human dependency may lead to errors
- Lack of verifiable documentation
- Not eco-friendly disposal of dye

ELECTROLAB Solution

ELT-201WP (Patented Design)

Electrolab Leak Tester (ELT-201WP) is the **first & only** leak tester which replaces human subjectivity by machine verification in tracer liquid test. Leak detection is automatically verified by weight, reducing human error and providing traceability to the results.

USP Compliance

Analytical Verification

Programmable Vacuum, Retention & Penetration Time

Multiple Packages

Patented

D'light™ Technology

Security for Data Integrity

20 Products Methods Storage

Printout of Report

ELECTROLAB Cares

- As leak detection is verified by weight, test can be carried out using water rather than methylene blue dye, thus helping in waste management
- Use lint free cloth to wipe the packages before recording the post-test readings
- Record the readings into the system only when the reading on the weighing balance is stable

Contact Us

401 Tirupati Udyog, I. B. Patel Road, Off Western Express Highway, Goregaon (E), Mumbai - 400 063, India.
☎ . : 91 22 4041 3131 ✉ . : sales@electrolabgroup.com

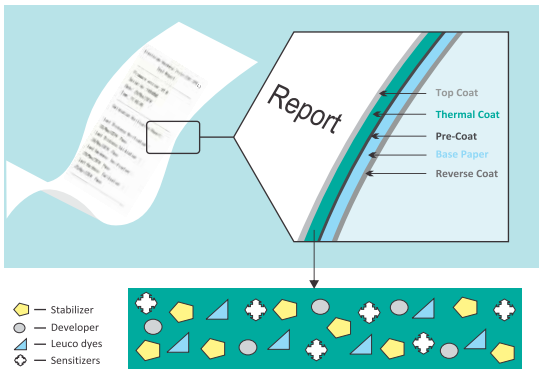
To know more, please contact our ***Specialist*** on support@electrolabgroup.com

STARLITE - 12

Thermal Paper with 12 years life

- GMP regulations from PIC/S, USFDA and EU regulations require maintenance of accurate back-up files of input data for a minimum period of 5 years which should be secured from alteration, loss or inadvertent erasure.
- If a record is poorly documented, then the manufacturing or QA/QC of a product can be negatively impacted, potentially reducing it's reliability.

Elements of Thermal paper



Components of Thermal Coat

Impact Printing v/s Thermal Printing		
Features	**Impact Printing**	**Thermal Printing**
1. Printing Details		
Print head	Moving	Stationary
Printing speed	Low (8 Lines/sec)	High (52 Lines/sec)
Noise	More (60 dB - 62 dB)	Less (48 dB)
Printing ability	Unable to print complex typographic characters as well as graphs	Prints complex typographic characters as well as graphs efficiently
2. Operational Cost		
Ribbons and cartridges	Yes : Requires ink for printing	No : Inkless printing
Cartridge change	More frequent	Not applicable
Printer outage and repairs	Frequent due to more moving parts	Less
Maintenance	High	Low
3. Type Of Paper		
Non-thermal paper	Fibers of paper dislodge from paper to printer head, eventually causing breakdown of printer head	-
Thermal paper with top coat	No dislodging of fibers on printer head	Extended life

ELECTROLAB Solution

STARLITE-12

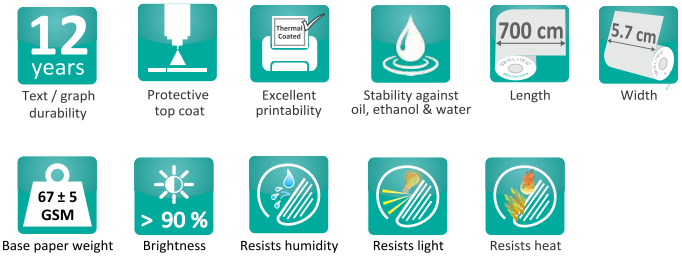
Commonly available thermal paper v/s STARLITE-12

Commonly available thermal paper — STARLITE-12

Use STARLITE-12 in weighing scale printers (impact printers) for increased life of printer head.

STARLITE-12 Thermal paper roll (Set of 24)

Part No. - 0905A00007



ELECTROLAB Cares

- Avoid exposure to direct sunlight and hot or humid environment for long-term durability
- Avoid prolonged contact with plasticizers (PVC) and solvents (acetone, alcohols etc)
- Avoid rough handling of thermal paper. Friction, scratching, or pressure from fingernails, paper clips and metal objects can cause impressions to develop, obstructing the printed image

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Sampling Zone

Recommend your friend or colleague

The USP defines the sampling point as “A zone half way between the top of the media and top of the paddle or basket not less than 1 cm from the vessel wall". Ref: USP <711>

Advantages of sampling

- Reproducible results
- Higher accuracy in results
- Unattended long duration test with multiple samples
- Reduces cost per test
- Efficient sampling & cleaning system

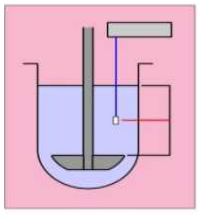
Sampling Time

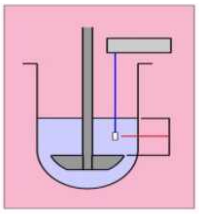
- As per USP, ±2% variation is allowed in sampling. Ref: USP <711>

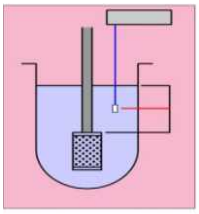
Sampling Volume

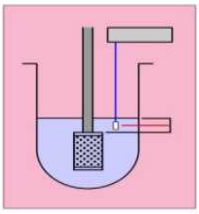
- Within ±1% (Data on file)

Note: Sampling position


PADDLE WITH 1000ml MEDIUM

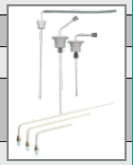

PADDLE WITH 500ml MEDIUM

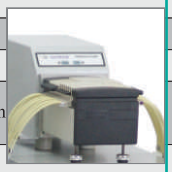

BASKET WITH 1000ml MEDIUM


BASKET WITH 500ml MEDIUM

ELECTROLAB Solutions

Feature	Manual sampling	Sampling with peristaltic pump	Sampling with syringe pump
Height adjustment	Fixed	Programmable	Programmable
Accuracy	User dependent	Low	High
Time taken in routine calibration	More	Less	—
Contact material	User dependent	Marprene and Tygon	Inert syringes, glass and teflon material
Split rinse	User dependent	Yes	Yes
Dead volume (wastage)	User dependent	More	less
Coarse filtration	Very good	Good	Good
Fine inline filtration	2 ways (cannula and disc filter)	1 way (cannula filter)	2 ways (cannula and disc filter)
Dilution	User dependent	*	**
Mixing	User dependent	*	**
Carryover removal	User dependent	Recirculation method	Recirculation and split rinse
Cleaning	User dependent	-	Auto
Validation	User dependent	Required	Not required





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For the long life of the tubes always check tubings for in automated sampling for -

- Leakage
- Cracks
- Reduced elasticity

Pull the release lever for removing cassettes for stand by situation

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Topical & Transdermal Drug Delivery

Recommend your friend or colleague

Topical / Transdermal drug delivery system works by diffusion, which is self - contained, discrete dosage form that, when applied to intact skin, is designed to deliver the drug(s) through the skin to the systemic circulation

[Ref : Pharmacopeial forum Vol. 35 (3)]

Commonly used dosage forms include:

- Ointments
- Emulsions
- Creams
- Lotions
- Gels
- Foams
- Pastes
- Powders
- Sprays
- Collodion
- Topical suspensions
- Ophthalmic ointments
- Other novel drug delivery systems

Franz Diffusion Cell

The Franz Diffusion Cell is a static diffusion system used for characterizing drug permeation through a skin model

Different membrane can be used :

Natural

Stratum corneum plus epidermis , Stratus corneum, Mouse, Hairless mouse, Rat, Guinea pig, Rabbit, Monkey, Pig, Egg -shell membrane, etc

Synthetic

Cellulose media, Synthetic polymers, etc

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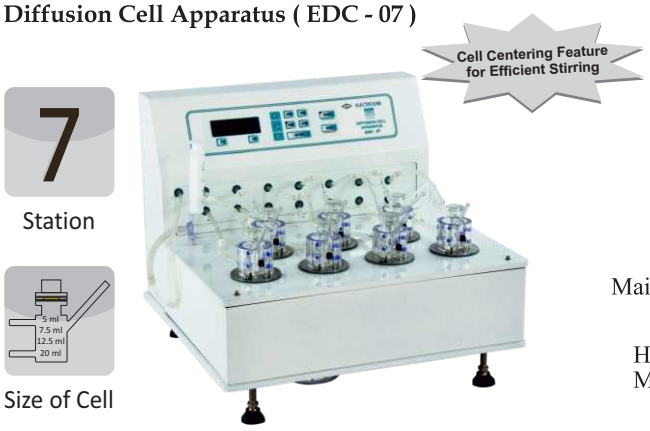
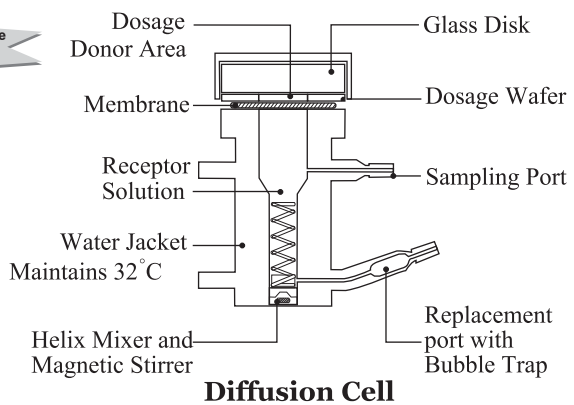
Diffusion Cell Apparatus (EDC - 07)





Diffusion Cell

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- To increase the service life, change the water regularly in circulation system of Diffusion Cell Apparatus

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Investigation and evaluation of OOS & OOT

Recommend your friend or colleague

FDA Part 211, subparts I (Laboratory Controls) and J (Records and Reports) recommends to investigate the cause of OOS and OOT to avoid the batch rejection. A meaningful OOS & OOT investigation should be: thorough, timely, unbiased, well-documented and scientifically defensible.

Some of the obvious errors that could invalidate results

- Spilling of a sample
- Incomplete transfer of sample
- Obvious pipetting errors
- Improper sampling
- Dropping more than one tablet into dissolution vessel

Practices used in the laboratory phase of an OOS & OOT investigation

- Retesting a portion of the original sample
- Re-sampling test data
- Using outlier testing
- Testing a specimen from the collection of a new Sample from the batch

If the investigation results of OOS & OOT are unsatisfactory, the batch is suspect and must be rejected or held pending for further investigation.

ELECTROLAB Solutions

iDisso™ - 06

Observation and recording of the drug dissolution process

Recording

LAN

Document

Snapshot

Patented

Recommended by USP Chapter <1092>

Date & Time Stamp

Share

Eco-friendly

Security

- Retrofitting system i.e. compatible with most ELECTROLAB Dissolution Testers made over 10 years
- Perfect tool to help in evaluation of OOS & OOT
- Accessory : BlackOut™ with photo -protective monochromatic lights for light sensitive drugs
- Over 1000 hours continuous recording can be stored

To view the video of iDisso™ - 06 click here

ELECTROLAB Cares

- To save energy & environment, iDisso™ - 06 has eco-friendly and low power consumption lights

iDisso™ - 06 : 6 W

Other lights : 40 W

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Commonly Associated Problems with Particle Analysis

Recommend your friend or colleague

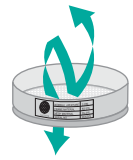
Problems, Probable Causes & Solutions

Problems	Probable Causes	Solutions
Sieving inaccuracy	Resulting from load and power frequency differences, crevices and label rivets which trap sample powder	Sieves of corrosion resistant material to prevent contamination of sample
Sieving inefficiency	Mesh size change due to attached material /particle within the mesh	3D sieving increases efficiency
Change of pore size	Due to using harsh cleaning agent / brush	Use gentle cleaning agent and regular verification of mesh size
Fine particles containment during sieving	Improper fitting of sieves result in the release of fine particles in environment	Snug fitting sieves to prevent release of fine particles in environment
Retention of excess powder on sieves	Excessive mesh binding and blockage, adhesive properties of powder, high ambient or powder humidity	Proper vibration decreases the powder retention on the sieve
Traceability	Label stuck or riveted to sieve body comes apart	Individualized laser engraving allows full traceability throughout life of sieve

ELECTROLAB Solutions

Electromagnetic Sieve Shaker (EMS-8 Plus)

- Particle size analysis
- Programmable amplitude
- Larger LCD display
- Programmable sieving duration
- Low noise
- Low maintenance



3D Sifting Motion

- Intermittent and continuous sifting motion with programmable amplitude (0.5 mm to 2 mm) in increments of 0.1 mm
- Continuous amplitude measurement and correction to give reproducible results independent of load
- Programmable sieving duration from 1 min to 99 min
- Suitable for dry and wet sieving

SieveEasy ™
Particle Size Analyzer Software

Application industries

& Many more....

ELECTROLAB Cares

- Clean sieves by sonicating them in water or a special detergent (Eg. deconex 12) to ensure accurate and reproducible sieving results
- It is advised not to run the machine without proper locking and tightening both the locking knobs, this may result in an abnormal sound and can damage the machine

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Filtration in Dissolution Testing

Recommend your friend or colleague

Filtration stops the dissolution process, removes undissolved drug, and allows for sample analysis. The downstream analytical evaluation technique – UV spectrophotometer, HPLC or UPLC – following dissolution usually warrants filtration before analysis because particulate impurities can affect the analysis.

Commonly Used Types of Syringe Filters

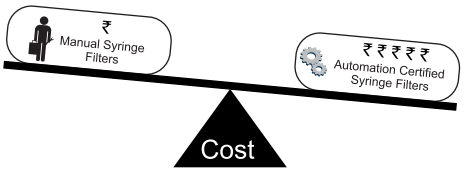
Frits	Syringe filters / Disc type filters
Pore size: 10 µ – 15 µ • Stainless steel (Reusable after sonication) • Disposable (Single use)	Pore size: 0.22 µ – 1 µ • PTFE • PVDF • Nylon 66 • PES

Properties of Syringe Filters

Features	PTFE	PVDF	Nylon 66	PES
Chemical compatibility	★★★★	★★★	★★½	★★
Dual direction operation	✓	✓	✓	Limited
Cost	₹ ₹ ₹	₹ ₹	₹ ₹	₹

Filter Pore Sizes Used in Various Analysis

Pore size	0.22 µ	0.45 µ	1 µ	10 µ - 15 µ
UV		■	■	
HPLC	■	■		
UPLC	■			



Get 25 % more filtration area with larger filters (33 mm Dia)

* Data on file

ELECTROLAB Solutions

Most Versatile Solution in the Market with Multiple Filtration Options

New

- Powerful Syringe Pump enables the filtration process up to 2 or 3 stages to enable sample to be used directly in HPLC / UPLC without further filtration
- Benefits of using Manual Syringe Filters:
  a) Ease of method transfer
  b) Reduced operating cost
  c) Filter re-validation studies not required

ELECTROLAB *Pre pump filter manifold & Post pump filter manifold are compatible with 25 mm and 33 mm manual syringe filters.*

*Syringe filters tests done on Merck-Millipore filters
For more details on Merck Millipore membranes, email techsupport.bioscience@merckgroup.com

ELECTROLAB Cares

- Verify filter retention volume in addition to chemical compatibility while making a choice of filters
- Reduction in aliquot volume may suggest filter clogging

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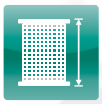
USP Apparatus 1 (Basket)

Recommend your friend or colleague

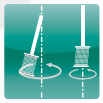
Critical Considerations


Basket Height
(USP: 37.0 ± 3.0 mm)


Basket ID
(USP: 20.2 ± 1.0 mm)


Basket OD
(USP: 22.2 ± 1.0 mm)

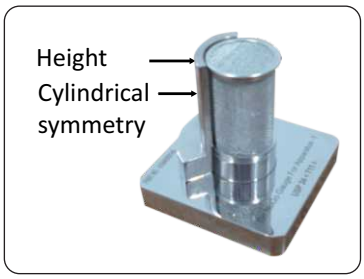
Cylindrical symmetry

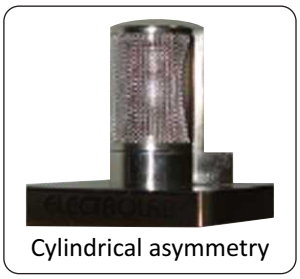

Wobble


Opening


ELECTROLAB Solutions

USP 35 Basket Go-NoGo Gauge





USP Ph.Eur JP
Regulatory Compliant

OOS
Reduce Investigation Report

Method Transfer

1 min Verification
Time Saving

Increases Productivity

Basket Go-NoGo gauge not only controls the parameters set in USP <711> (height, cylinder i.d., and o.d.) but also controls the cylinder symmetry

ELECTROLAB Cares

- Always hold the basket via the top lip of the basket and avoid putting pressure on the mesh
- Store the baskets in specially designed storage containers

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Impact of Paddle / Basket Height on Dissolution Testing

Recommend your friend or colleague

"The distance between the inside bottom of the vessel and the basket or paddle blade should be 25 mm ± 2 mm" Ref : USP <711>

Effects of inappropriate distance

Shorter distance increases hydrodynamics on dosage

Greater distance reduces hydrodynamics on dosage

Precisely controlled paddle height can reduce variability in results by :

- 3.5% of standard deviation
- 0.5% of mean percent dissolved

As a component of 2-factor analysis when combined with non-manufacturer's vessels, it could contribute to :

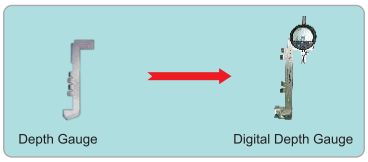
- 24.2% variability in mean percent dissolved
- 9.8% variability in standard deviation results

Ref : Eaton J et al. Perturbation Study of Dissolution Apparatus Variables - A Design of Experiment Approach. Dissolution Technologies;14(2):20-26.

USP recommends use of vernier caliper or depth gauge to measure the distance

ELECTROLAB Solutions

Calibrated Digital Depth Gauge



Digital value

Easy to use

Accurate value

Data transfer

Print

Certified

Available for 2 ltr and 4 ltr vessel

ELECTROLAB Cares

- Heights should be periodically checked to ensure reliability of results
- ELECTROLAB recommends to calibrate the depth gauge once a year
- For longer operational life of paddles, baskets and depth gauge, store them in specially designed storage containers

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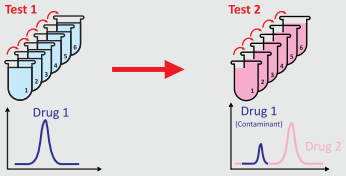
Importance of Rising in Dissolution Testing

Recommend your friend or colleague

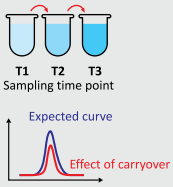
What is Contamination?

The sample which is rendered impure by the addition of foreign substance - usually debasing, or devaluing the first



What is Carryover?

Effect of previous sample on the next sample due to the remainder in the transfer tubings

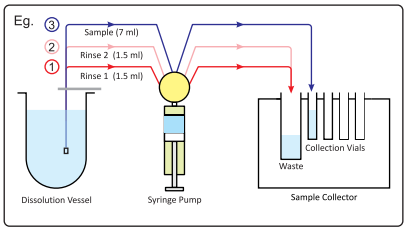


	Contamination	Carryover
How to reduce?	Cleaning cycle	Rinse cycle
When to run the cycle?	After the test	Before sample withdrawal

Types of rinse cycle

1) Simple Rinse : Purge volume of sampling media to waste

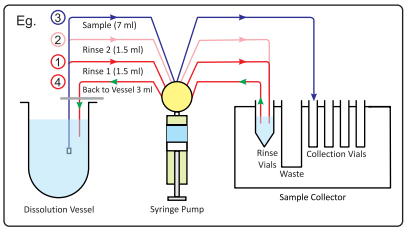
2) Split rinse :
Purge small volume of sampling media by splitting into 2 parts to waste to ensure effective rinsing



Split Rinse

57% reduction in rinse volume compared to simple rinse

3) Loop back :
Circulate the initial volume through the transfer tubings back to vessel to eliminate waste volume



Loop Back

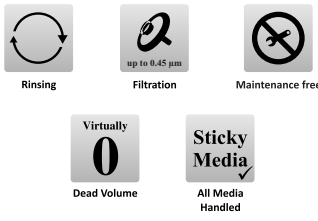
Virtually **0%** Waste volume

For your complimentary copy of rinse cycle verification SOP, contact ELECTROLAB

ELECTROLAB Solutions

Smart Syringe Pump & Sample Collector

Syringe Pump (ESP-64)



Sample Collector (Dx)

ELECTROLAB Cares

- Rinsing cycle should be run after every sample to ensure better sampling results
- No. of cleaning cycles should be programmed to run after every test
- The use of dedicated sampling cannulas, for manual sampling minimizes contamination
- Thoroughly clean entire apparatus before start of test

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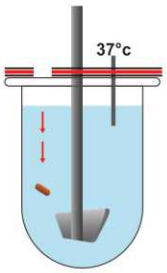
Dosage Dispensing in Dissolution Testing

Recommend your friend or colleague

- Timing of drop of one dosage to another
- Timing of test initiation
- Ensuring non rotation of paddles during dosage introduction



- Temperature of media when dosage is introduced
- Position of dosage introduction
- Drop velocity

ELECTROLAB Solutions

Dosage Dispensing

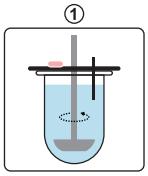
Manual

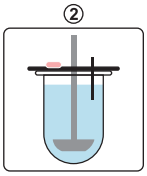
- Simultaneous dispensing of dosage forms with a gentle push facility
- Extra wide aperture to accommodate dosage and sinkers up to 24 mm
- Easy to clean by removing the dispenser

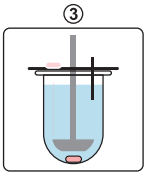
Auto DropSync™

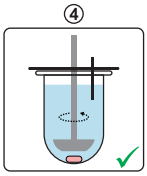
- Simultaneous automatic introduction of dosage forms on attainment of set vessel temperature
- Extra wide aperture to accommodate dosage and sinkers up to 24 mm
- Easy to clean by removing the dispenser
- User defined test start (immediate / delayed) when the media temperature is attained
- Manual operation is also possible

Working of Auto DropSync™

① 
Paddle is rotating as set temperature is yet to be attained

② 
Set temperature is attained and recorded in test report and paddle has stopped rotating

③ 
Dosage form is introduced in the vessel

④ 
The test is initiated

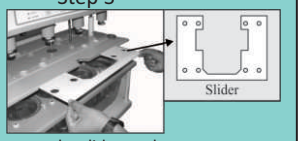
ELECTROLAB Cares

- Regular cleaning ensures smooth operation of the dosage dispenser
- Removal process of the dosage dispenser :

Step 1 
Remove gasket from dosage dispenser

Step 2 

Press two slider release buttons from below

Step 3 

Remove the slider to clean

Contact Us

401 Tirupati Udyog, I. B. Patel Road,
Off Western Express Highway,
Goregaon (E) Mumbai - 400 063, India.
☎ . : 91 22 4041 3131
✉ . : sales@electrolabgroup.com

ELECTROLAB NEWS
Advancing the science of physical testing
www.electrolabgroup.com

Friability Testing

Recommend your friend or colleague

Problem

The strength of a tablet plays a very important role in its marketing & dissolution. Less strong tablets by loosing their shape not only lack elegance & consumer acceptance but also spoil the areas of manufacturing such as coating & packaging.

Reason

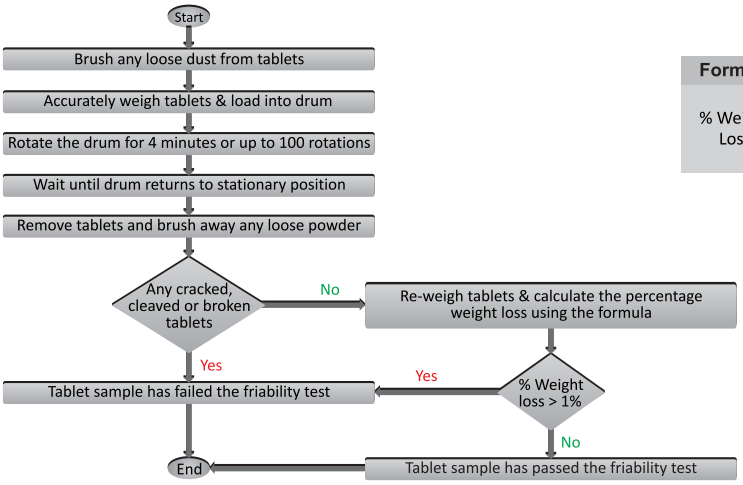
Measuring the hardness of a tablet is not a reliable indicator for tablet strength as some formulations when compressed into hard tablets tend to 'cap' or loose their crown portion on attrition. Such tablets tend to powder, chip & fragment.

Factors affecting friability:-
1) Poor/worn punches
2) Internal factors like moisture

Solution

The Friability test is closely related to tablet hardness and is designed to evaluate the ability of the tablet to withstand abrasion, Friction & shock in packaging, handling & shipping. The loss in weight due to abrasion is a measure of the tablet friability.

Procedure



Formula

$$\% \text{ Weight Loss} = \frac{\text{Initial Weight - Final Weight}}{\text{Initial Weight}} \times 100$$

ELECTROLAB Solutions

Friability Tester (EF – 2W) with weighing scale interface

Abrasion Drum

Abrasion drum for more rigorous informational testing of tablet and coating integrity.

10° Tilt

If tablet size or shape causes irregular tumbling, adjust the drum base so that the base forms an angle of about 10° with the bench top and the tablets no longer bind together.

ELECTROLAB Cares

Validation parameters*

Parameters	A	B	C	D	E	F	G
Description	Center hole dia.	Center disc dia.	Inside dia.	Outer dia.	Depth	Tablet drop	Inside curve
USP Specification (mm)	10 ± 0.1	25 ± 0.5	287 ± 4.0	302.5 ± 4.0	38 ± 2.0	156.0 ± 2.0	80.5 ± 5.0

*** Contact ELECTROLAB for detailed procedure for verification of above parameters.**

Maintenance

- Routinely check drum(s) for signs of cracks or chips
- Clean drum thoroughly using de-ionized water and dry with a soft cloth

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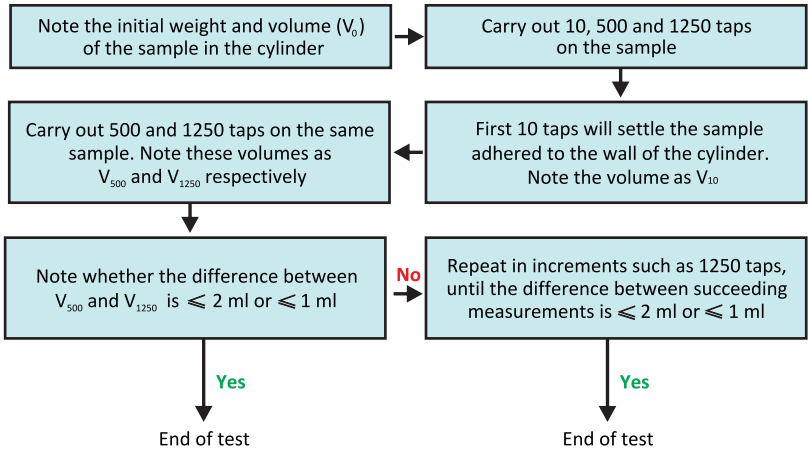
To know more, please contact our ***Specialist*** on support@electrolabgroup.com

Is your Tap Density Tester compliant to USP 39-NF 34?

USP Chapter <616> Bulk Density and Tapped Density of Powders

Features	METHOD 1		METHOD 2	
	Taps/min	Height	Taps/min	Height
Taps/min and Fixed drop height	300 ± 15	14 mm ± 2 mm	250 ± 15	3 mm ± 0.2 mm
	250 ± 15	3 mm ± 0.2 mm		
Number of tap counts	10, 500, 1250			
Specifications for graduated cylinder	250 ml (readable 2 ml)		100 ml (readable 1 ml)	
Weight of graduated cylinder	220 g ± 44 g		130 g ± 16 g	
Weight of support for the graduated cylinder and holder	450 g ± 10 g		240 g ± 12 g	
Difference between succeeding measurements	⩽ 2 ml		⩽ 1 ml	

Methodology



Note:

- Weight of sample ⩽ 100 g.
- Tapped density, Compressibility index and Hausner ratio can be calculated using the tap density tester.

ELECTROLAB Solution


(ETD – 1020x)

- 2 Methods — USP Method 1 and USP Method 2
- Simultaneous Rotation and Tapping Motion
- Snap-Lock™ Mechanism
- Date and Time Lock
- GMP — SS Construction (optional)
- 24x2 abc123 — Alphanumeric Display
- Results
- Print
- LAN (optional)
- User Friendly Operation

- Test can be performed at two different modes :
  - **USP mode :** Test will run at set number of taps as per USP requirements
  - **User mode :** Test will run at set number of taps as per user requirements
- Facilitates calculations of Tapped density, Compressibility index and Hausner ratio.

For firmware upgradation, contact ELECTROLAB

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