USP General Chapter <711> Dissolution

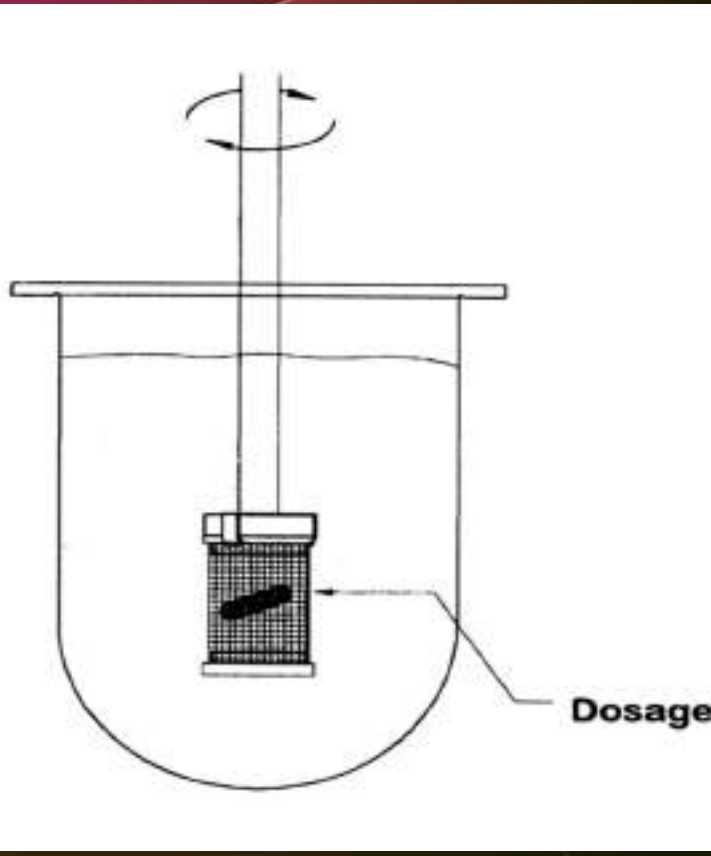
- **Apparatus 1 and 2**
  - **Disintegrating Tablets for *USP Dissolution* Performance Verification Test: Prednisone RS Tablets, lot P0E203**
  - ***USP Dissolution Calibrator, Non-disintegrating* Type*: Salicylic Acid Tablets RS, lot Q0D200***
- **Apparatus 3**

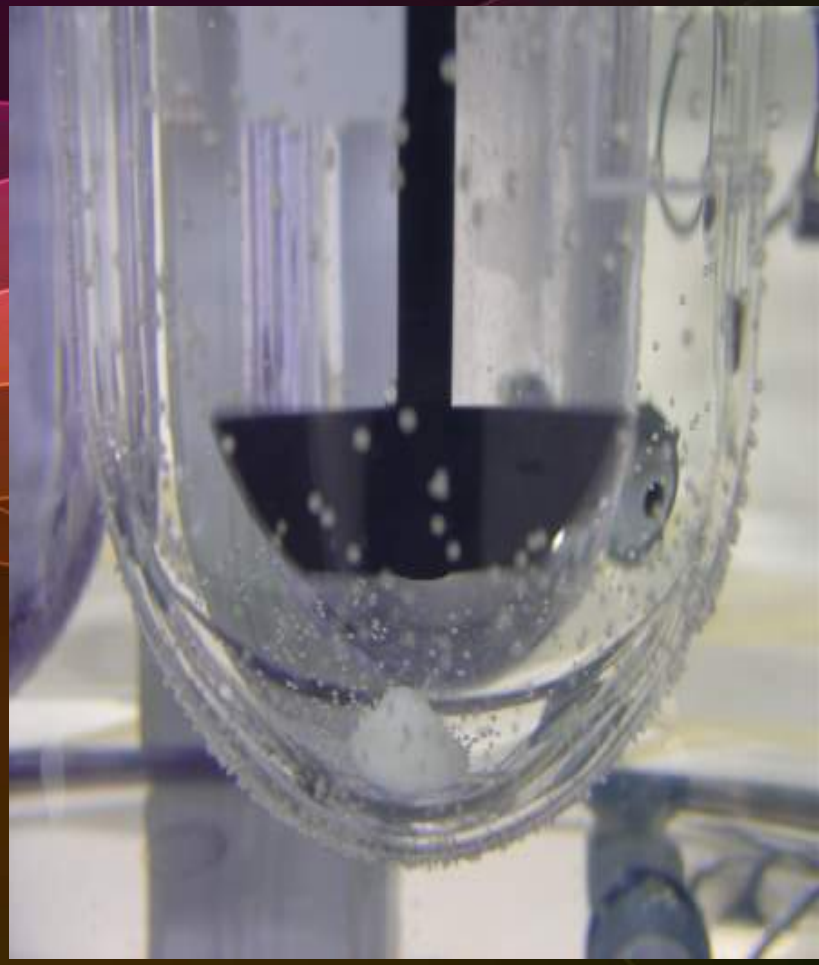
  USP Drug Release Calibrator for Apparatus 3:

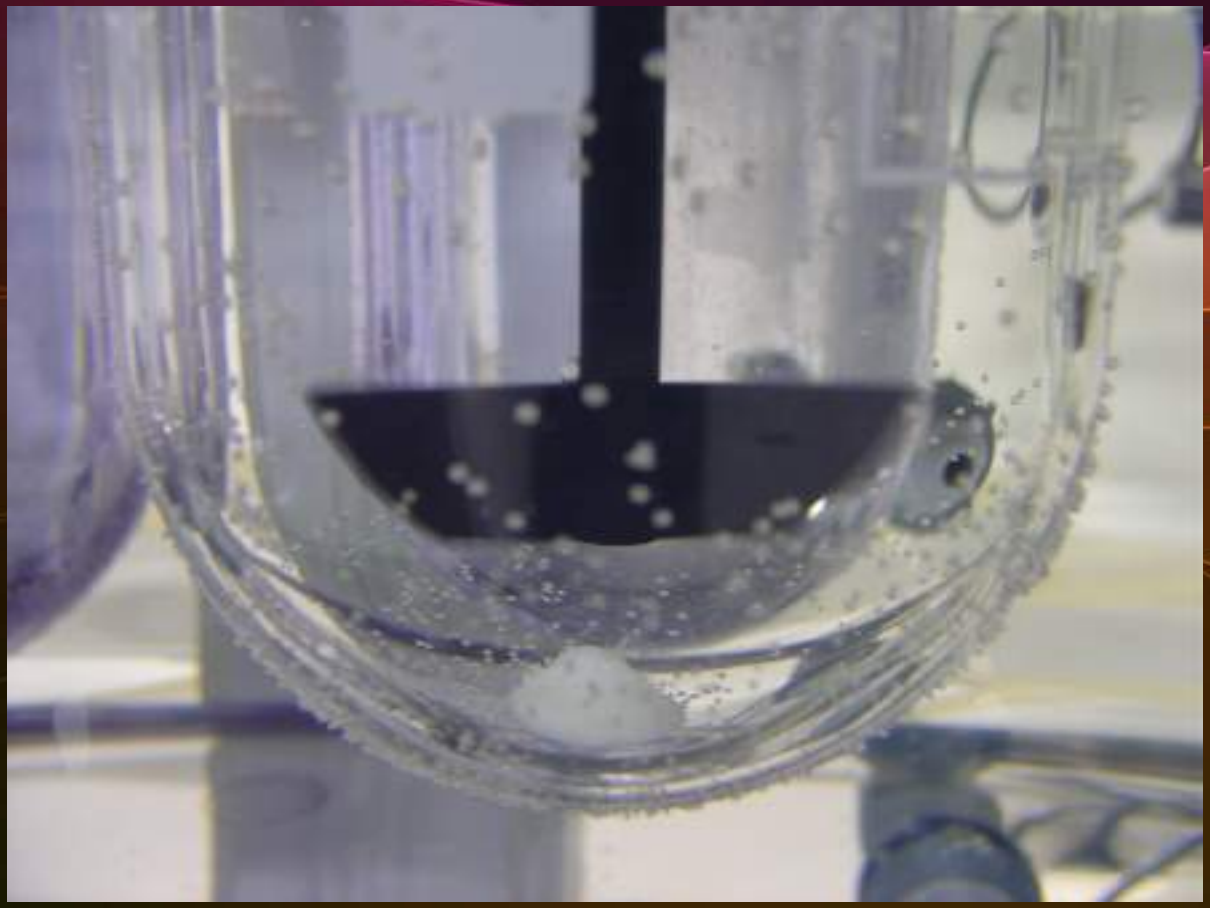
  USP Chlorpheniramine Maleate Extended Release Tablets RS lot G0B259
- **Apparatus 4**

  to come
- **Apparatus 5, 6 and 7**

  to be specified


Dosage





USP Chapters <711>, <724>

USP apparatus

Apparatus 1	Rotating Basket	Capsules,Tablets
Apparatus 2	Paddle	Tablets, Capsules, modified drug products, suspensions
Apparatus 3	Reciprocating cylinder	Extended release drug products
Apparatus 4	Flow cell	Drug products containing low-water-soluble drugs
Apparatus 5	Paddle over disk	Transdermal drug products
Apparatus 6	Cylinder	Transdermal drug products
Apparatus 7	Reciprocating disk	Extended release drug products
Rotating bottles	(Non-USP-NF)	Extended release drug products (beads)
Diffusion Cells (Franz)	(Non-USP-NF)	Ointments, Creams, transdermal drug products

USP Chapters <711>, <724>

USP apparatus

- Apparatus 1 (basket)
- Apparatus 2 (paddle)

Solid Oral Dosage Forms

- Apparatus 3 (reciprocating cylinder)
- Apparatus 4 (flow-through cell)

Various Dosage Forms

- Apparatus 5 (paddle over disk)
- Apparatus 6 (cylinder)
- Apparatus 7 (reciprocating holder)

Topical Dosage Forms

APPARATUS 3

(Reciprocating Cylinder)

APPARATUS 4

flow-through cell

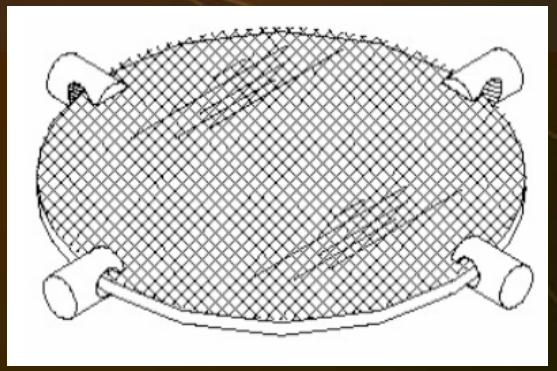
APPARATUS 4

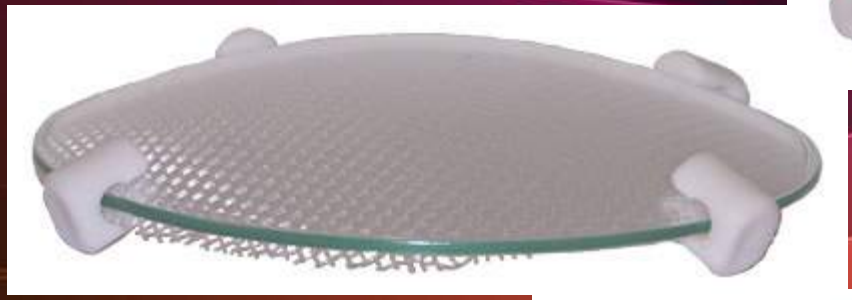
flow-through cell

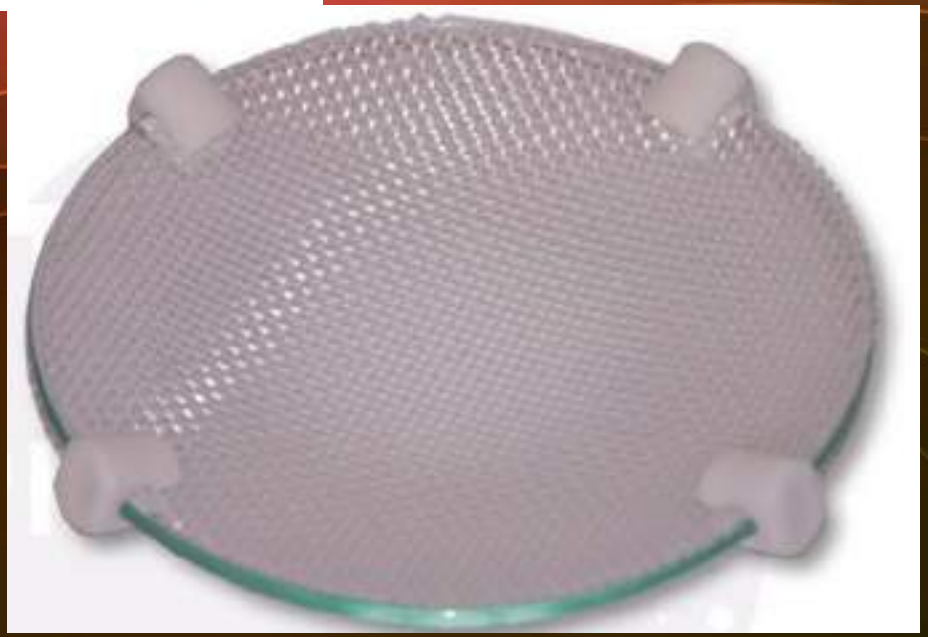
USP 724 Apparatus 5
Transdermal Patch Retainer (Hanson Style)

- The ***Transdermal Patch Retainer*** is a simple economic device which is used with any standard Dissolution Test Station.
- The patch dosage form is placed against the glass disc (delivery side up) and retained with the 17 mesh Teflon screen.
- Four Teflon clip/feet retain the assembly and position the assembly in a standard 1 liter dissolution vessel.

- ***Materials: Borosilicate Glass and Teflon***
- ***17 mesh is standard, others available***
- ***Accommodates patches up to 90 mm***
- ***US Pharmacopeia 724 Compliant***

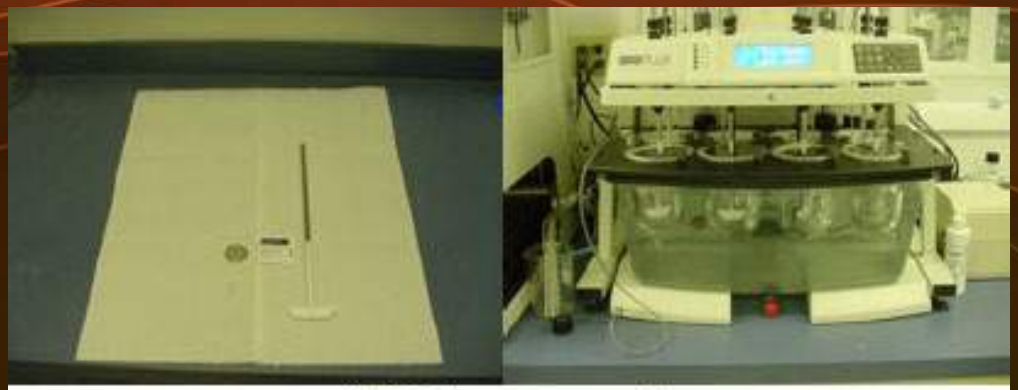






Apparatus 5

Modified Apparatus 5



USP Apparatus 5

USP 724 Apparatus 6
Transdermal Rotating Cylinder

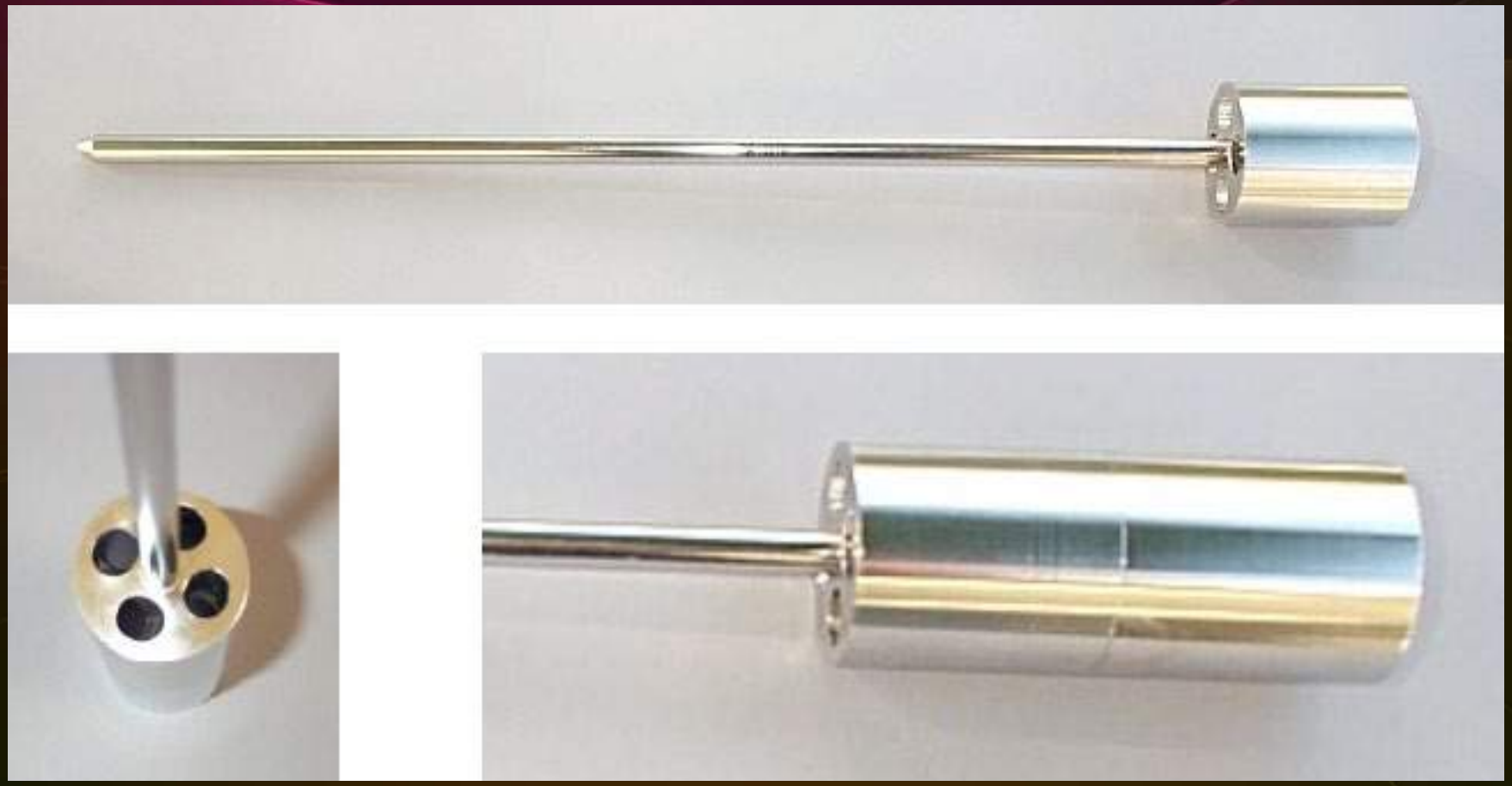
- The Apparatus 6 Rotating Cylinder is used for testing Transdermal Patches in any standard
- Dissolution Test Station. The optional extension is used for larger patches. The extension
- easily connects to the cylinder with a precision frictional fit. The Rotating Cylinder is
- serialized. The extension is also serialized with a serial number which corresponds to the
- Rotating Cylinder serial number. The precision friction fit requires the Rotating Cylinder and
- optional Extension be purchased as a matched set.

USP method 6

compliant rotating cylinder for transdermal testing

USP 724 Apparatus 6

Transdermal Rotating Cylinder



Apparatus 7

- It is for testing transdermal product
- A motor drive assembly is used to reciprocate the system vertically.
- Samples are placed on disc-shaped holders using cuprophan supports.
- The test is carried out at 32 °C.
- Reciprocating frequency is 30 cycles /min.

Apparatus 7

Figure 1. USP Apparatus 7 and the temperature controller (VK 750D Heater/Circulator) made by VanKel/Varian.

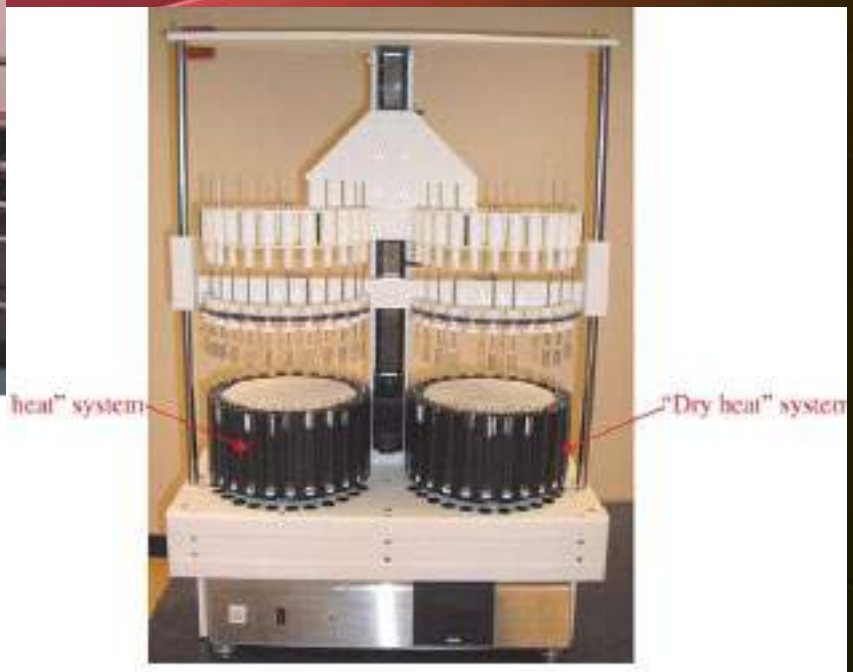
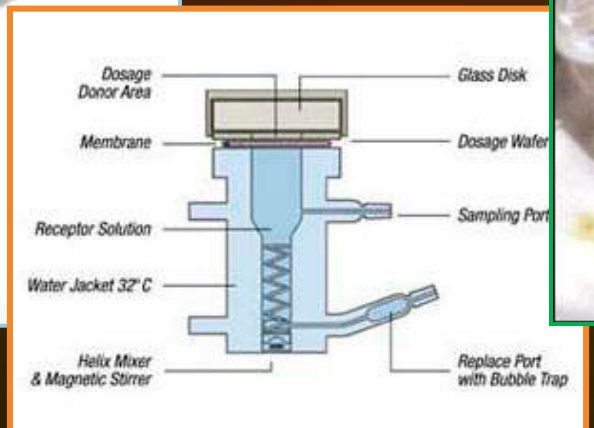


Figure 2. USP Apparatus 7 and the temperature controller made by Logan Instruments.

Diffusion Cells (Franz)

- Franz cells is used to characterize the in vitro drug release and drug permeation kinetics from a topical drug product (Ointment , Cream, Patches , …)
- The source of the skin is may be human cadaver skin or animal skin (hairless mouse skin).

Diffusion Cells (Franz)



Because it is easier to correlate the absorption time with the dissolution time

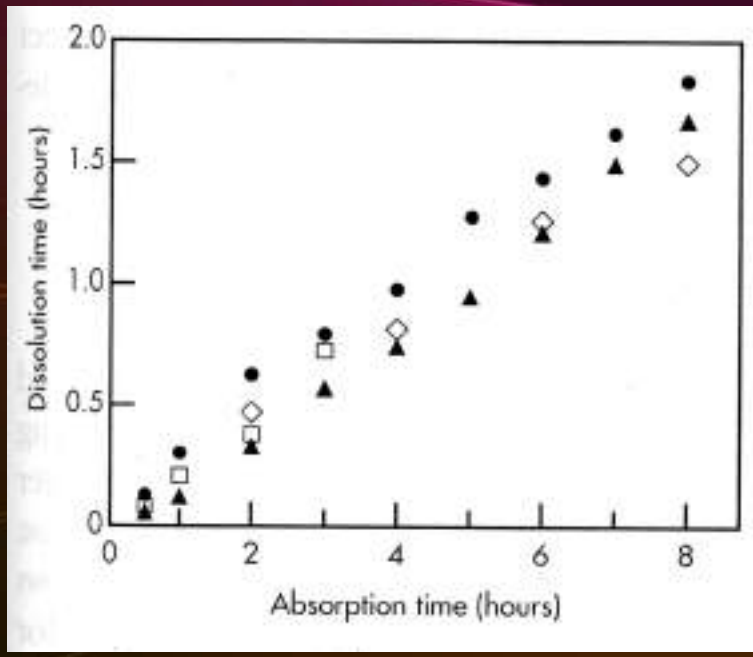


Figure 14-10. An example of correlation between time required for a given amount of drug to be absorbed and time required for the same amount of drug to be dissolved *in vitro* for three sustained-release aspirin products.
(From Wood, 1966, with permission.)

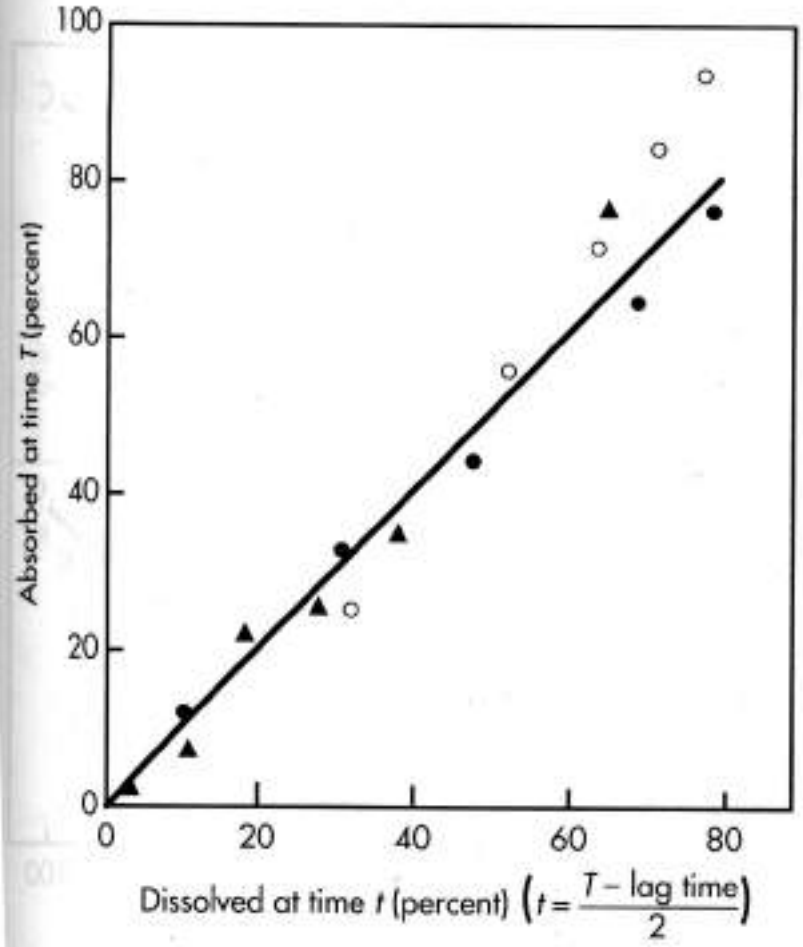


Figure 14-11. An example of continuous *in-vivo–in-vitro* correlation of aspirin.
(From Levy et al, 1965, with permission.)

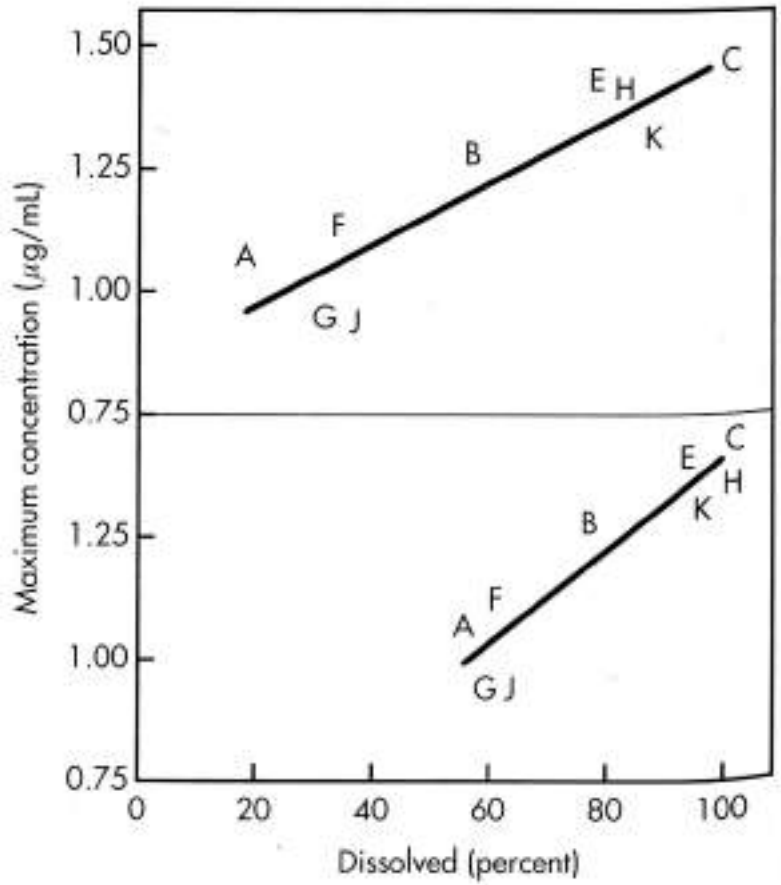


Figure 14-12. *In-vitro–in-vivo* correlation between C_{max} and percent drug dissolved. Top, 30 min (slope = 0.06, $r = 0.902$, $p < 0.001$). Bottom, 60 min (slope = 0.10, $r = 0.940$, $p < 0.001$.) (Letters on graph indicate different products.)
(From Shah et al, 1983, with permission.)

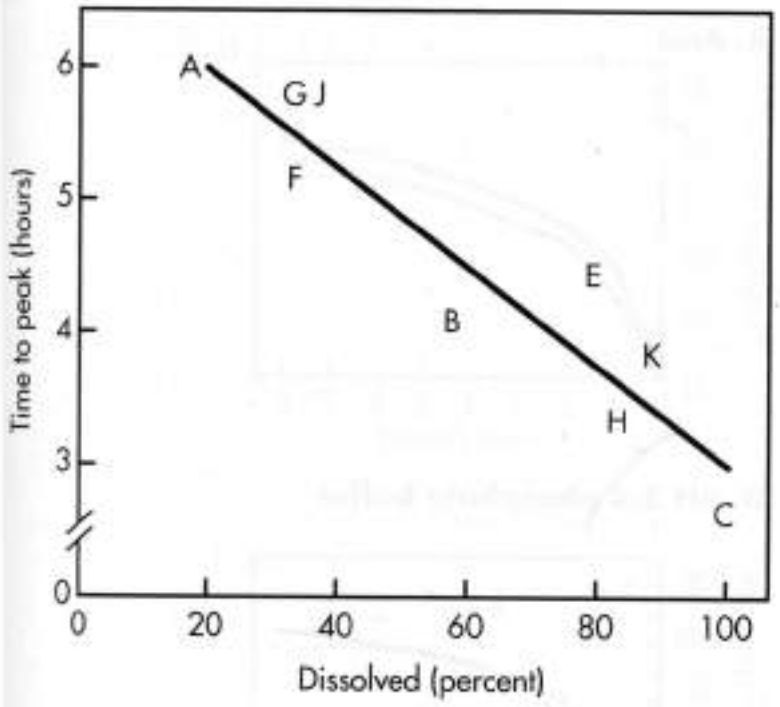


Figure 14-13. *In-vitro–in-vivo* correlation between t_{max} and percent drug dissolved in 30 minutes by basket method. Letters on graph indicate different products.
(From Shah et al, 1983, with permission.)

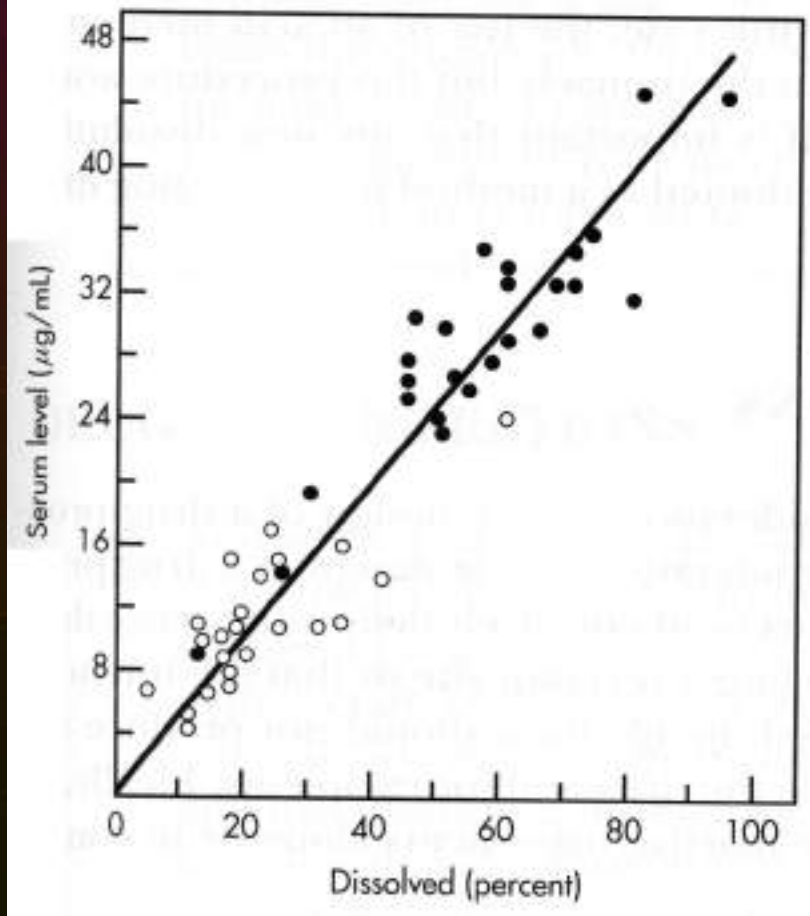


Figure 14-14. Example of *in-vivo–in-vitro* two-point correlation between 10-minute serum level and percent dissolved at 1.2 minutes (O) and the 20-minute serum level and percent dissolved 4.2 minutes (●).
(From Wood, 1966, with permission.)

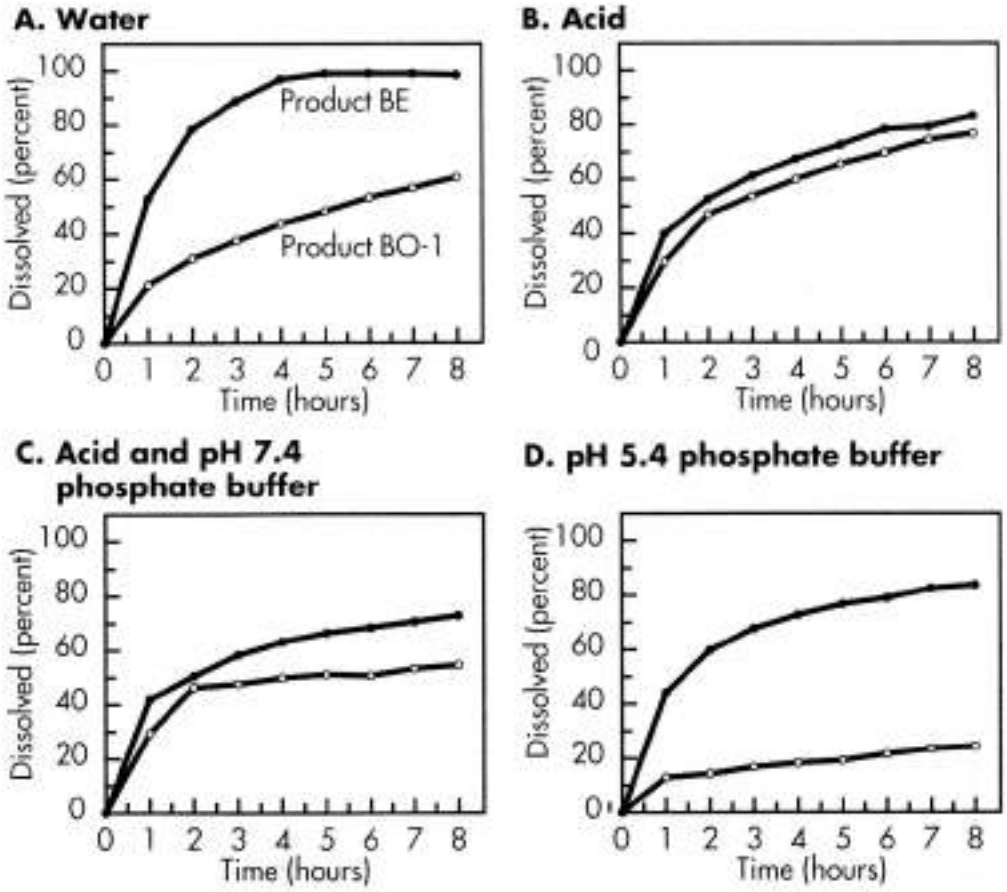


Figure 14-15. Dissolution profile of two quinidine gluconate sustained release products in different dissolution media. Each data point is the mean of 12 tablets. (● = product BE, O = product BO-1.) (From Prasad et al. 1983. with permission.)

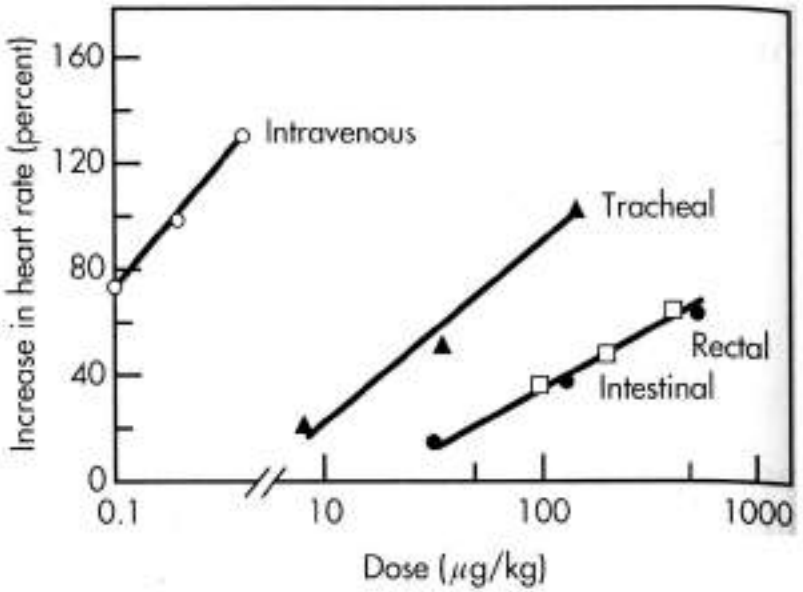


Figure 14-16. Dose–response curve to isoproterenol by various routes in dogs.
(From Gillette and Mitchell, 1975, with permission.)