

分泌型的子宮內膜，分泌大量的肝醣和醣蛋白，藉此子宮內膜始能供受精卵的着床（implantation）。如果卵沒有受精，黃體的分泌量降低，黃體激素的產生減少，分泌型的子宮內膜不能再繼續維持，月經就來臨了。黃體激素也能夠減少或抑制子宮平滑肌的收縮，為一種有利於懷孕的前期效果。

3 乳房—黃體激素作用於動情激素作用過的乳房，以促進乳房小葉和分泌細胞的發育。

§3-2 [中樞神經的作用] (effect on CNS)

傳統上認為月經前和妊娠後的心理煩燥可能和數量驟降的黃體激素有關。

據研究顯示，患癲癇病的女性，在黃體期的發作比例往往降低，所以黃體激素似可減少癲癇的發作。

女性在黃體期的基礎體溫（Basal Body Temperature）都會升高，此種現象和黃體激素有關。當體溫剛一上升，一般人都認為就是排卵時。（此種預測不怎麼可靠）

§3-3 [心臟血管系統]

黃體激素可以明顯降低特發性或腎臟性高血壓（Primary or renal hypertension）病人的血壓，但並不損失鈉。

參考書目

1. M.B. Aufrere, H. Benson: J. Pharm. Sci, 65 783 (1976).
2. Bruce S. Mc..Ewen. Scientific American July 50 (1976).
3. Wilson-Pharmaceutical Chemistry.

§3-4 [肌肉的成長]

黃體激素可促進蛋白質的異化作用。

§4. 臨床用途

黃體激素的半衰期很短，服用後大部分又被分解，並不是很理想的臨床用藥。最近的研究顯示，黃體激素已經可以局部給藥，減少因系統性代謝（Systemic metabolism）所造成的損失。

1 癌—黃體激素可用來治療子宮內膜癌和乳癌。

2 習慣性流產—但合成的會使胎兒男性化或畸形。

3 婦人病（Gynecological disorder）—治療卵巢性痛經（dysmenorrhea），月經閉止（Amenorrhea）和功能不良的子宮出血（dysfunctional Uterine bleeding）。

4 避孕—和動情激素一齊合用可以當避孕藥。

藥廠組織和製藥機械簡介

林見源

前言

筆者於今年內曾經參觀國內拾幾家的藥廠，其中有的是國人自營，有的是外人投資，也有的是所謂技術合作者。今筆者把所見所聞有關藥廠組織和製藥器械整理出來供各位同好參考，個人才學所限若有不善處請求指正。

藥廠組織

一般藥廠不論其為中藥或西藥製造廠或是兩者兼營，也不論其為獨資、合夥或採取公司制，其組織都分為行政、製造、品質管制、銷售、新產品開發等部門。

行政部門負責整個組織的維持和推動、生產計劃的擬定、財務、人事等的管理、各單位協調……等。

製造部門負責各種產品的生產。

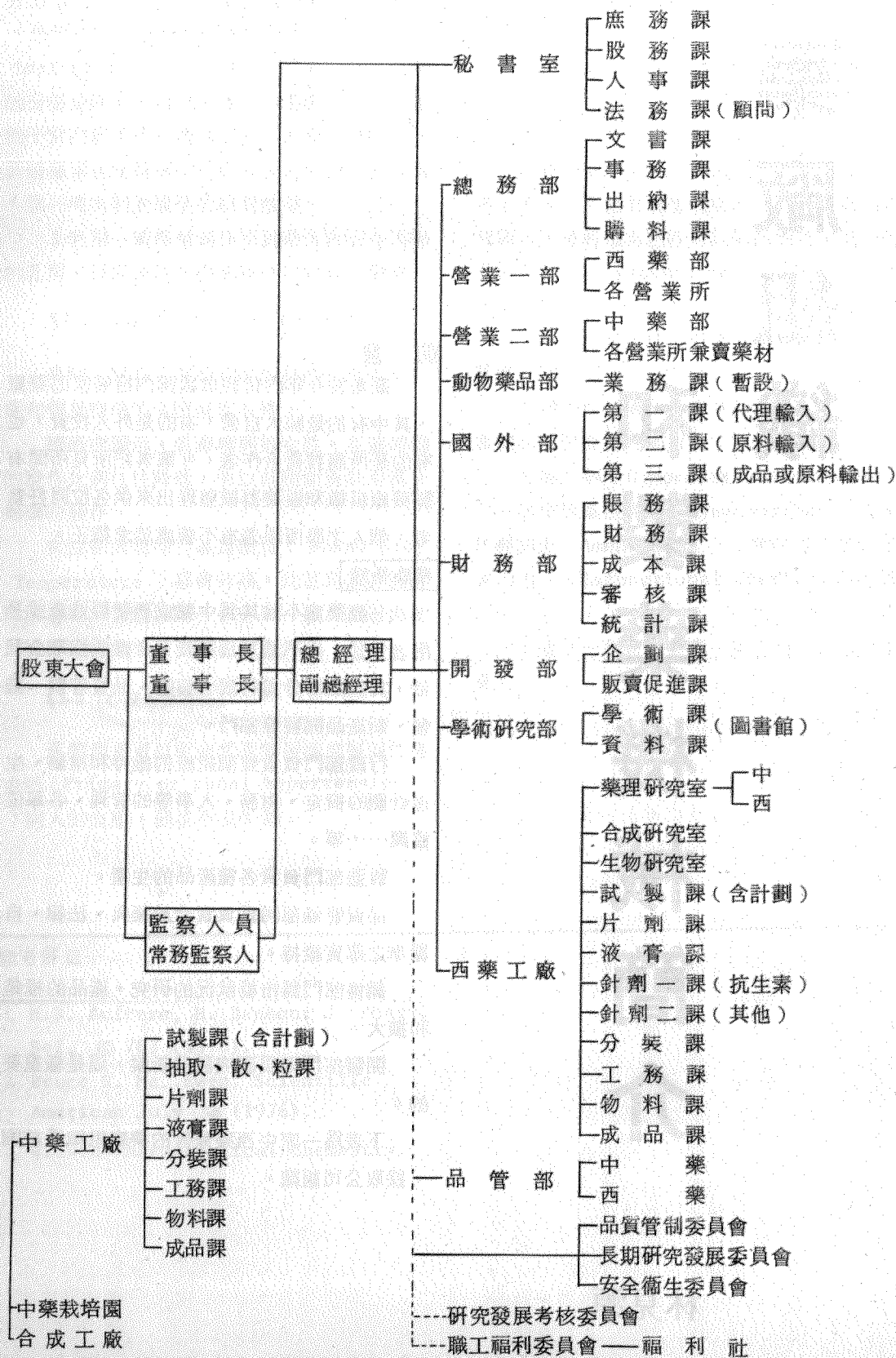
品質管制部門為負責合於藥典、法律、自標準之確實維持。

銷售部門為市場狀況的研究，產品的推銷和擴大。

開發部門則為研究發展新藥，這是極重要的。

下表為一家中西藥兼營的藥廠組織系統圖，採取公司組織。

組織系統表



製藥器械

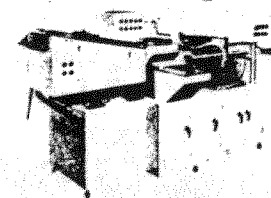
製藥器械是和生產的劑型 (dosage form) 有關，除了一般共同的檢驗器械外，每種劑型都有較特殊的製造器械；因此以下的製藥器械簡介將以劑型為主，先提出劑型，稍加說明製造方法或原則，最後是配以圖示的製藥器械，由於篇幅的關係原理無法說明。

依據十九版美國藥典，藥物劑型計有下列：
 氣化噴霧劑 (Aerosols)、膠囊劑 (Capsules)、洗眼劑 (Collyrias)、醑膏劑 (Creams)、醑劑 (Elixirs)、乳劑 (Emulsions)、浸膏劑 (Extracts)、流浸膏劑 (Fluidextracts)、凝膠劑和乳糜劑 (Gels & Magmas)、凍膠劑 (Jellies)、吸入劑 (Inhalations)、洗劑 (Lotions)、乳糜劑 (Milks)、軟膏劑 (Ointments)、糊劑 (Pastes)、粉劑 (Powders)、溶液劑 (Solutions)、醑劑 (Spirits)、栓劑 (Suppositories)、懸浮劑 (Suspensions)、糖漿劑 (Syrups)、錠劑 (Tablets)、酹劑 (Tinctures)、芳香水劑 (Water-Aromatic)、水劑 (Waters)。

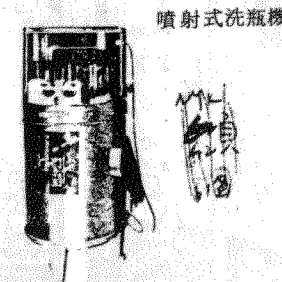
一、含非揮發性物質的溶液劑：
 定義：指一種或一種以上之藥物或其他化學物質通常溶於水所成的液體劑劑。

- 製造原則：(1)簡單溶解法 (Simple Solution)
 (2)化學反應法 (Chemical reaction)
 (3)簡單溶解法並滅菌 (Simple Solution with Sterization)
 眼用溶液劑、滅菌詳見注射劑。
 (4)抽取法 (Extraction)

製造器械：大規模的溶液劑製造其一般設備包括①裝有攪拌器的混合桶②各種大小不等的量器③過濾機④充填設備⑤洗瓶設備⑥封口設備，各設備間或有連通管相通。



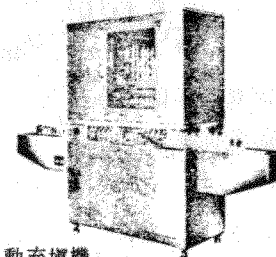
全自動充洗機



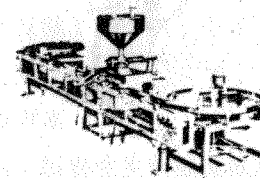
噴射式洗瓶機



充填機

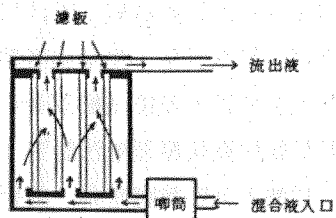
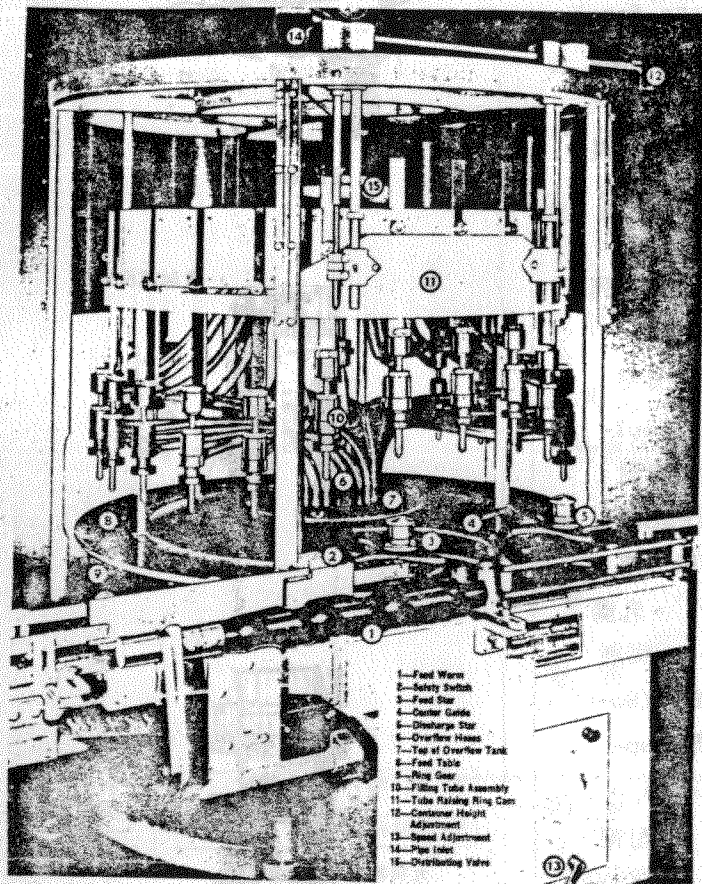


全自動充填機



全自動充填機

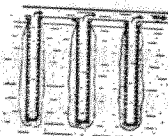
回轉式充填機



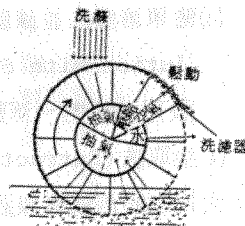
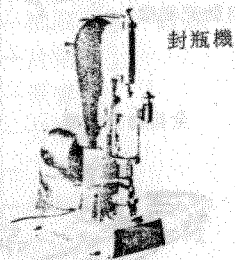
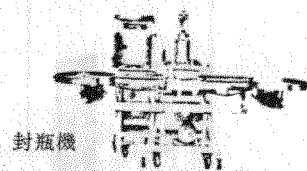
板框壓濾器之流動圖



彈形濾器



錐形濾器

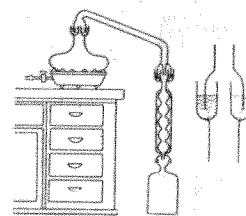


迴轉式濾器

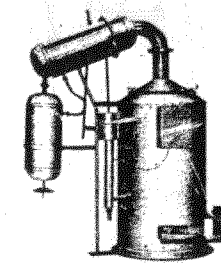
二、含芳香成分的水溶液：水劑、糖漿劑和汁劑 (Juices)

(一)水劑：包括純化水、注射用水、滅菌注射用水、制菌注射用水、滅菌灌洗用水。

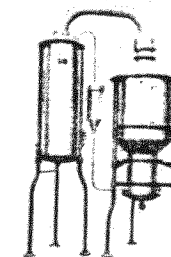
製造原則：除純化水可用蒸餾法、離子交換



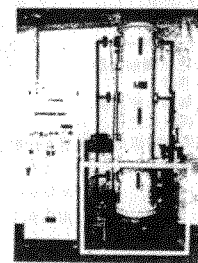
林式蒸留器



自動蒸留水製造裝置



自動蒸留水製造裝置 工業用



全自動純水製造裝置



離子交換樹脂純水製造器

(二)芳香水劑

定義：為含有揮發油或其他芳香成分之飽和澄明溶液 (通常為水溶液)。

製造原則：蒸餾法、溶解法、交替溶解法、稀釋法。

製造器械：略

(三)糖漿劑

定義：藥用或芳香成分溶於濃糖溶液 (常為蔗糖) 所成之液體製劑。

製造原則：加熱溶解、振搖、混合、滲濾 (Percolation)

製造器械：滲濾器詳見流浸膏劑。

四汁劑：由植物新鮮部份壓榨而得之液體製劑。

三、混合溶媒的溶液劑：酞劑、醃劑及抽提製劑。

(一)酞劑

法、反滲透法外，其餘只能用蒸餾法或反滲透法並需滅菌。

製造器械：(1)蒸餾器(2)離子交換器(3)反滲透純水裝置(4)滅菌裝置。(詳注射劑)

定義：揮發成分溶於酒精之溶液。

製造原則：單純溶解法、浸漬溶解法、化學反應法、蒸餾法。

製造器械：略。

(二)醃劑

定義：含芳香或醫療物質之甜味水醇溶液。

製造原則：溶解法、混合溶解法。

製造器械：略。

(三)抽提製劑

(1)酞劑

定義：生藥之抽提液或純化學物質之醇或水醇溶液。

製造原則：浸漬法、滲濾法。

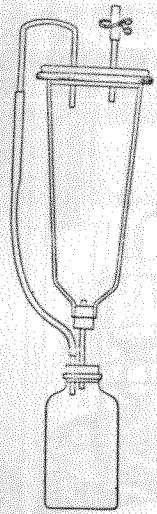
製造器械：略。

(2)流浸膏劑

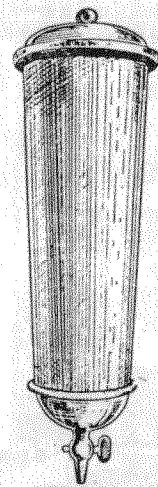
定義：植物性生藥抽提液之液體製劑。

製造原則：滲濾法。

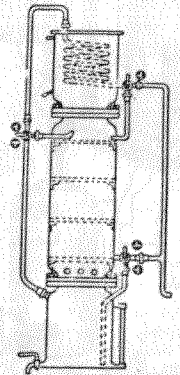
製造器械：①生藥粉碎機（詳粉劑）②滲漉器③一貫抽提裝置。



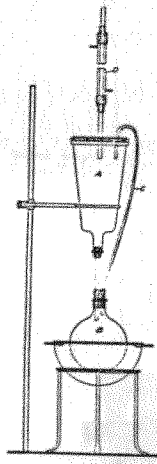
揮發性藥材抽提用之封閉式滲漉器。



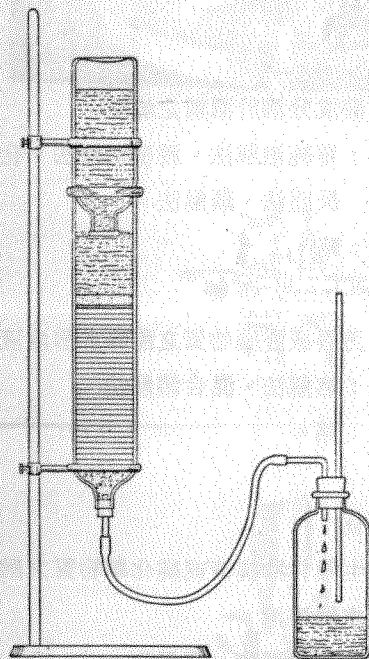
metal percolator. 金屬滲漉器



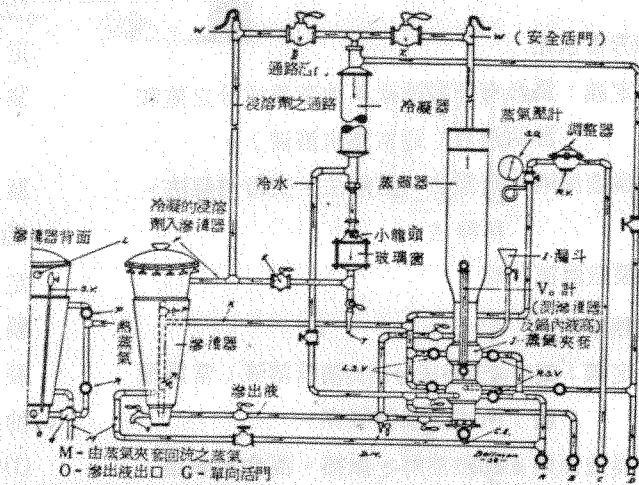
大規模之加熱抽提器



改良後之連續抽提器
A: 滲漉器
B: 收集器出液並供溶媒氣化之瓶
C: 供氣化溶媒由B通至A的管
D: 冷凝器



Fractional percolator.



Lloyd 抽提裝置
A: 回流蒸氣 P: 蒸氣進入滲漉器夾套之活門 C.E. 收集提出物
B: 冷水 S.V. 安全活門 R: 熱蒸氣流入滲漉器並洗淨之
C: 熱蒸氣 RV: 減壓活門 L.S.V: 熱蒸氣活門
D: 廢水 E: 濃縮時活門關閉 R.S.V: 回流蒸氣活門
DM: 滲漉劑之收集 S: 滲出液之龍頭 T: 濃縮時收集器出液

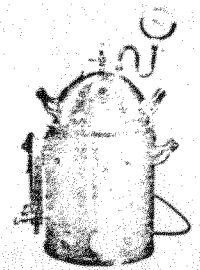
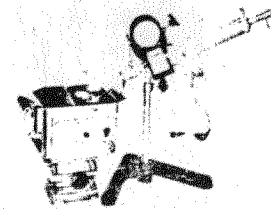
(3)浸漬劑

定義：動植物生藥之濃縮半固體、塊狀、粉狀製劑。

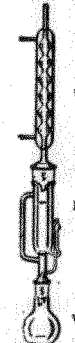
製造原則：滲漉、濃縮。

製造器械：①滲漉器②濃縮裝置。

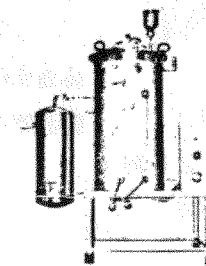
旋轉蒸餾器



万能減壓蒸留、濃縮、乾燥裝置



Soxhlet 抽提器
V: 氣化室
E: 抽提室
C: 冷凝室



電氣定溫浸出器

(4)樹脂及油樹脂 (Resins & Oleoresins) (三)凝膠劑和乳糜劑

採用滲漉法製造。

定義：不溶性藥物以水為媒劑所製成之懸浮液，乳糜劑之質粒較大。

四、膠體分散液：膠漿劑、合劑、乳糜劑、凝膠劑

膠體分散液的製造原則：混合、攪拌。

(一)膠漿劑

定義：為從樹木之滲出物，將其中所含之碳水化合物成分溶解或分散於水中之稠厚且黏滯之液體製劑。

製造器械：主要為混合機，計有下列幾種形式

(1)一次混合機：①推動機式，圖1、2 ②空氣噴射式，圖3 ③流體噴射式 ④附加障板式，圖4 ⑤Z-刀葉式，圖5。

(二)合劑

定義：一種膠體分散物質供口服之水或小醇液體。

(2)連續式混合機：流體不斷經混合機向前流動。

參考：圖4、圖6、圖7、圖8為膠體磨。

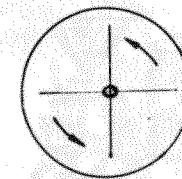


圖1.

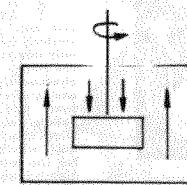


圖2.

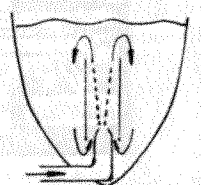


圖3.

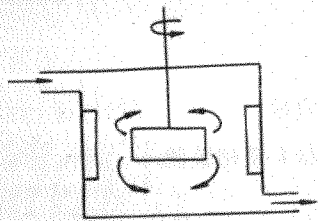


圖4.

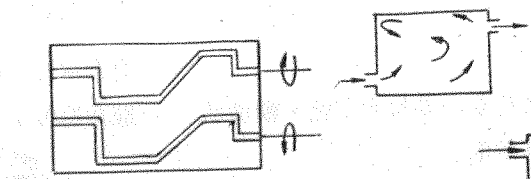


圖5.

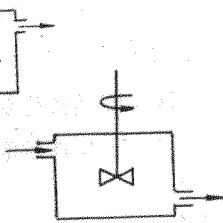


圖6.

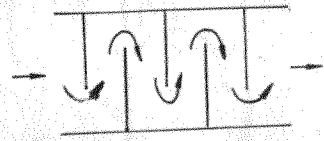


圖7.

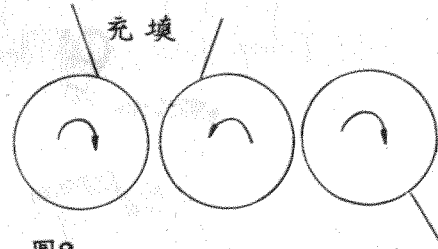


圖8.

五、粗分散液：懸浮劑、乳劑及洗劑

(一)懸浮劑

定義：含有微細不溶性藥品懸浮於媒液中之粗分散液或臨用時可分散於液體中之乾粉。

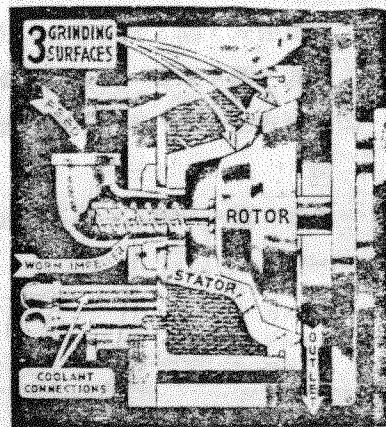
製造原則：混合、研勻，若為乾粉者需研碎磨細。

製造器械：(1)小規模：研鉢和研棒 (Mortar and Pestle)

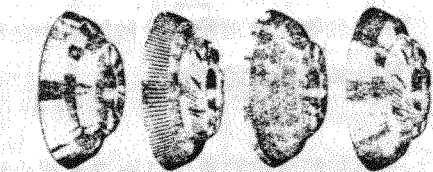
(2)大規模：①均勻器②膠體磨③粉碎機。

(二)乳劑

定義：含有二種不相溶液體（常為油和水）



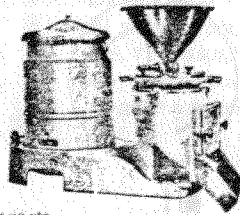
A colloid mill shown in cross section (courtesy, Tri-Homo). 膠體磨切面圖



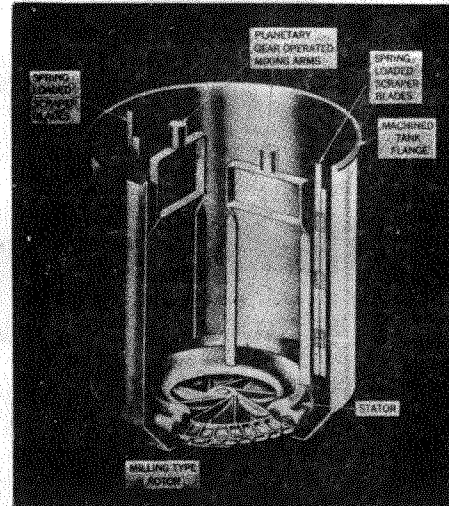
Types of rotors used in colloid mills. These may be smooth (for emulsification of most emulsions), serrated (for the emulsification of ointments and very viscous products), or of vitrified stone for the emulsification of paints and pigment dispersions (courtesy, Tri-Homo).

膠體磨內之幾種轉磨

The Premier colloid mill, a gravity flow, vertical colloid mill with only one moving member, the rotor. Adjustment of clearance between the rotor and stator can be made from 0.001 in. upward. Speeds range from 3600 to 17,800 rpm for this type of mill, which may be used for the even and uniform distribution of the ingredients in a wide range of pharmaceutical products.

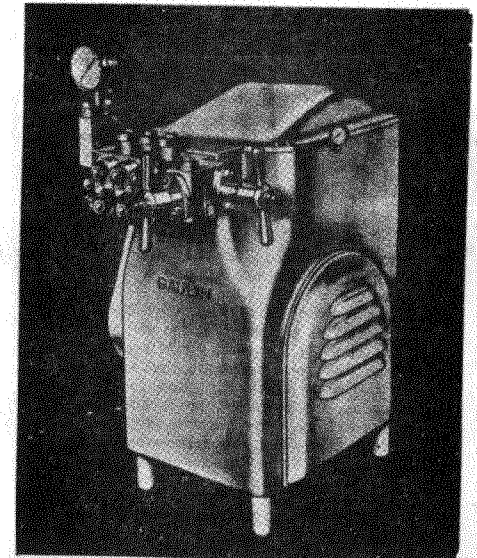


雷管式膠體磨



Standard paste-type dispersal mixer with "cupped-rotor" milling element and double-rotating mixing arm circulating element (courtesy, Abbe Eng.).

具杯狀轉子和雙臂旋轉件之混合機



Two-stage homogenizer (courtesy, Manton Gaulin).

二段均勻器

(二)洗劑

定義：供外用的液體製劑。

製造原則：混合、研勻。

製造器械：略。

六、半固體劑型：軟膏、酪膏劑、糊劑。

(一)軟膏

定義：含有藥用成分供外用的半固體製劑，包括眼用軟膏。

製造原則：混合、研勻、研細。

製造器械：①軟膏板和刀②研鉢和研棒③軟膏磨④充填機⑤包裝機⑥混合機。

(二)酪膏劑：為油溶於水或水溶於油之半固體乳劑。

製造原則和器械同上。

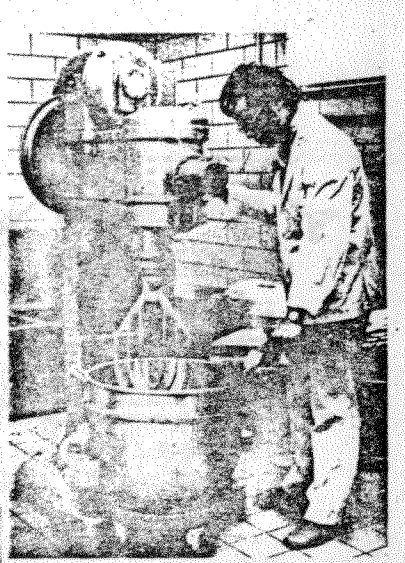
(三)糊劑：含固體粉粒較多之軟膏狀外用製劑。製造原則和器械同上。



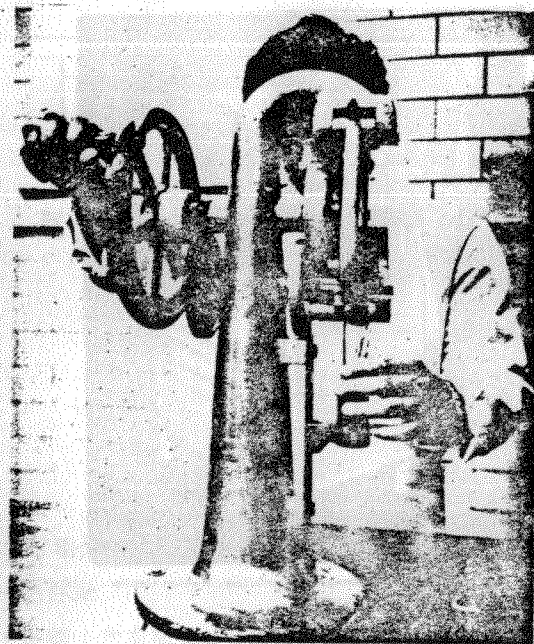
腳操作糊劑'酪膏'充填器



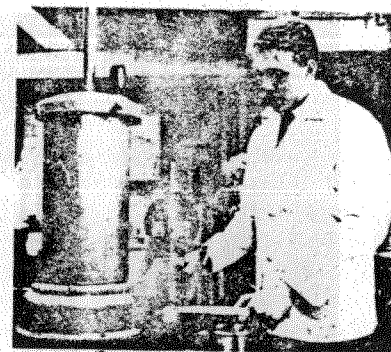
三轉子膠體磨



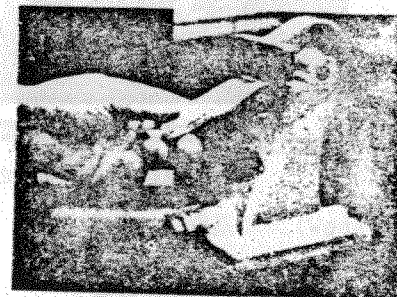
Hobart 混合器 (軟膏)



手操作模膏管封閉機



手操作模膏管封閉機



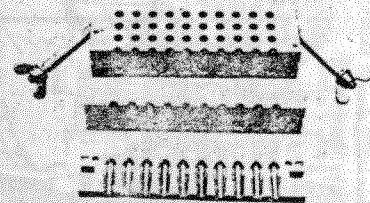
腳操作模膏管封閉機

七、模型固體製劑：栓劑

定義：各種重量和形狀之供直腸、陰道、尿道用固體製劑。

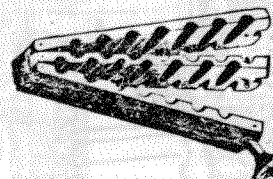
製造原則：混合、手工法、壓製法、熔合法。

製造器械：①手工栓劑壓製機②自動栓劑模製機。

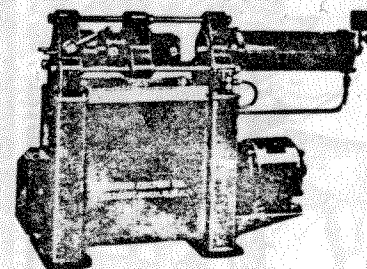


Partially opened suppository mold capable of producing 50 torpedo-shaped suppositories in a single molding. (Courtesy, Chemical and Pharmaceutical Industry Co., Inc.)

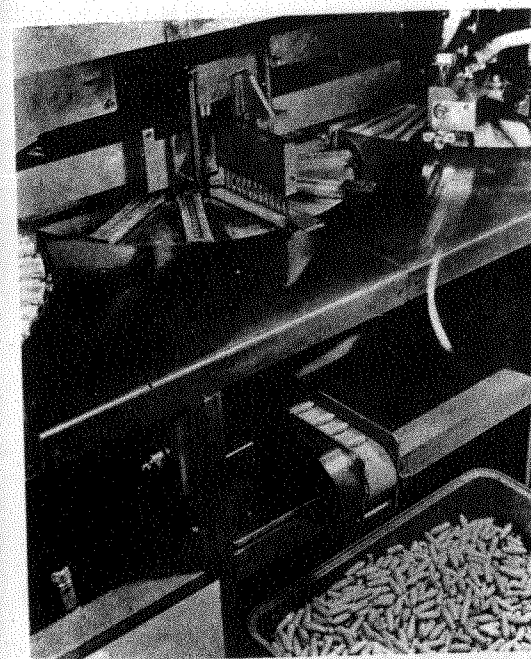
可做 50 隻之栓劑模



可製二種大小不同的栓劑之模

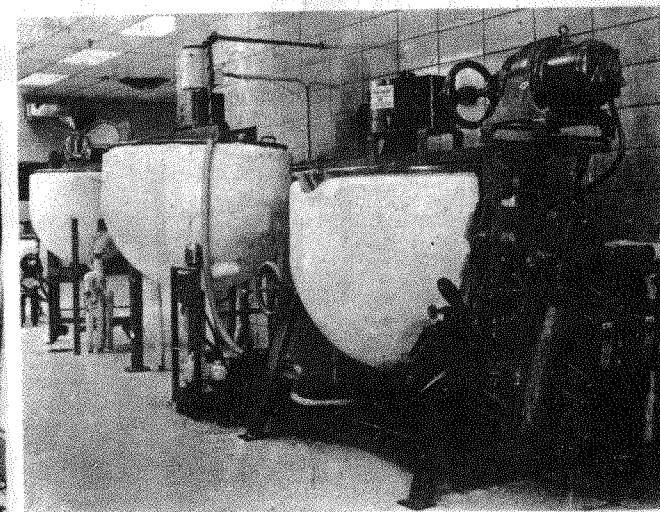


用馬達帶動的栓劑冷壓機



Highly automated large-scale production of molded suppositories. Molding operation (at the right) is followed by the removal of the suppositories from the molds, dropping them onto a conveyor belt and into a collection basket. (Courtesy, Wyeth Laboratories)

高速自動栓劑製造機



Large heated tanks for the preparation of the melt in the commercial production of suppositories by molding. (Courtesy, Wyeth Laboratories)

商業上裝模製栓劑溶液之大桶

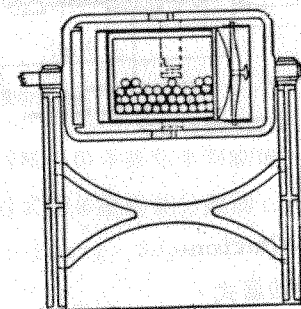
八、粉狀劑型：散劑

定義：乾燥細粒並充分混合之藥物或其他化學物質供外用或內用製劑。

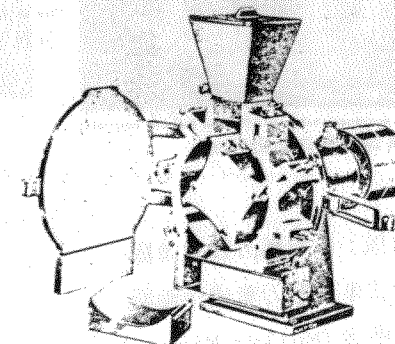
製造原則：研細、混合、乾燥、篩選。

製造器械：(1)研細器械：①槌磨機 (Hammer mills) ②旋轉式切碎機 (Rotary Cutter mills)

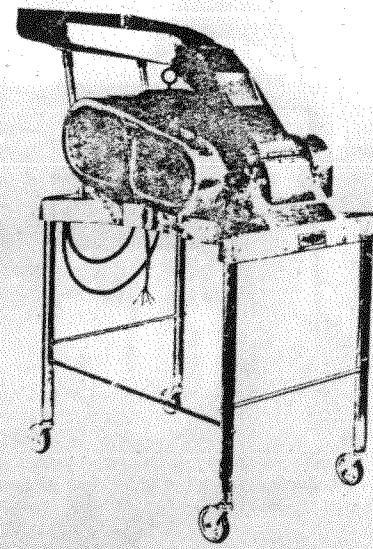
③球磨機 (Ball mills) ④流體能磨粉機 (Fluid energy mills) ⑤研磨磨粉機 (Attrition mills) ⑥追逐式磨粉機 (Chaser mills) ⑦離心撞擊式研碎機 (Centrifugal-Impact Pulverizers).



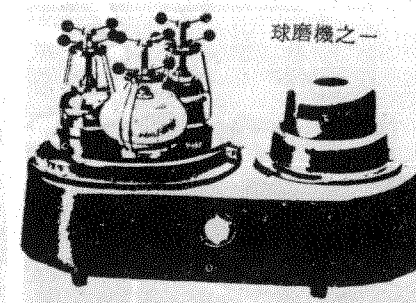
單桶球磨機 Single jar mill.



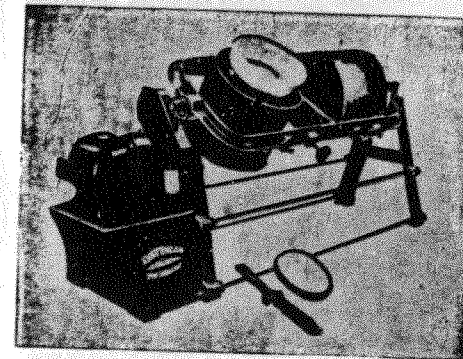
旋轉式切碎機之一 Wiley mill.



Fitzpatrick Model D comminuting machine. Machine is assembled ready for use.
槌磨機之一種



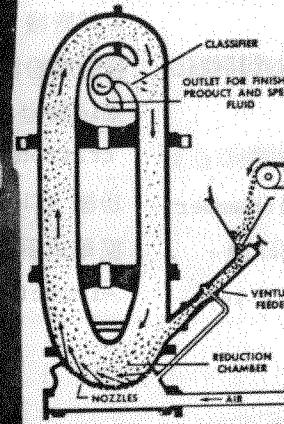
球磨機之一



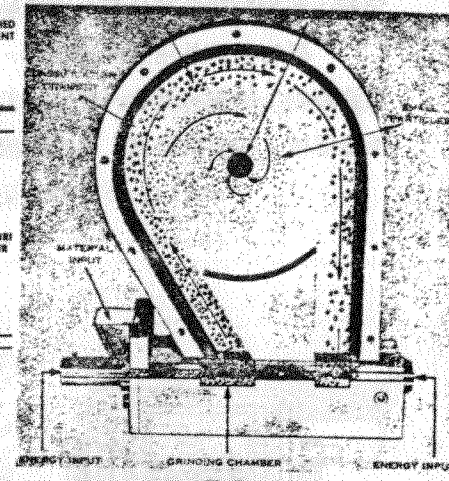
雙桶式球磨機



Universal automatic laboratory mortar grinder (courtesy, Geoscience).
實驗室用自動研碎機



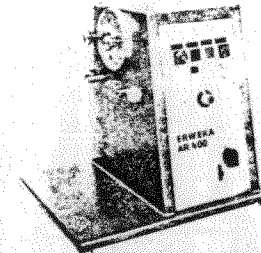
The Jet-O-Mixer fluid energy mill
流體能磨粉機之一



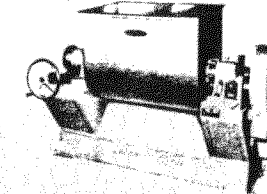
The Trost Pulverizer.
流體能磨粉機之一

(2) 混合器械：① 旋轉外殼式 ② 固定外殼式 ③ Σ 形刀葉或平面槳式 ④ 碾槽式 (Muller Mixers)

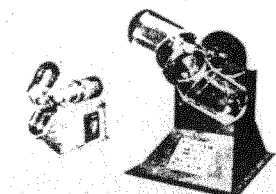
⑤ 流體式 ⑥ 固定式 (Motionless Mixers) ⑦ 過篩式。



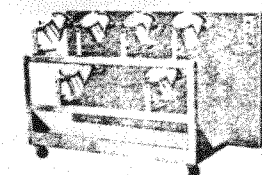
混合、攪拌 多用途設備



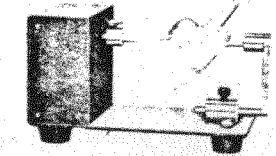
大型混合機



S型完全混合機



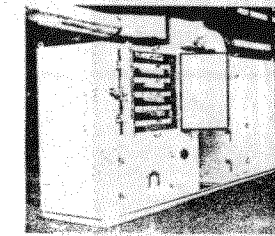
六連式V形混合機



V形混合機

(3) 乾燥器械：① 碟式乾燥 ② 冷凍乾燥 ③ 真空乾燥 ④ 鼓式乾燥 ⑤ 噴射乾燥 ⑥ 氣體流動乾燥 ⑦ 紅

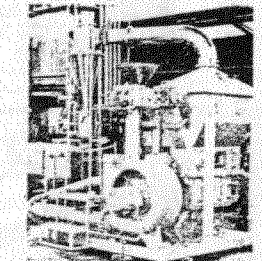
外線乾燥 ⑧ 高頻率電場乾燥 (Dielectric heat dryer)。



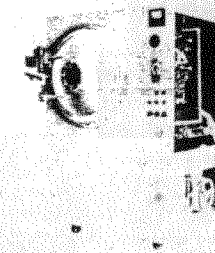
恒溫·恒濕乾燥機



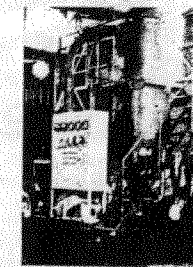
流動層乾燥機



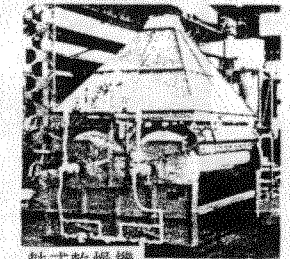
橫型連續流動層乾燥機



真空乾燥機



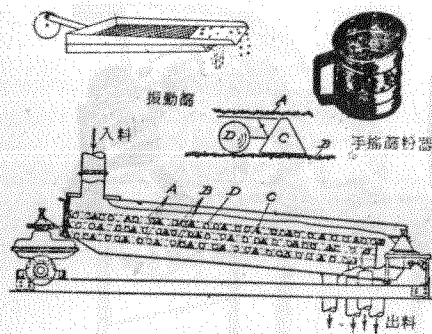
實驗用噴霧乾燥機



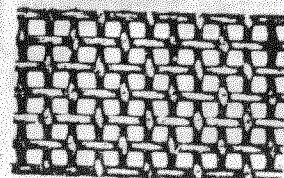
鼓式乾燥機
ドラム乾燥機

(4) 篩選器械：① 手搖篩 ② 簸動篩 ③ 電磁式篩 ④ 振動能分離器 (Vibro-Energy Separator)

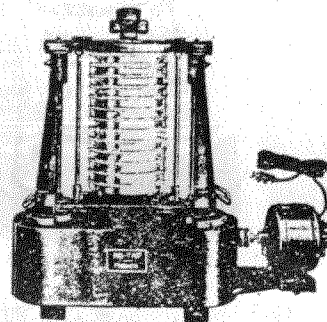
⑤ 離心式篩選器 (Centrifugal Screen)。



Rotex 震動器，橡皮球 (D) 在 A、B 兩間與木塊 (C) 料面碰撞，敲擊磨面



標準高之筒孔結構



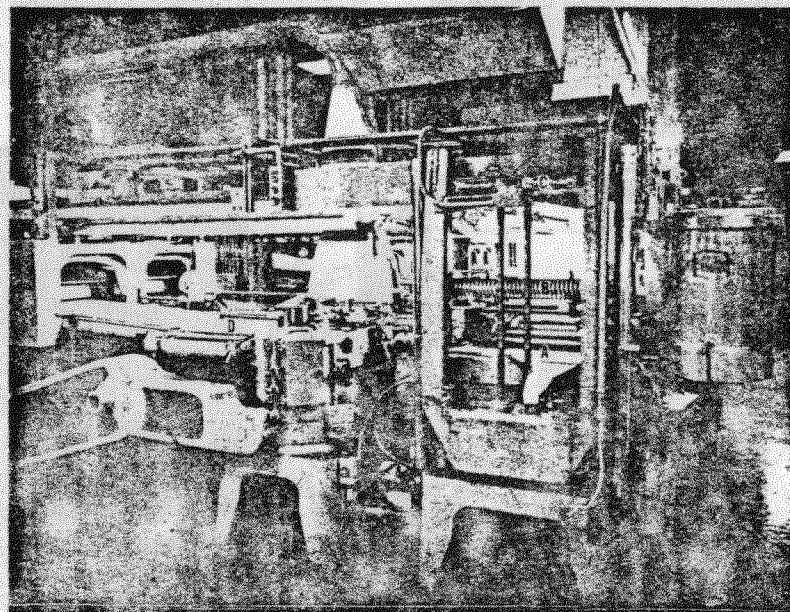
機動震動器

九、膠囊劑：

定義：藥物充填於硬或軟膠囊內的固體劑型

(一) 硬膠囊殼製造

(1) 手工操作器 (2) 半自動操作器 (3) 全自動製造機。

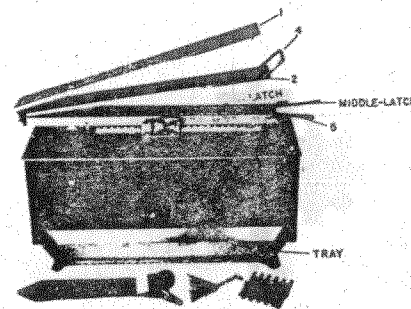


Automatic capsule-making machine at Eli Lilly and Company. (A) Stainless-steel body molds are dipped in gelatin solution; molds for caps are treated similarly on the opposite side of the machine; (B) molds are rotated as they are raised to the top of the machine to ensure uniform distribution of gelatin; (C) molds are conveyed to the drying kiln; (D) molds are conveyed from the drying kiln; (E) dried gelatin is stripped from the molds and bodies and caps joined; (F) finished capsules are delivered on other side.

自動膠囊殼製造系統

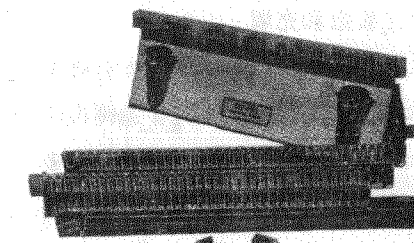
(二) 硬膠囊充填

(1) 小規模手操作型：① Sharp and Dohme 充填機 ② 蓋式充填機 (Cap-Fill Machine).



Hand-operated capsule machine (courtesy, Chemi-Pharm).

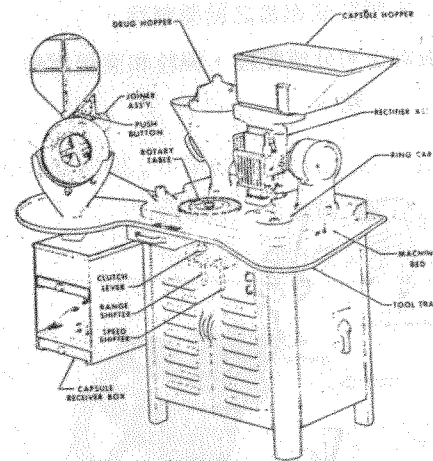
手操作膠囊充填機



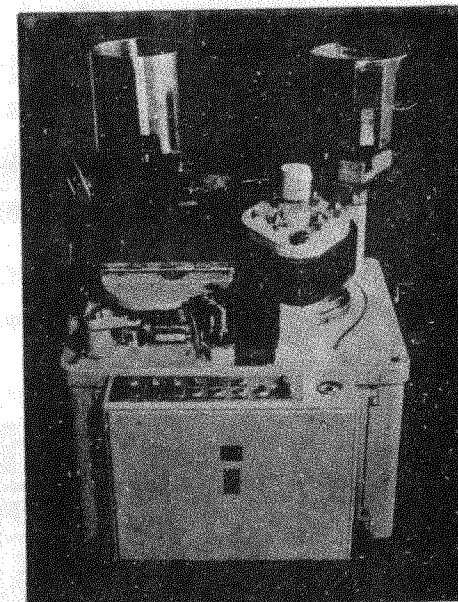
Capsule filling machine made of leucite and aluminum (courtesy, Cap-Fill).

蓋氏膠囊充填機

(2) 大規模充填機：① 半自動型 ② 全自動型

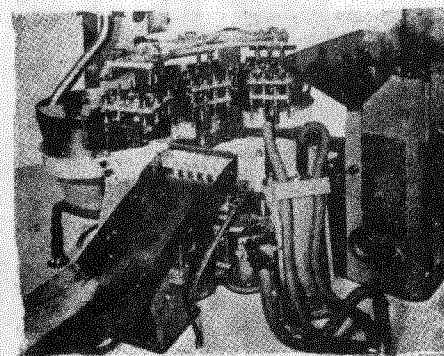


Schematic of Type 8 capsule-filling machine (courtesy Parks-Davis).



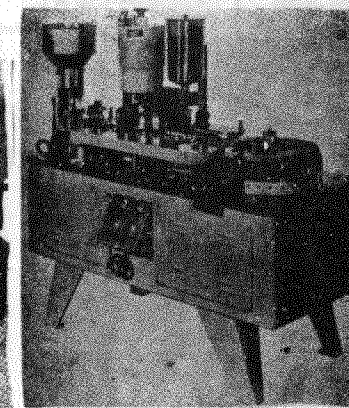
Hoefiger & Karg automatic capsule filling machine, Model GFK 1200 (courtesy, Amasco).

自動膠囊充填機之一



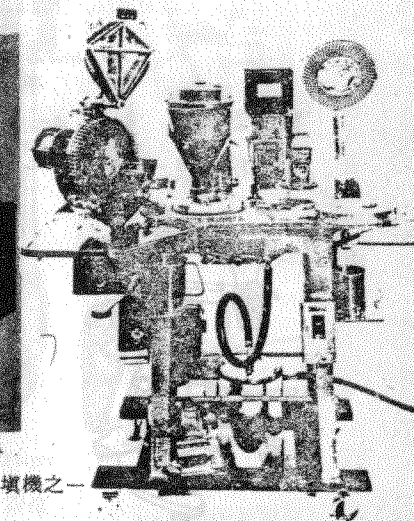
Zansel automatic filling machine, Model AZ-68. The set of filling heads shown at the left collects the powder from the hopper, compresses it into a soft slug, and inserts it into the bottom half of the capsule (courtesy, United Machinery).

自動膠囊充填機之一



MG-2, automatic capsule-filling machine (courtesy, Supermatic).

自動膠囊充填機之一

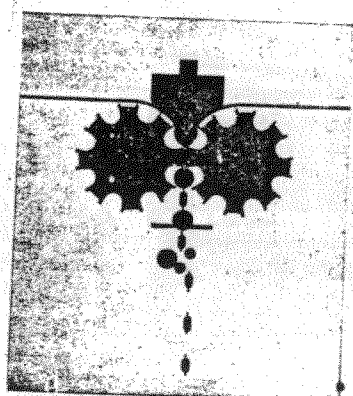


半自動膠囊充填機

Type 8 capsule-filling machine (courtesy, Lilly).

(三) 軟膠囊之製造和充填

- ① 平板法 (Plate Process)
- ② 旋轉模法 (Rotary die Process)
- ③ 迴轉模法 (Reciprocating die Process)
- ④ Accogel 充填機 (可以充填乾粉)。



Rotary die elastic capsule filler.

彈性膠囊旋轉模充填器

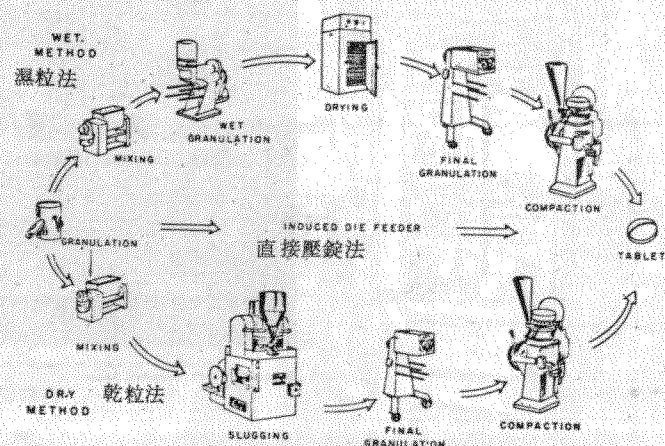
末壓製成適當之給藥劑型。

十、錠劑和包衣

(一) 錠劑

定義：含有一種或多種藥品，加或不加稀釋劑，由細粉混合模製或顆粒性粉末製成。

(1) 壓製錠：可分成乾粒、濕粒和直接壓錠法。



Steps in the manufacture of tablets by wet granulation, dry granulation, and direct compression with induced die feeder. (Courtesy: Cherry-Burrell Corporation)

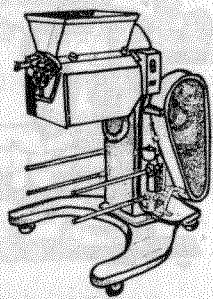
錠劑之製造程序圖

製造器械：

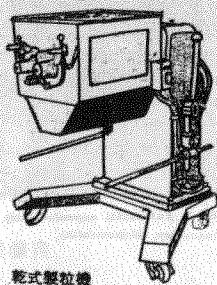
(1) 磨粉器械：見前。

(2) 混合器械：見前。

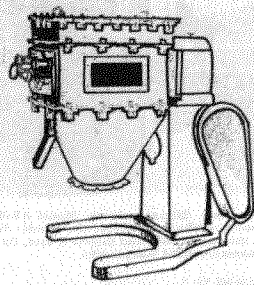
(3) 濕性製粒機和乾式製粒機。



製粒機



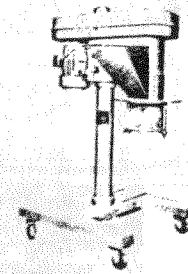
乾式製粒機



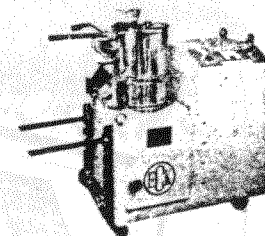
製粒機



造粒機



破碎型造粒機

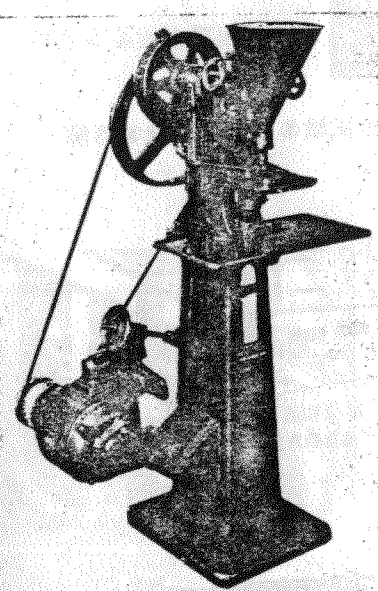


整粒機

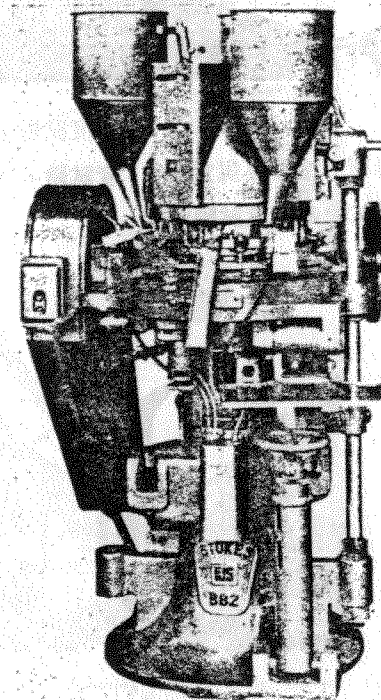
(4) 乾燥器械：見前。

(5) 整粒器械：

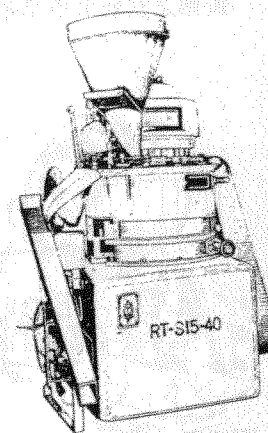
(6) 壓錠器械：① 單銃式 (Single Punch Press) ② 旋轉式 (Rotary Press) ③ 多層錠壓製機 (Multi-layer tableting mechine).



Single punch press. (Stokes, Philadelphia.) 單銃式壓錠機

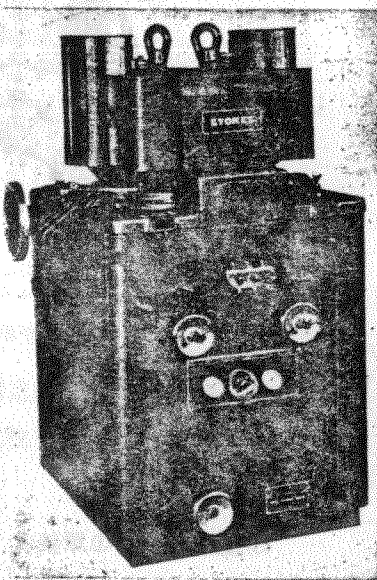
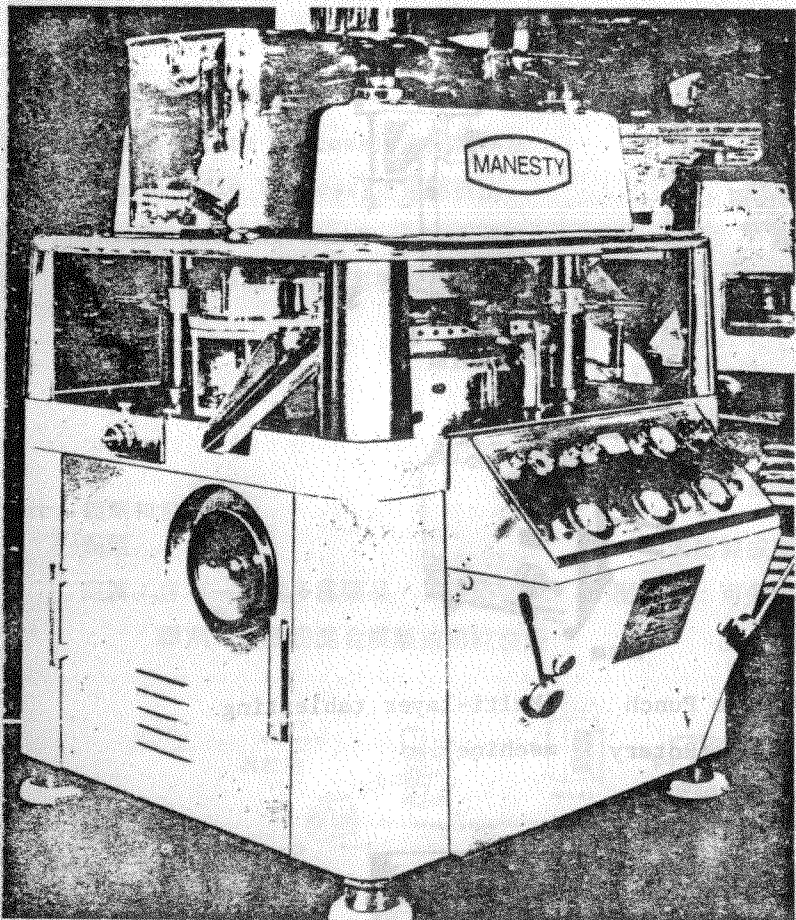


Twenty-seven station, 3-layer rotary tableting machine. (Stokes, Philadelphia.) 三層錠旋轉式壓錠機 27位



強庄回轉式錠劑機

附有多種物理性質控制儀表的高速壓錠表



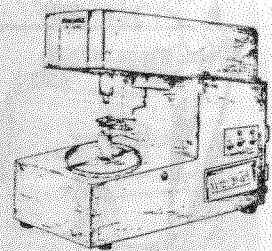
Rotary machine, 41-station. (Stokes, Philadelphia.) 41位旋轉壓錠機

(2)模製錠：略。

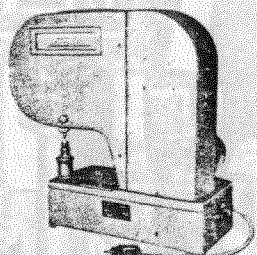
(二)錠劑之物理性質測定器械：按藥典規定，

錠劑之試驗①重量差異試驗②厚度試驗③

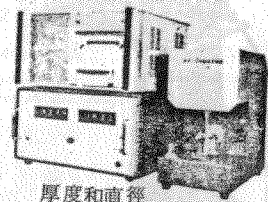
硬度試驗④脆度試驗⑤崩散度試驗⑥溶解度試驗。



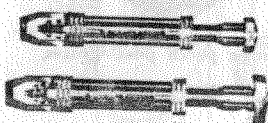
錠劑破壞強度測定裝置



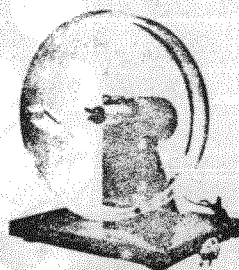
錠劑硬度計



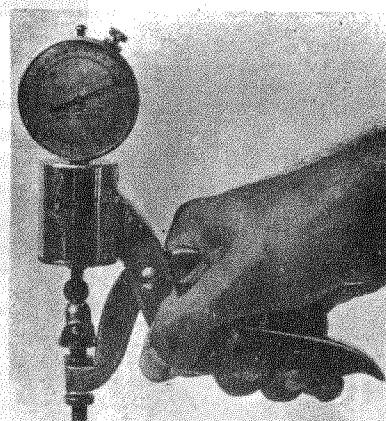
厚度和直徑錠劑寸法自動測定裝置



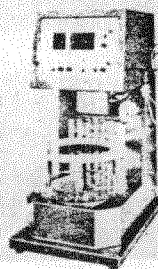
錠劑用硬度計



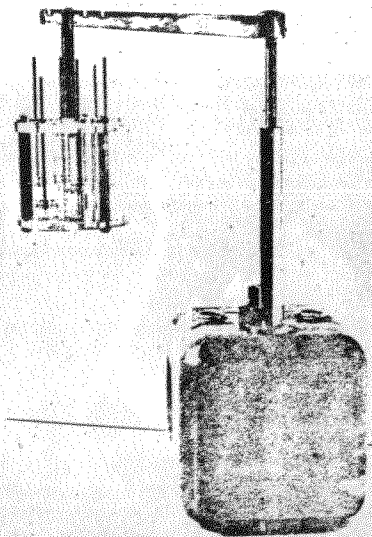
錠劑磨損度試驗器



Pfizer tablet hardness tester. (Courtesy, Pfizer Laboratories) 硬度計



溶解度崩散度併用



Erweka disintegration tester. The apparatus may be used to test the disintegration of coated and uncoated tablets, capsules, and suppositories. (Courtesy, Chemical and Pharmaceutical Industry Co., Inc.) 崩散度計

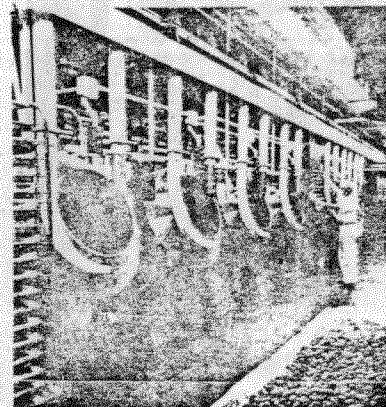
(三)包衣 (Coating)

(1)錠劑之包衣包括糖包衣、改良型糖包衣、膜包衣 (film coating)、壓製包衣 (compression coating).

(2)包衣製造之原則：①鉢式包衣②噴霧包

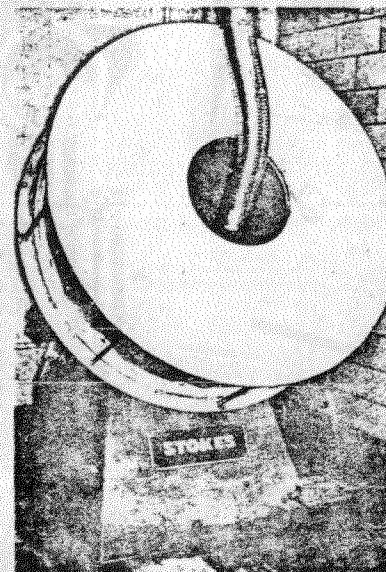
衣③空氣懸液包衣④共聚包衣 (Coacervation coating) ⑤壓製包衣⑥浸入包衣⑦層狀包衣。

(3)包衣製造器械：①包衣鉢②打光機③熱風輸送系統。

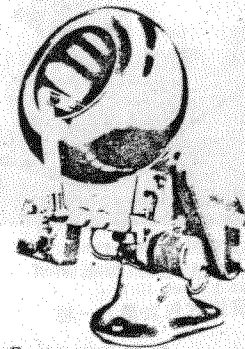


Tablet polishing in canvas-lined pans. Air and exhaust ducts to facilitate drying are automatically operated from central board. Similar pans without canvas linings are used in coating operations. (Courtesy, Eli Lilly and Company)

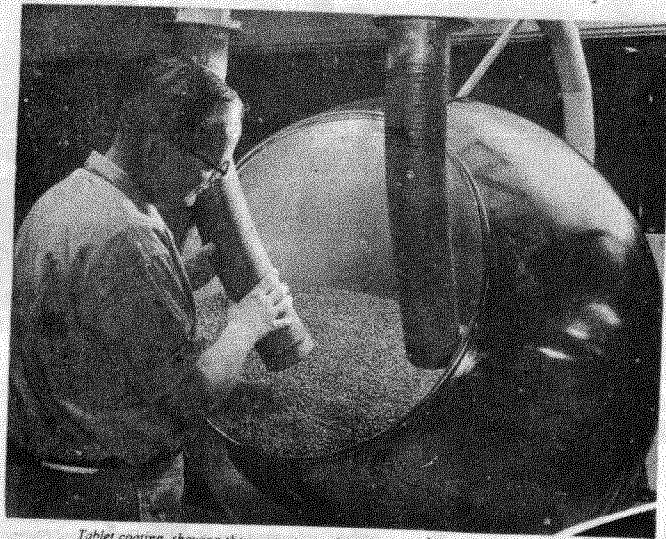
包衣打光操作



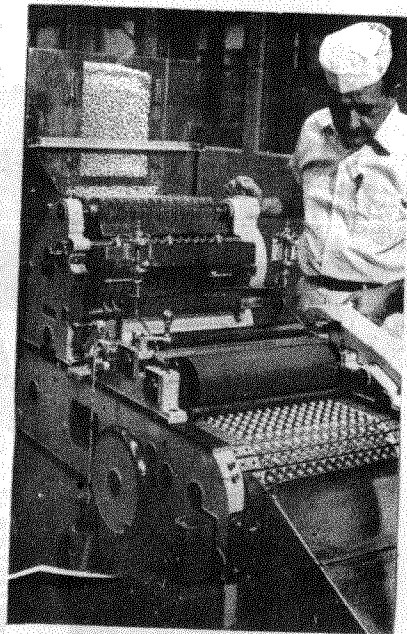
打光鉢 Polishing pan. (Courtesy Warner-Lambert Pharmaceutical Co.)



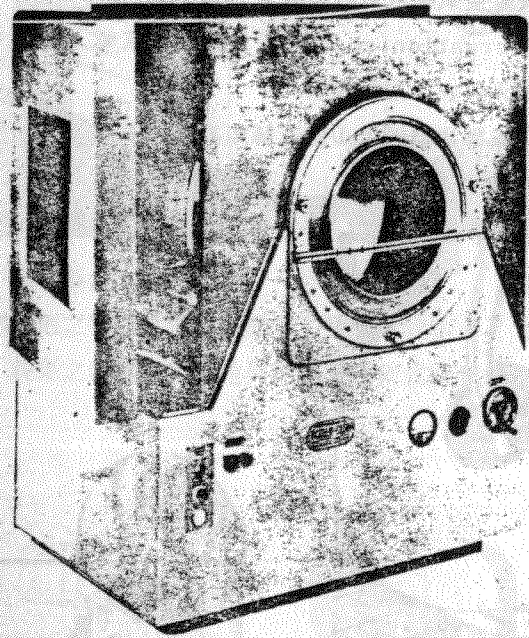
Coating pans. (Courtesy Thomas Engineering, Inc.) 包衣鉢



Tablet coating, showing the warm air supply and the exhaust. (Courtesy, W. H. Laboratories)
包衣之熱流供給和排氣

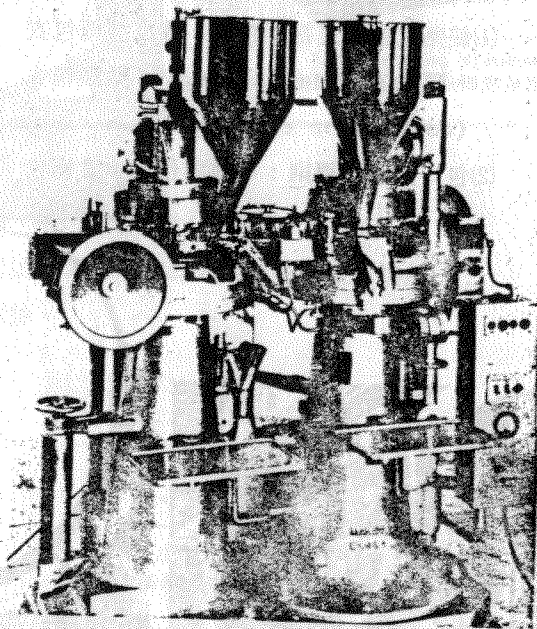


Branding of coated compressed tablets on a Harmer branding machine. (Courtesy, The Upjohn Company)
包衣製錠之蓋商標



Accela-Cota side-vented coating pan. (Thomas Engineering, Hoffman Estates, Ill.)
噴氣式包衣機之一種

The perforated wall of the cylindrical revolving drum can be seen through the open door, with the fixed positioned exhaust plenum shown at the lower quadrant of the drum.



Manesty Bi-cota compression coating tablet machine. (School of Pharmacy, Purdue University)
雙層衣直接壓衣機

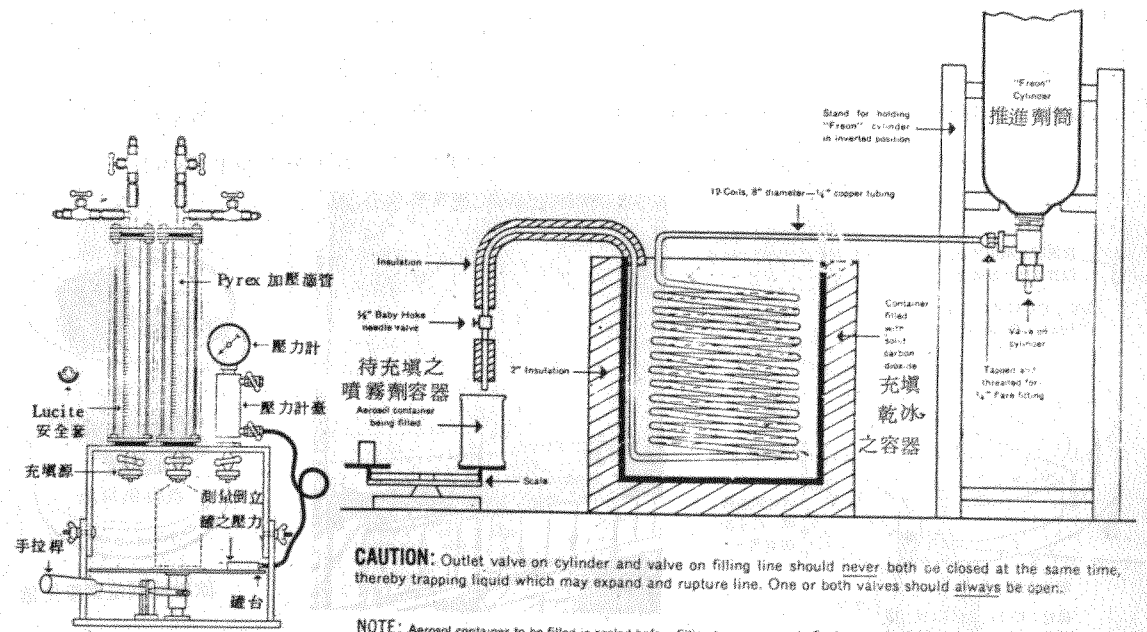
產品經由打開的活門噴出之一種製劑。

製造原則：加壓或冷卻充填。

製造器械：

十一、氣體分散劑：氣化噴霧劑和噴霧劑 (Aerosols & sprays)

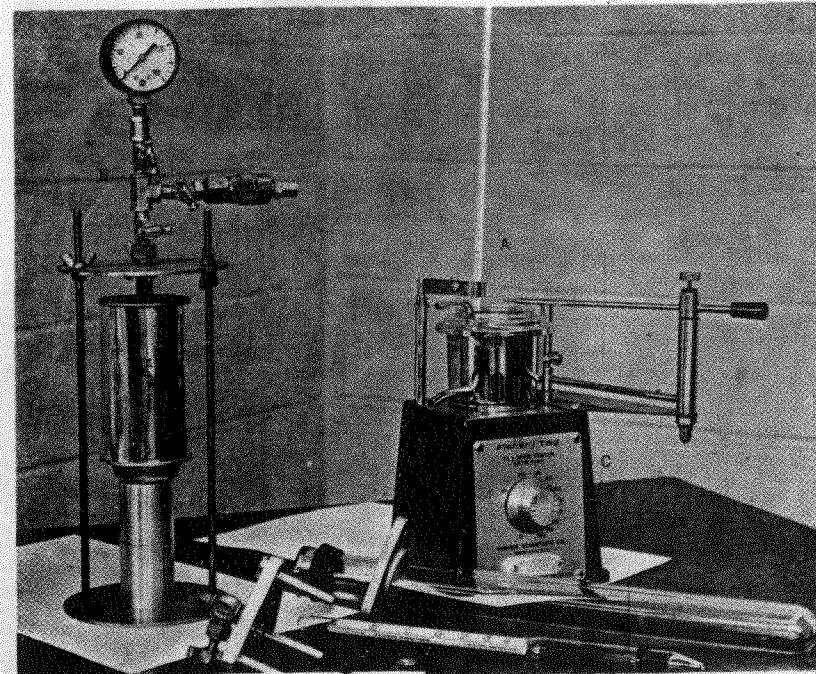
定義：一種含有成品和推進劑的包裝，可把



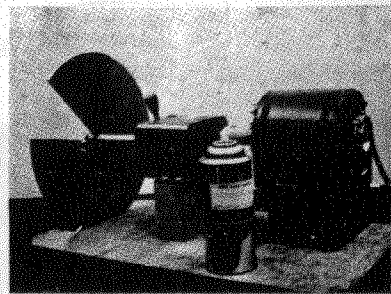
CAUTION: Outlet valve on cylinder and valve on filling line should never both be closed at the same time, thereby trapping liquid which may expand and rupture line. One or both valves should always be open.

NOTE: Aerosol container to be filled is cooled before filling by immersing in finely ground solid carbon dioxide.
氣化噴霧劑之冷卻充填裝置
Apparatus for cold filling process. (E. I. duPont de Nemours and Co., Inc.) 冷卻充填

檢驗器械：檢驗包括①漏氣②壓力③噴出率 ④噴出型式⑤淨重⑥水份含量⑦ 毒性……等。



著火溫度、壓力、密度測定器
Flash point (A), pressure determination (B), and density apparatus (C).



Determination of spray patterns.
噴出型式測定器

十二、放射性藥劑：

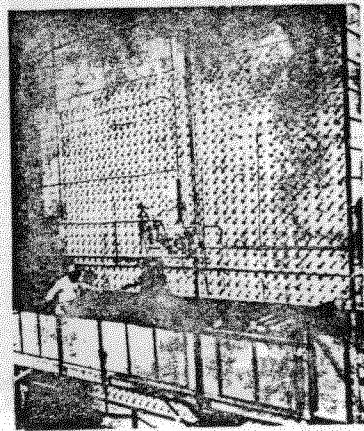
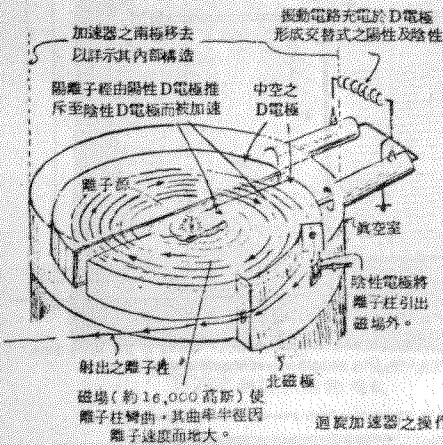
定義：指含有特殊放射性藥物的劑型。

製造：①質粒加速器 (Particles accelerators)，製造缺中子放射核。

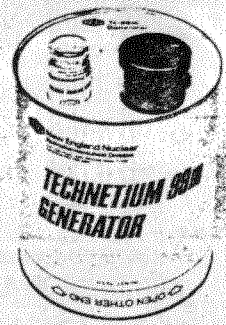
②核反應器 (Nuclear reactors)，

製造多中子放射核。

③同位素產生器 (Isotope generators)。(Radio-Istop Cow)



核反應器



放射性同位素產生器

十三、滅菌製劑：

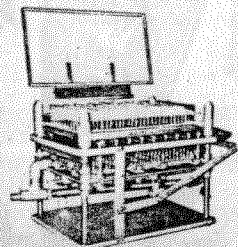
定義：供注射用、眼用或灌洗用之製劑。

製備場所：①純水製造室②容器洗淨室③藥液調製室④充填熔封室⑤無菌室⑥滅菌室⑦檢驗室(各室相隣以

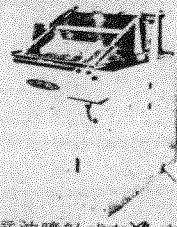
利一貫作業生產)。

製造器械：①注射用水生產裝置：詳前。

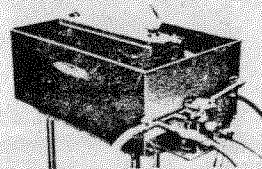
②洗淨裝置(注射瓶、安瓿洗淨器)。



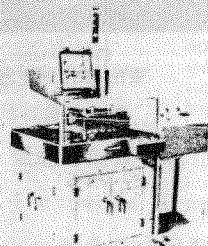
噴射式安瓿充洗機



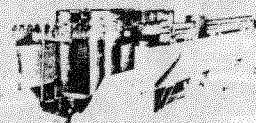
超音波噴射式安瓿充洗機



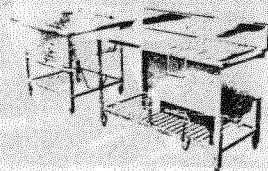
眼藥水瓶噴射式洗淨機



噴射式自動安瓿充洗機



噴式且旋轉型

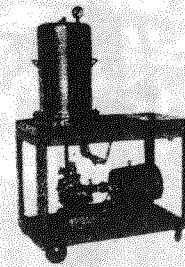


盒式加熱型

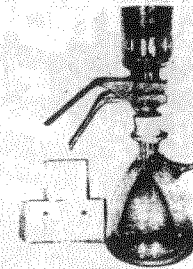
③燒瓶、量桶……等。

④天平(上皿天秤、毒藥天秤……等)

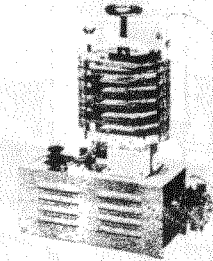
⑤過濾裝置(漏斗、玻璃斗、細菌過濾器、脫脂棉、紗布、濾紙、吸引裝置……)。



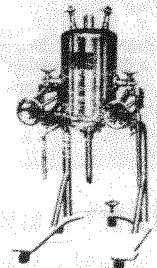
熱原濾過器



膜濾器

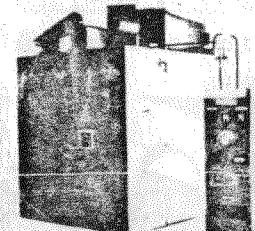


板式膜濾器



滅菌濾過器

⑥容器乾燥器



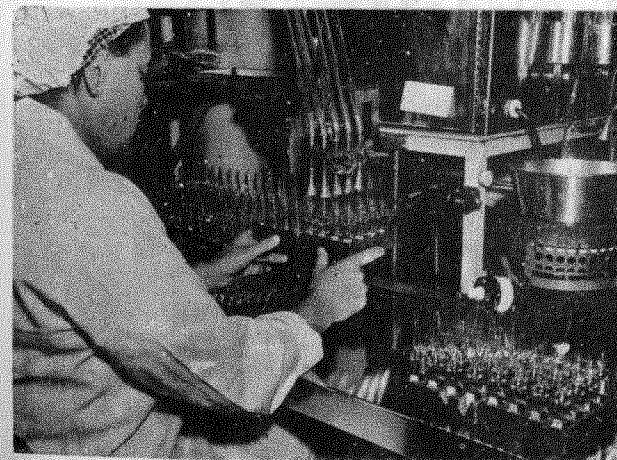
熱風循環式乾燥機



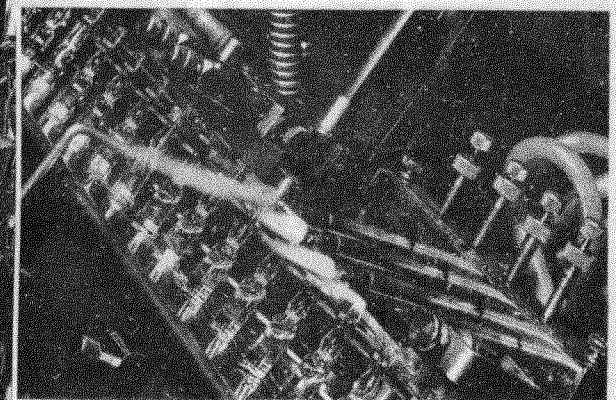
自動滅菌乾燥機

⑦充填裝置(安瓿充填機)

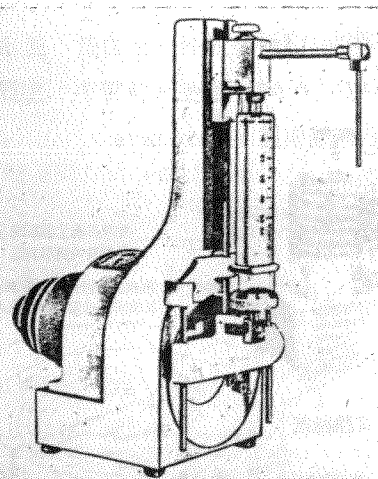
⑧熔封裝置(安瓿熔封機)



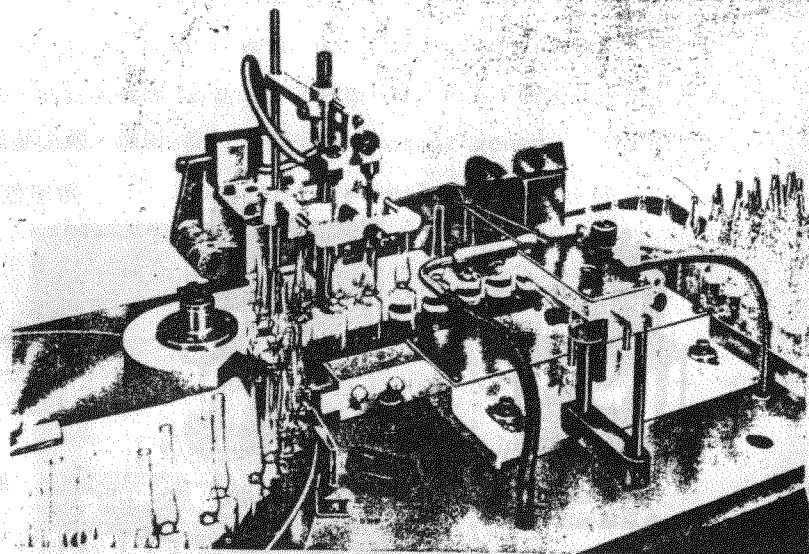
Ampul filling. (Courtesy, Abbott Laboratories) 安瓿充填器



Ampul sealing. (Courtesy, Abbott Laboratories) 安瓿熔封器



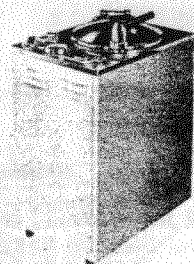
A simple but efficient ampul-filling machine which measures one volume at a time. (Popper and Sons, Inc., 300 Fourth Avenue, New York) 單一安瓶熔封器



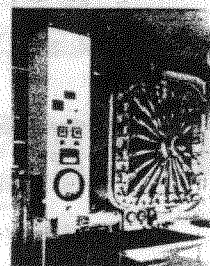
Automatic ampul-filling and-sealing machine which mechanically fills, flushes with inert gas, pull-seals and ejects the ampuls. (Popper and Sons, Inc., 300 Fourth Avenue, New York) 自動安瓶充填、熔封器

③滅菌裝置（高壓滅菌器、流通蒸氣滅菌器、乾熱滅菌器、無

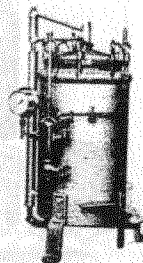
菌操作箱、殺菌燈、過濾滅菌器……等）。



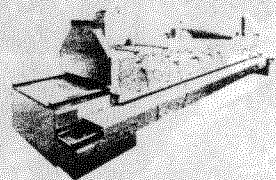
高壓滅菌器 整型KT-20



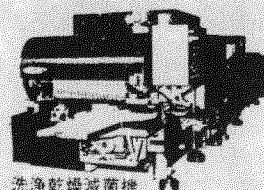
用自動高壓蒸氣滅菌器



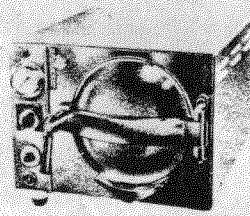
高壓滅菌器 電氣加熱式



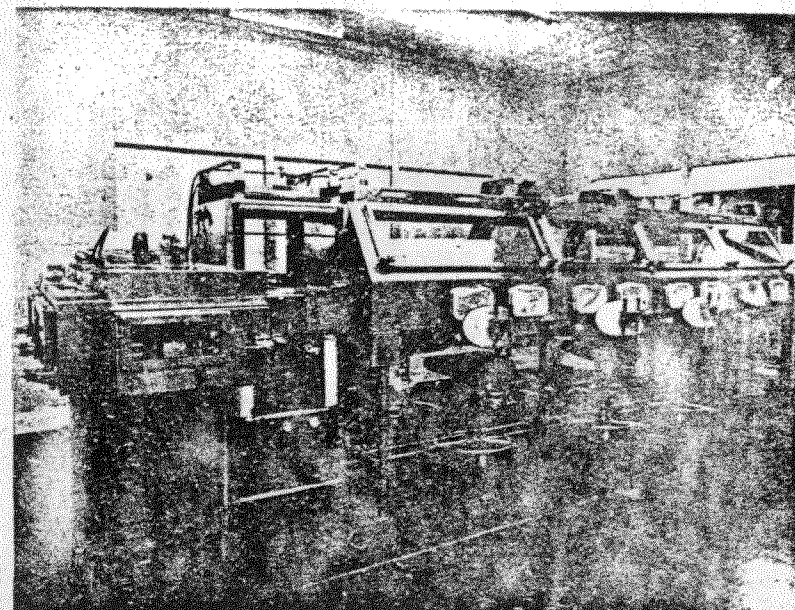
乾熱滅菌機



洗淨乾燥滅菌機



高壓滅菌器 橫型KY-20

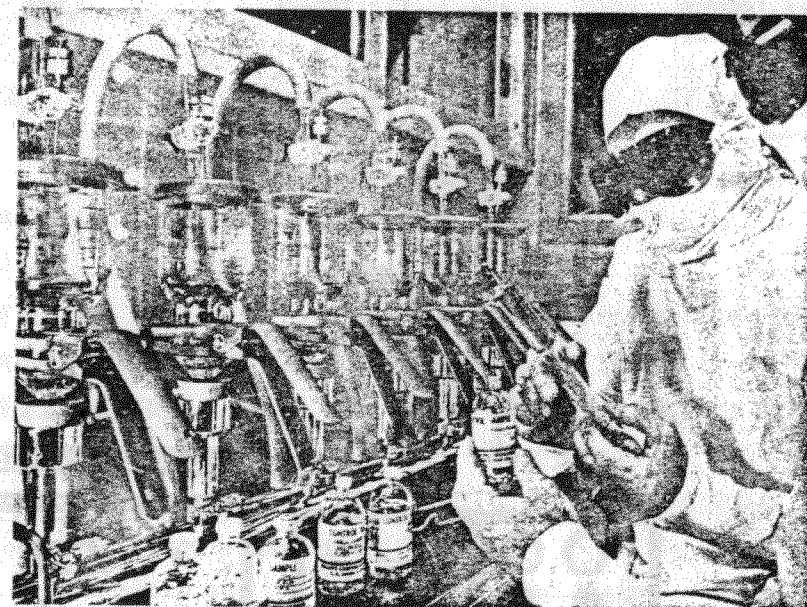


A clean room, showing an enclosed cabinet in which filling and sealing operations are performed. (Courtesy of Schering-Plough Corporation) 無菌安瓶充填熔封箱

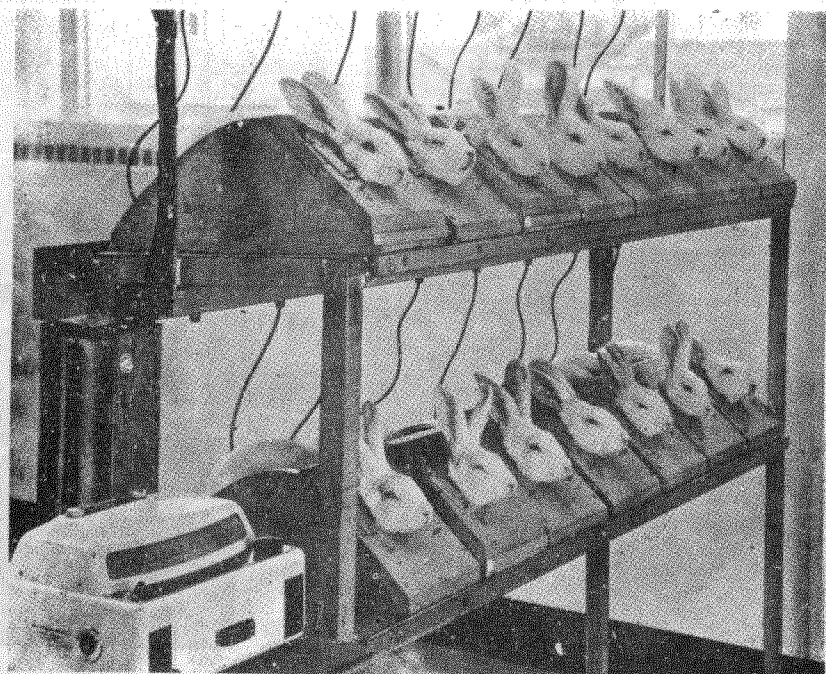


無菌操作服

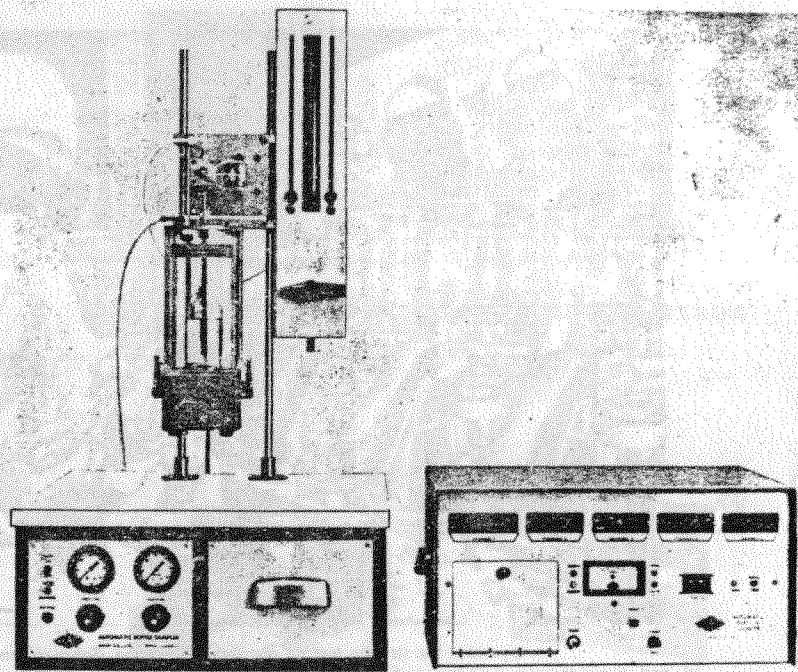
檢驗裝置：①洩露檢查(Leak Testing) ②熱原試驗(Pyrogen Test) ④清滅菌檢查(Steriling Test) ③潔度檢查(Clarity Test)。



Apparatus for sterility test by membrane filtration. Solutions are added to flasks and passed through 0.22-micron filters. The filters are then transferred to sterile culture media to determine if microorganisms are present on the filters. (Courtesy of Millipore Corp.) 膜濾滅菌器

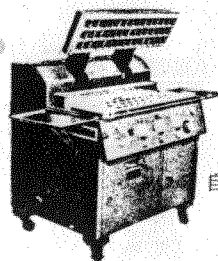


Rabbits being subjected to a pyrogen test with temperatures being taken by rectal thermocouples connected to an electric thermometer. (Courtesy of Wyeth Laboratories.)
熱原試驗

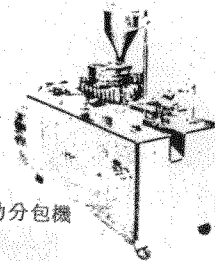


An electronic counter used for monitoring particulate matter. (Courtesy of High Accuracy Products Corporation)
異物試驗

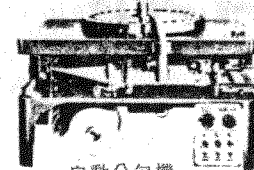
十四、附(-)：包裝機器



自動包裝機
之一 自動分包機



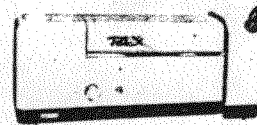
自動分包機



自動分包機

附(=)：其他器械

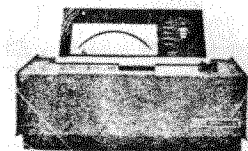
偏光計



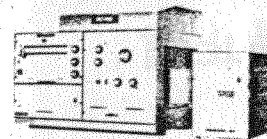
發光光度計



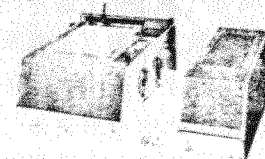
分光光度計



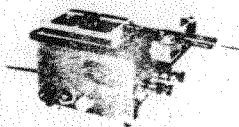
分光式自記濃度計 SD-92型



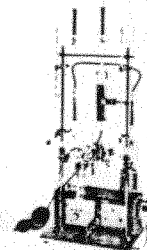
臺灣赤外分光光度計 IR-400形



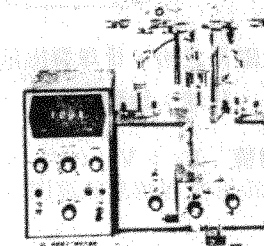
雙光束分光光度計 UV-200



微量注射器



Karl Fischer's
水分自動滴定器



(7) Remington's Pharmaceutical
Sciences 15th ed.

後記

本稿之完成得感謝下列諸先生及其著作

- (1) 黎漢德、林宗旦老師率領敝班同學參觀藥廠。
- (2) 黃占甲：藥劑學
- (3) 劉正雄：新藥劑學
- (4) Lewis W. Dittert: Sprowls American Pharmacy 7th ed.
- (5) Joseph B. Sprowls: American Pharmacy 6th ed.
- (6) Leon Lachman: The theory and Practice of Industrial Pharmacy 1st ed.
- (8) Howard C. Ansel: Introduction to Pharmaceutical Dosage Forms 1st ed.
- (9) 日本藥科機器協會編：N Y K '72 藥科機器總覽
- (10) 不破龍登代等：最新藥劑學 第2改稿版
- (11) 內藤俊一：錠劑——藥劑學理論應用 初版

又本稿承黎漢德老師代為校正謹表謝意。