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THE DESIGN AND PERFORMANCE OF AN INSTRUMENTATION SYSTEM FOR AQUEOUS FILM COATING IN AN INDUSTRIAL TABLET COATING MACHINE

G.C. Cole, G. May, P.J. Neale, M.C. Olver
Merck Sharp & Dohme Research Laboratories,
Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU

and K. Ridgway
School of Pharmacy, University of London,
29/39 Brunswick Square, London, WC1N 1AX

ABSTRACT

In recent years tablet coating has undergone several fundamental changes. The original sugar coating technique has been largely replaced by film coating processes using organic solvents. The organic solvents are now being replaced by water because of the development of suitable polymers, improvements in the coating process, and impending government legislation regulating the discharge of pollutants into the environment.

This change has resulted in increased interest in equipment designed for film coating based on cylindrical shaped side vented pans which allow the drying air to be drawn through the tablet bed. However, the process is complex and requires careful monitoring and control to ensure satisfactory results. The empirically derived conditions are not fundamentally understood and there are important differences in the operation

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of the commercially available equipment. This paper describes the instrumentation and performance of one of these systems. It illustrates how considerable process improvements can be made and how changes in parts of the equipment can provide a reduction in the overall coating cycle.

An integrated computer controlled instrumentation system has been designed for the aqueous film coating process in the Manesty Accela-Cota so that it provides improvement in the operation of the process and offers an alternative spraying and control system to that provided by the Manesty Co-Tab Unit and Walther spray guns.

All the major operational coating parameters can be measured and recorded under the overall control of a PET 3032 micro computer. The monitored values are displayed on a computer screen at selected short intervals, e.g. 5 seconds. At selected longer intervals, e.g. one minute, they are printed as hard copy by an Anadex D.P. 8000 printer.

This paper describes the selection of instruments to measure the appropriate parameters and how the coating process may be optimised using a Manesty Model 10 Accela-Cota.

It will be shown how this original concept was simplified and modified on scale up to successfully control the coating of a batch size of 50-60 kg in the model 75 coating pan and in the model 350 with a batch size of 350 kg.

INTRODUCTION

In the last twenty-five years tablet coating has undergone several fundamental changes. Coating of tablets and pills is one of the oldest techniques available to the pharmacist and references can be traced as far back as 1838 (1). The sugar coating process was regarded as more of an art than a science and its application and technology remained secretive and in the hands of a very few. Although a very elegant product was obtained its main disadvantage was the processing time which could last up to five days. Many modifications were advocated to improve the basic process such as air suspension techniques in a fluidised bed, the use of atomising systems to spray on the sugar coating, the use of aluminium lakes of dyes to improve the evenness of colour and more efficient drying systems. However the process remained complicated. Generally the sugar coating process resulted in the weight of the core being doubled but the use of spraying systems enabled this increase to be reduced dramatically.

The first references to tablet film coating appeared in 1930 (2) but it was not until 1954 that Abbott Laboratories produced the first commercially available film coated tablet. This was made possible by the development of a wide variety of materials such as many cellulose derivatives. One of the most important of these is Hydroxypropyl Methylcellulose which is prepared by the reaction of methyl chloride and propylene oxide with alkali cellulose. The 50 cps type is generally used in organic solvents at a concentration of between 2 and 4 per cent w/v.

Many advantages can be cited for film coating in place of the traditional sugar coating process:

1. Reduction in processing time, savings in material cost and labour.
2. A very small increase in the tablet weight.
3. Standardisation of materials and processing techniques.
4. The use of non-aqueous coating solutions and suspensions.
5. The tablets could be engraved with a code and house logo which remained legible after coating. Many sugar coated tablets were printed with a house symbol, name of product, or code after coating. This was a difficult and costly process which added nothing to the value of the product.

During this period the lower viscosity (3-15 cps) polymers of Hydroxypropyl Cellulose did not receive much attention because of the cheapness of organic solvents and the ease with which the coating could be applied. However in recent years this trend has changed and the use of aqueous coating has become more widespread.

There was also a belief that the lower viscosity grades produced weaker films which would not meet a formulators requirement for stability and patient acceptability. Coating may also be used to improve the handling of a product on a high speed packaging line and improve the marketing presentation by eliminating objectionable dust that may act as an irritant. If coloured it can stain clothing or the product container such as blisters, resulting in an unattractive pack. However, there is now a trend towards aqueous film coating for the following reasons:-

1. The cost of organic solvents has escalated.
2. A number of regulatory authorities are considering banning halogenated hydrocarbons because of environmental pollution.
3. The development of improved coating pans and spraying systems has enabled more difficult coating materials to be applied.
4. Flameproof equipment is not required which reduces capital outlay and a less hazardous working environment is provided for the operator.

Most of the early development work for aqueous film coating concentrated on the use of existing conventional coating pans and tapered cylindrical pans such as the Pellegrini,[(3)]. This pan is open at front and rear, and the spray guns are mounted on an arm positioned through the front opening. The drying air and exhaust air is blown onto the surface of the tablets and due to the power of the extraction fan most of the heat is lost with the exhaust air. Very poor thermal contact results and when tablets are aqueously film coated a very poor finish is obtained. The perforated coating pan which permits the drying air to be drawn through the pan and through the tablet bed during film coating offers better heat transfer and a more efficient coating process.

There are several companies which offer equipment of this type; the Manesty Accela-Cota[4], the Driam Driacoater[5] and the Freund Hi-Coater[6] are the three best known. There are significant differences between each of them. The Manesty Accela-Cota was chosen for the early experimental work because of its availability and the initial investigational experimentation was very encouraging. The processing time was reduced to between one and two hours depending on the product and an elegant coated tablet was produced which compared favourably with examples of the solvent coated tablets. However, concern was expressed over the large volumes of drying air required and the energy required to heat this air.

The Accela-Cota suffered from the disadvantage that very few instruments were incorporated into the machine and its accessories for measuring the parameters necessary for film coating. For instance the drying air flow measurement was taken from the exhaust fan rating. It was not possible to determine how much air was being introduced from the inlet side of the pan and how much was being drawn into the pan from the environment through leakage. The temperature of the exhaust air was measured but not the bed temperature or the humidity of the exhaust air. The spray rate was calculated using the coating reservoir positioned on a balance and the average rate calculated over a period of several minutes.

In an attempt to resolve these unknowns and to design a completely automated process and develop a better understanding of aqueous film coating a project team was set up in collaboration with Manesty Machines Ltd.

EXPERIMENTAL

The experimental programme was divided into four parts:-

A. Formulation and preparation of placebo core tablets.

B. Formulation and preparation of aqueous film coating suspension.

C. Selection and installation of instrumentation including the Programming of the Computer and printer. Description of Accela-Cota and Instrumentation.

D. Experimental film coating.

A. Preparation of placebos

To ensure that the coating conditions were not affected by changes in the physical characteristics of either the core tablet or the film coat, two standard batches of tablets were prepared from 8 sub-lots using the following formulation and method.

Formula	Unit Weight
Calcium Phosphate Dibasic Hydrous U.S.P.	416.57 mg
Ethyl Cellulose N.F. N100	28.0 mg
Alcohol, Ethyl Absolute	q.s.
Guar Gum	15.0 mg
Solka Floc Dev. 2030	12.0 mg
Aerosil	2.0 mg
Magnesium Stearate U.S.P.	1.43 mg
Tablet Weight	475.00 mg

Eight sub-lots of 30 kg were prepared using a Diosna P100 mixer granulator[7] and an Aeromatic fluid bed drier Model S3[8] 12.7 litres of absolute alcohol per 1.0 kg of ethyl cellulose were used to prepare the granulating solution. Four sub-lots were blended into one master batch.

The tablets were compressed to the following core specification:

Weight: 475 mg (10 tablets 4.75 g Range 4.66-4.86)
Thickness: 4.5 mm (Range 4.38-4.62 mm)
Hardness: minimum 10 kg on the Heberlein scale, maximum 15 kg
Disintegration: maximum 15 minutes B.P. method

Each sub-lot was inspected visually for defects (200 tablets) and from tests on the compressed tablets they may be characterised as follows:-

Tablet Weight (Range) mg	Average Weight mg	Coefficient of Variation	Moisture Content range percentage Karl Fischer
469-490	472	1.3	2.5-4.0

Hardness Heberlein Kp (Range)	Friability percentage loss (Range)	Thickness mm (Range)	Disintegration minutes
11.5-14.0	0.6-1.1	4.50-4.59	All within 4 mins.

B. Preparation of coating suspension

Sufficient coating suspension to coat 240,000 tablets was prepared using the following formulation:

Formula

Ingredients	Per Tablet
Hydroxypropylmethylcellulose 6 cps USP	7.35 mg
Propylene Glycol USP	1.22 mg
Titanium Dioxide USP	1.15 mg
Tartrazine F.D. & C. Yellow No. 5 Aluminium Lake (24 per cent pure dye)	0.088 mg
Propyl Hydroxybenzoate	0.016 mg
Methyl Hydroxybenzoate	0.12 mg
Purified Water	q.s.

The parabens were dissolved in water at 60°C. The H.P.M.C. was added and allowed to stand overnight. A high speed Silverson mixer Model AX[9] was used to disperse the titanium dioxide, talc and dyes.

C. 1. Description of Accela-Cota and Instruments.

2. Instrumentation and Computer Programme.

Accela-Cota.

Initial work was carried out on a model 10 (24 inch) Accela-Cota with larger scale experiments in the model 75 (36 inch) and model 350 (60 inch). The model 150 (48 inch) is shown diagrammatically in Figure 1.

Essentially the Accela-Cota consists of a cylindrical drum with the flat perforated periphery section mounted horizontally above the drive rollers. The perforations extend over the whole of the flat circumference of the pan. This is an important difference between the Accela-Cota and the other coating pans of similar design e.g. the Hi-Coater, the Driam Driacoater and the Pellegrini.

The Accela-Cota and Hi-Coater are both designed so that there is consistent and complete control of the flow pattern of the drying air and the tablet movement. In the Accela-Cota the periphery of the rotating pan is perforated, and by locating an exhaust plenum outside this perforated section it is possible to draw the drying air through the batch of tablets to provide even and consistent drying throughout the bed. Since all tablet surfaces are equally exposed, the danger of dead spaces within the pan is eliminated. The spray guns are positioned to ensure concurrent spraying with the drying air.

One important feature of the Accela-Cota is the construction of the drum. The angle of the front and rear sides of the pan are 56° and 61° respectively and this was originally intended to ensure complete mixing of the tablets from the top of the bed to the bottom and from front to rear. However, it was found that this was insufficient to ensure homogeneous mixing and baffles were fitted. Generally, they are of the same shape but of different size for each model and can be easily removed or replaced with different designed baffles depending on

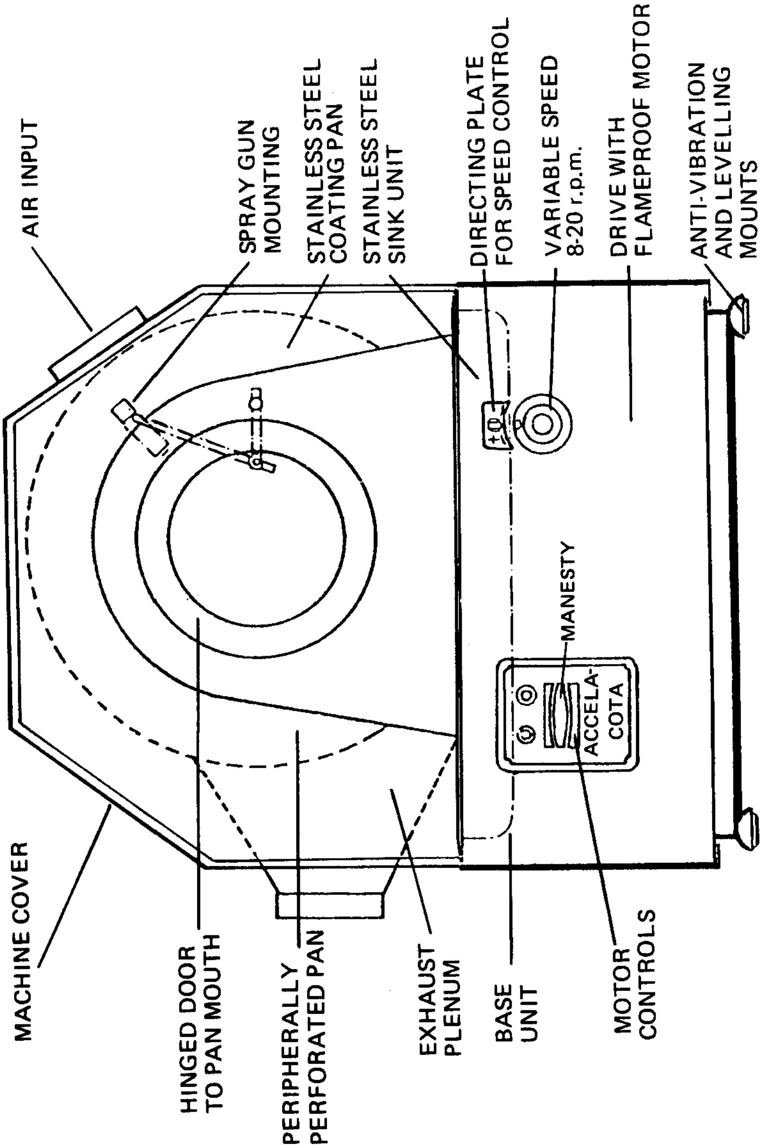


FIGURE 1

Manesty Model 150 Accela-Cota.

the physical characteristics of the tablet to be coated e.g. friability.

Co-Tab Unit.[4]

A diagrammatic sketch of the functions of the Co-Tab Unit is shown in Figure 2.

The Co-Tab Unit has been specially designed for the application of aqueous film coating solutions and suspensions. The Unit is housed in a cabinet which contains the pump and all the necessary regulators together with the controls and gauges.

The controls are mounted on the top face of the Co-Tab Unit and comprise gauges for pump air pressure, fluid pressure and atomising air pressure. Below each gauge is the regulator which controls the circuit to which the pressure gauge applies. The adjustment is effected by rotating the main control knob of each regulator whilst the adjustment is secured by the inner lockscrew. On the panel there are also two valves controlling the flow and return of coating solution.

The operation of the Unit is briefly as follows:-

Compressed air is supplied to the air inlet manifold and from there to three different internal supplies. One supply passes through an air pressure regulator to the liquid pump and the pressure of this air is shown on the pump air pressure gauge. This pressure governs the pressure of the liquid. The pump has an operating ratio of 2:1 and, therefore, the liquid on the discharge side of the pump is at a pressure twice that shown on the pump air pressure gauge. A second air supply passes through a regulator which controls the atomising air pressure gauge and the air is then supplied direct to the atomising air connection on the spray bar in the Accela-Cota. Also connected into this circuit is a pressure stop valve which controls the signal air to the spray bar.

The third air supply taken from the air inlet manifold passes through an air pressure regulator which feeds air to two

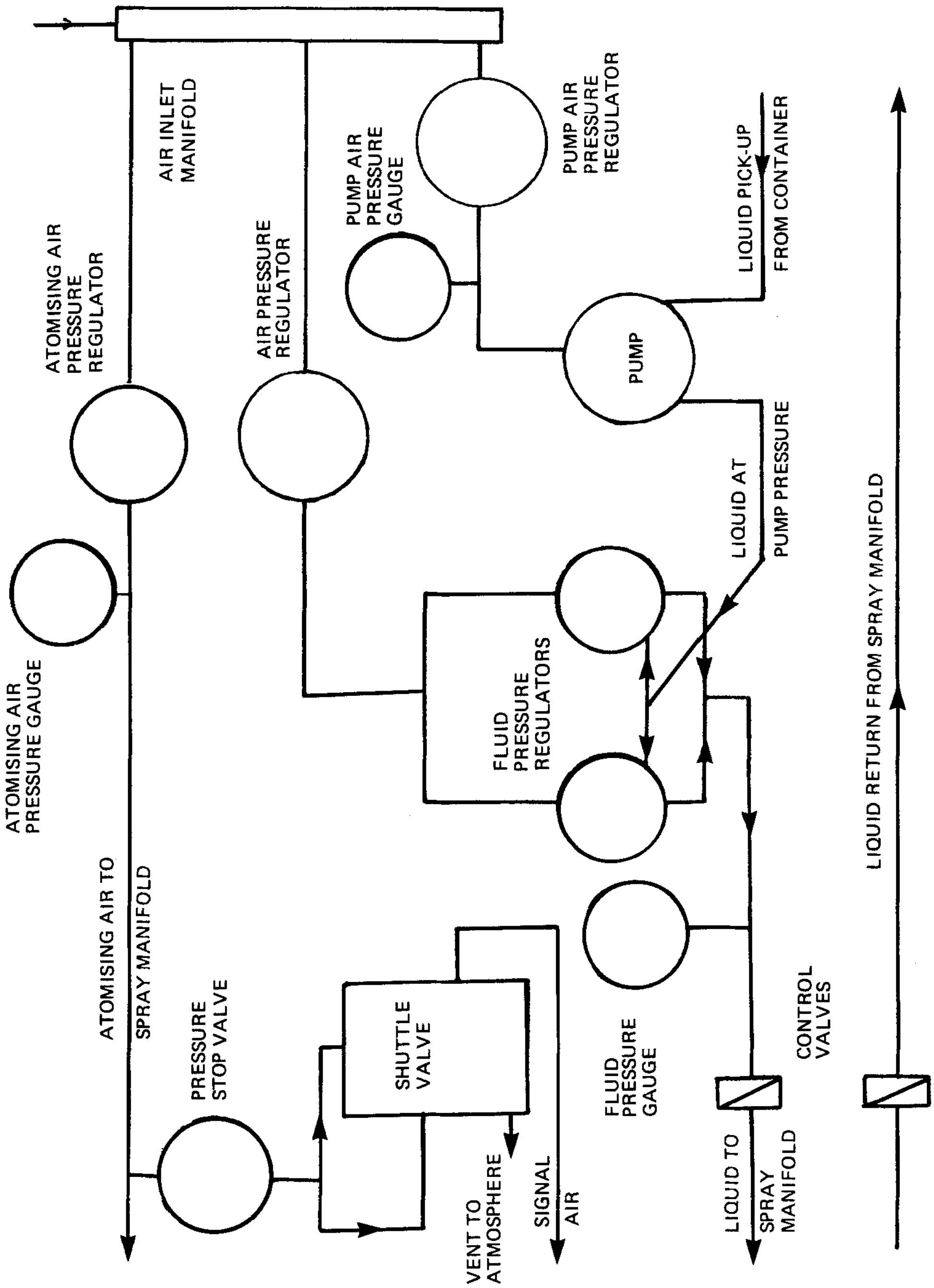


FIGURE 2

Diagrammatic sketch of functions of Co-Tab Unit.

air controlled diaphragm type fluid pressure regulators. Two regulators are necessary to supply the relatively large volumes of fluid used on the larger models of Accela-Cota. This method of control has been employed so that there is no differential in pressure between the outputs from the two regulators.

Coating fluid is picked up from the container by an air operated pump, and pumped at pressure to the fluid pressure regulators where the supply pressure is controlled and maintained. This pressure is shown on the fluid pressure gauge. The coating solution is then fed through a valve to the Accela-Cota spray bar and is allowed to circulate returning by means of a second pipe, through a second valve, to the solution container. In the case of low viscosity liquids, the return control valve can be used to create a necessary back pressure in the system to keep the flow rate constant.

The spray bar fitted to the model 150 Accela-Cota consists of three chambers one of which contains the coating fluid, one the atomising air, and one the signal air. The spray guns are mounted directly on the chamber which contains the coating solution and separate pipe connections are made between the gun and the two air chambers.

The Walther Pilot WA XV Automatic Spray Gun[(4)] is an automatic unit with micro adjuster for spraying. Connections are provided for the supply of coating solution, atomising air, and signal air.

The gun is constructed of light metal alloy with nose piece, nozzle needle and a material hose connection piece of stainless steel. A micro spray control is fitted with a counterscrew to provide additional air control of the round spray. A flat fan spray configuration is the conventional spray used.

PET computer 3032 series[10]

This is a multifunction desk-top computer. The language used is extended basic and its memory has a capacity of 32K words. The PET can be used to generate graphics plus alpha numerics.

Dew Point Hygrometer. Model 1100AP[11]

The hygrometer used in these experiments was of the optical condensation type. In this instrument a surface is cooled by a thermoelectric or Peltier cooler until dew or frost begins to condense on a mirror. The condensate surface is maintained electronically in vapour pressure equilibrium with the surrounding gas, and surface condensation is detected by an optical or an electrical technique. The condensation surface, when maintained at the temperature at which the rate of condensate exactly equals the evaporation is then the dew point temperature. Such a sensor is a fundamental measuring device. The temperature of the surface when so controlled is typically measured with a platinum resistance thermometer, thermocouple or thermistor embedded in the mirror surface.

The main drawback of this type of hygrometer is its complexity and higher cost when compared to most other humidity sensors. It is also subject to contamination by materials other than water condensing on the cooled surface.

Pitot Tube - Furness FC050 Differential Pressure Transmitter[12]

Pitot tubes determine local or point velocities by measuring the difference between impact pressure and static pressure. The pitot we used was connected to a low pressure transmitter which operates on a diaphragm capacitance principle.

Two pressure cavities are separated by a taut metal diaphragm with an electrode supported close to it on either side producing two air di-electric capacitors. A pressure difference between the cavities deflects the diaphragm changing the capacitance of the circuit. The volume displacement for full scale deflection is typically $0.003cm^3$.

The capacitors on either side of the diaphragm form two tuned circuits with inductors in the circuit board. These tuned circuits are equally coupled to an R.F. transistor oscillator which provides a stable signal. A change in the transducer alters the capacitance in each of the tuned circuits unbalancing the voltages across them. A differential rectifier voltmeter across the tuned circuits provides a D.C. signal from the change in pressure in the transducer. This transmitter has an output of 0-10 V. which is linear with respect to the air velocity.

The pitot tube consists of an impact tube whose opening faces directly into the stream of air to measure the impact pressure. It is sited in a section of duct at least 10 diameters from any bends or disturbances. It is very sensitive to its position in the cross sectional area of the duct.

Anaspec Analogue to Digital Converter [13]

This is an interface designed to accept data in one format and transmit data in another. The PET computer requires data to be presented in a correct and logical format. The Anaspec is one peripheral which is compatible with the PET system.

Compu/Think dual drive floppy disc unit [10]

This is a high speed data storage peripheral. A total of 343K bytes can be stored in two standard 5.25 inch discettes without using double density or double tracking techniques. Process data was printed out as a hard copy using an Anadex printer model BP-800. [14]

Infratrace - A non contact infra-red digital thermometer [15]

The Infratrace is simply aimed like a pistol at the target area using the two sights and triggered. It can also be used to measure and record temperatures through glass by using the correct emissivity setting.

Davis Telemeter [16]

The D.T.L. short range telemetry system is used to measure strains and temperature. It consists of a SO 1-22 oscillator and a SD 1-22 discriminator. It was used to measure shaft torque on the coating pan of the Accela-Cota. The oscillator and its battery are connected to a suitable strain gauge bridge fixed to the shaft. The earth side of the battery is also connected to the shaft, and the output from the oscillator taken to a metal band fitted around the shaft, but insulated from it.

C. 2. Instrumentation and Computer Programme

The original intention was to measure the following parameters:-

1. Inlet air flow rate
2. Inlet air temperature
3. Inlet air humidity
4. Outlet air flow rate
5. Outlet air temperature
6. Outlet air humidity
7. Leakage air rate to the atmosphere through the casing (by difference 1-4)
8. Spray concentration
9. Spray temperature
10. Spray flow rate
11. Filter exhaust air for attrition from cores
12. Filter exhaust air for spray not applied to tablets
13. Tablet bed temperature
14. Power/torque to keep the drum turning
15. Rotational speed of the drum
16. Electrical power consumption of fans
17. Heat input to inlet air (as a check)
18. Pressure drop, inlet - outlet air stream
19. Atomising air pressure.

As the result of a number of preliminary experiments a programme was written which linked the instruments through an analogue to digital converter to the PET computer and printer to measure and record the following parameters. These parameters were considered to be those which would critically affect the appearance of the film coated tablet. There are fifteen channels on the converter and a voltage reference source. The numbers refer to the channels on the converter.

Channel		
0	Coating spray rate	grammes per minute (g.p.m.)
1	Inlet air flow rate	cubic feet per minute (c.f.m.)
2	Inlet air temperature	Degrees Celsius (°C)
3	Outlet air flow rate	(c.f.m.)
4	Outlet air temperature	(°C)
5	Outlet air dew-point	(°C)
6	Fan rotational speed	revolutions per minute (r.p.m.)
7	Coating drum drive torque	pounds per foot (lb-ft)
8	Coating suspension temp.	(°C)
9	Tablet surface temp.	(°C)
10	Atomising air pressure	pounds per square inch (p.s.i.)
11	Not used	
12	Not used	
13	Not used	
14	Not used	
15	10-volt reference source	

Because of the problems of obtaining reliable air flow measurements two straight sections of duct of circular cross-section were built to incorporate the turbine flow meters.(17) These meters were inserted at a position in the duct to ensure a fully developed transverse velocity profile.

The inlet air duct was calibrated by the National Engineering Laboratory.(18)

D. Experimental film coating

The model 10 (24 inch) Accela-Cota was set up with the instrumentation linked to the PET computer. Figure 3 shows a schematic layout of the test rig. Two preliminary experiments were conducted to determine a number of standard conditions for film coating. These were:-

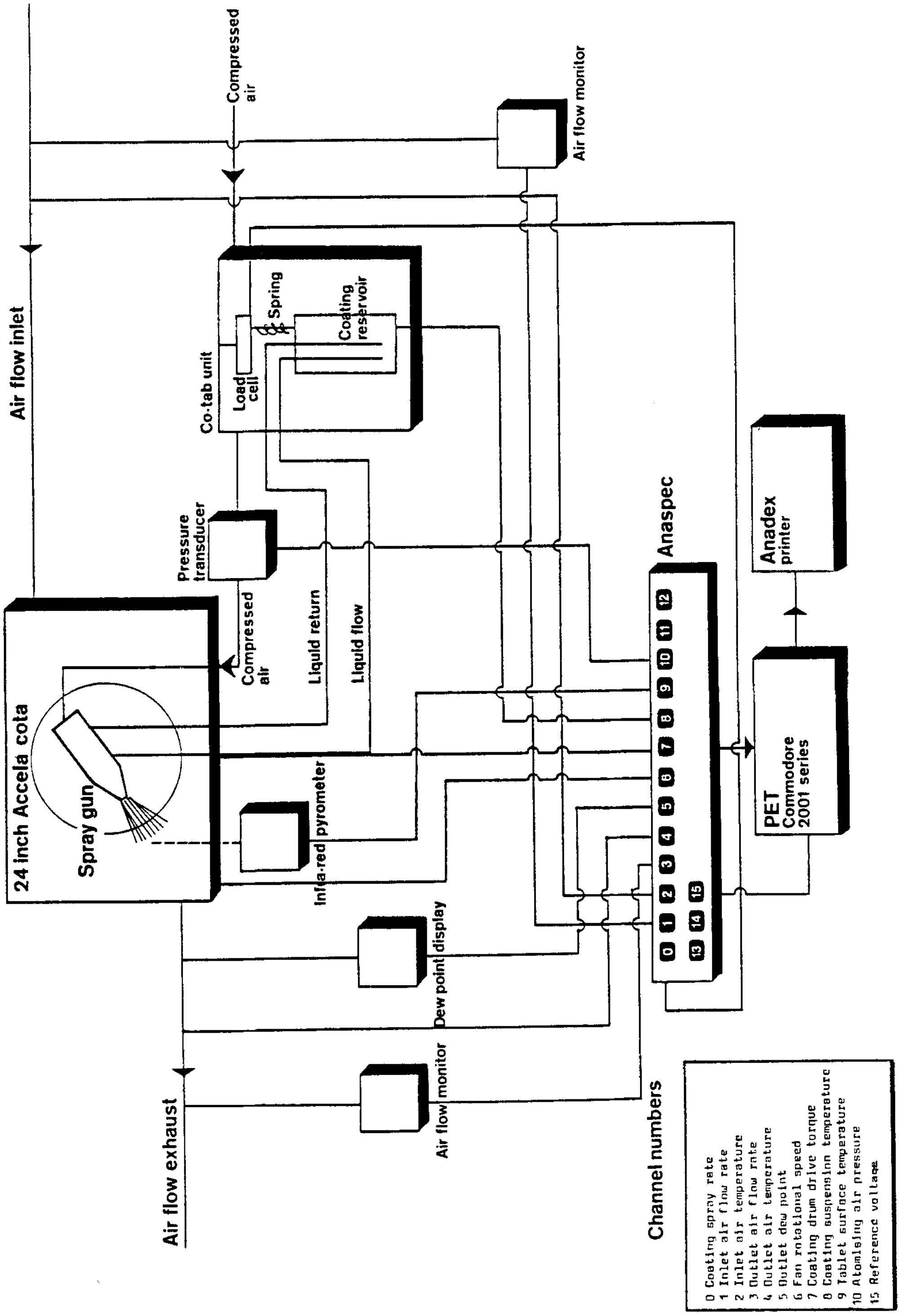


FIGURE 3

Schematic diagram of a model 10 instrumented Accela-Cota.

a. One Walther spray gun fitted with a 1 mm nozzle set at 15 cms from the surface of the tablet bed.

b. 8.0 kg of core tablets.

c. Drum speed of 10 r.p.m.

d. 2.0 L of coating suspension at 20°C.

e. Position of spray relative to tablet bed.

To determine the position of the spray gun relative to the tablet bed and the correct atomising pressure a series of experiments designed to measure the droplet size were conducted. A position of 30-33 cms had been determined empirically for the Model 150 (48 inch) and Model 350 (60 inch) pans but in the Model 10 (24 inch) pan this is impossible due to its geometry and the size of the spray gun. Attempts to establish a dynamic method for the measurement of the droplet size were inconclusive. Two approaches were taken:

1. Photographic.
2. The collection of droplets by impingement onto microscopic slides.

The photographic assessment of the droplet size and velocity distribution in an atomized spray presents no great problem when the droplet size is 50 μm or larger. Below this, however, in-flight photography becomes more difficult, and most previous workers[19,20,21] have found that 10-20 μm represented the lower limit of size that could be photographed. We used a 300 ns Argon Jet double flash unit to obtain pictures of the droplets produced by a Walther spray nozzle[22].

This method, supplemented by the collection of droplets by impingement on to microscope slides, was used to give size and velocity distributions for sprays produced at different atomizing pressures and coating suspension flow rates. Droplets smaller than 5 μm could readily be observed.

A classification scheme based on appearance only (Table 1) using a sample of 200 tablets from each batch was devised. This scheme showed whether the tablets would be acceptable for sale.

TABLE 1

Classification Scheme for Coat Quality.

i) Infilling of MSD housemark

ii) Pinholes, white spots

iii) Edge damage

iv) Orange peel effect

v) Surface roughness

vi) Peeling

increasing occurrence of i-vi (↓)	↑ ACCEPTABLE for marketing (+10 to 0)	Perfect coat	+10
			+9
			+8
			+7
			+6
			+5
			+4
			+3
			+2
			+1
			0
	UNACCEPTABLE for marketing (0 to −10) ↓		-1
			-2
			-3
			-4
			-5
			-6
			-7
			-8
			-9
		Incomplete coat	-10

The table of defects can be divided into sections. The negative scale indicates that the coat was incomplete. From 0-3 units, pinholes (less than 10 per cent of the surface) and damaged edges were present. These were considered unacceptable. From 4-6 units, pinholes and larger sections of the tablet surface were uncoated (10-25 per cent) and between 7-10 units more than 25 per cent of the surface was uncoated.

On the positive scale 1-4 units represented erosion of the housemark, uneven coating (orange peel effect) and uneven distribution of the colour. 5-7 units, represented in-filling of the housemark and less than 25 per cent with any defects. From 8-10 units, all were almost perfectly coated tablets with less than 5 per cent with minor defects.

A preliminary experiment was conducted to check the calibration of the second turbine flowmeter mounted in the exhaust duct against the meter calibrated by the National Engineering Laboratory. Good correlation was obtained when the Accela-Cota was completely sealed. It was decided to start the experimental programme without sealing the unit in an attempt to assess the effect of leakage into the pan on the coating characteristics. However during the first experimental run the blades of the turbine in the exhaust duct became thickly coated with dried coating material and spurious results were obtained for the air flow. The use of this meter was discontinued and at a later stage in the programme it was replaced by a pitot tube which operated satisfactorily.

The results from thirty-two experiments are summarized in Table 2.

In these experiments four independent variables were considered to have a direct effect on the quality of the coated tablet. These are:-

- spray rate
- inlet drying air volume

TABLE 2

Summary and comparison of the independent and dependent operating parameters on the model 10 Accela-Cota.

Independent Variables					Dependent Variables			
Run No. s: sealed u: unsealed	Spray Rate g.p.m.	Atomising Air Pressure p.s.i.	Air Flow c.f.m.	Inlet Air Temperature °C	Coat Quality Table 1	Dew Point Outlet Air °C	Outlet Air Temperature °C	Tablet Bed Temperature °C
01u	24			90	+8	18.8	42	39
02u	19		106-138	87	+4	15.3	46	43
03u	17			77	+5	13.3	41	38
04u	30	62-76		59	+6	15.9	31	27
05s	27			60	+8	18.6	41	39
06s	41		167-191	75	+8	21.4	47	39
07s	39			91	+9	22.4	59	48
08s	100			76	-10	25.1	41	28
09s	56		200-210	75	+2	23.0	41	32
10s	63	60		78	+1	6.3	34	29
11s	67			63	-10	20.8	32	24
12s	48			89	-2	22.4	44	36
13s	55		170-175	74	-10	22.6	37	26
14s	41			89	+7	20.8	47	38
15u	60		194	72	-10	21.5	35	26
16u	67	63-71		71	-10	21.0	32	23
17u	44			68	-5	21.0	34	30
18s	42		27-32	68	+7	22.9	39	34
19s	42			59	-10	18.0	34	29
20s	38	50		68	+8	20.4	39	37
21s	46	50		69	-5	20.7	39	34
22s	46	60		68	+8	21.0	39	33
23s	38			90	+8	11.8	66	64
24s	39			59	+8	15.0	45	40
25s	39			61	+6	17.2	44	43
26s	48	65-70		61	+2	16.0	43	42
27s	61		178-204	59	0	19.0	41	40
28s	55			59	+5	18.3	42	41
29s	61			50	-5	17.8	32	27
30s*	Run Aborted							
31s*	60	84		50	-8	16.1	38	37
32s*	34	84		50	+2	14.5	36	34

* Co-Tab Unit and Walther spray gun replaced by Watson-Marlow pump/Schlick nozzle.

- inlet air temperature
- the spray atomising pressure.

The objective was to obtain a satisfactory coated tablet with the minimum coating time. This means optimising the spray rate with the other three parameters. In a dynamic system such as this it is difficult to record all the operating parameters without the use of a computerised recording system. It is also difficult to exactly reproduce identical conditions for each run due to variations in such in-house systems as steam supply and compressed air. A close inspection of the results will show variations in parameters such as atomising pressure, temperature and air flow.

Included in Table 2 are the values obtained for the dependent variables,

- Dew point of exhaust air
- Outlet air temperature
- Tablet bed temperature
- Coat quality.

Each of these values is dependent on the value of the settings for the independent variables.

It was also determined that a more efficient process was obtained when the unit was completely sealed. All further experiments were conducted using the sealed unit.

In Runs 30-32, the Co-Tab Unit was replaced by a Watson-Marlow[(23)] peristaltic pump model 501 fitted with a universal drive module 501U which provided a maximum speed of 50 rpm. The flow was controlled by:

a. The speed of the pump.
b. The internal diameter of the flexible silicone tube which provides a range of flow rates from 0.1 ml per minute to over 500 ml per minute.
c. The nozzle setting.

This arrangement was found to be more versatile and simpler to operate compared with the Co-Tab Unit. It also was easier to clean. No metal surfaces of the pumping system are in contact with the coating suspension during the spray operation and this reduces the risk of cross-contamination. It is possible to control the speed of the pump by linking it to a signal such as the temperature of the exhaust air, inlet air or tablet bed temperature. It was decided to use the exhaust temperature as a controlling parameter as this is an indirect measure of tablet bed temperature and is sensitive to process changes. It had been shown that at an air flow rate on the inlet duct of between 112 and 128 cubic feet per minute it was possible to produce satisfactory coated tablets at an exhaust air temperature of 31°C (Run 04). We decided therefore to set a minimum exhaust temperature of 35°C and link the spray rate directly to this temperature. If the temperature fell below this level the pump was automatically stopped. For each degree rise in temperature above this level the speed of the pump increased, up to a maximum of 50 rpm thus increasing the spray rate. The relationship between these three variables is shown in Figure 4. The factor numbers represent the instruction in the computer programme. By altering this factor number, different spray rates can be obtained depending on the size of the Accela-Cota used and the spray rate required e.g. the model 10 would use the 8.5 factor and the model 75 a factor of 20. It was also demonstrated that a balance could be achieved between the inlet temperature, exhaust temperature and spray rate.

A simplified programme was written to provide automatic control of the coating process in the model 75 Accela-Cota (batch quantity 40-60 kg).

Channel No.		
0	Inlet drying air temperature	°C
1	Outlet drying temperature	°C
2	Pump speed	r.p.m.
3	Coating suspension used	Gm
4	Atomising air pressure	p.s.i.

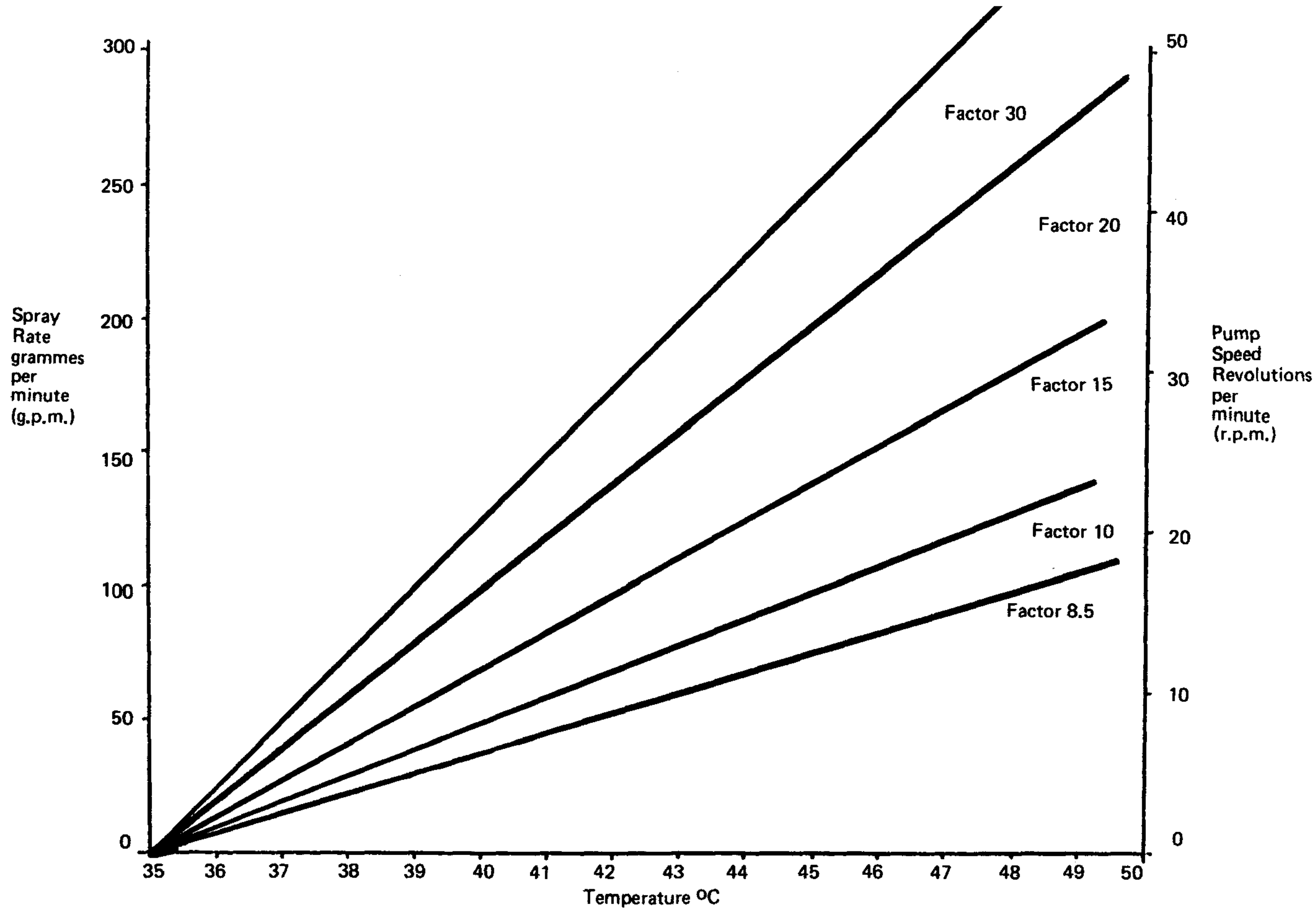


FIGURE 4

Relationship between pump speed, temperature and spray rate.

TABLE 3

Results from three runs in an unsealed model 75 Accela-Cota. Runs 33, 34 and 35.

Coat quality all +8 to +10.

Load kg	Number of tablets	Weight of core (mean) mg	Inlet air temperature °C Range	Outlet air temperature °C Range	Spray rate g.p.m. Range	Coating time minutes	Increase in core weight mg	Weight of film coat as percentage of applied film coat	Loss per cent
50	105,264	475	62 - 79 mean 75	44 - 55 mean 48	93.1-225 mean 194	103	15.5	91.4	8.6
60	125,316	474.2	65 - 74 mean 70	42 - 48 mean 43	192-312 mean 230	115	16.5	96.3	3.7
60	126,316	474.7	42 - 69 mean 63	35 - 50 mean 42	22-285 mean 208	97	15.2	91.0	9.0

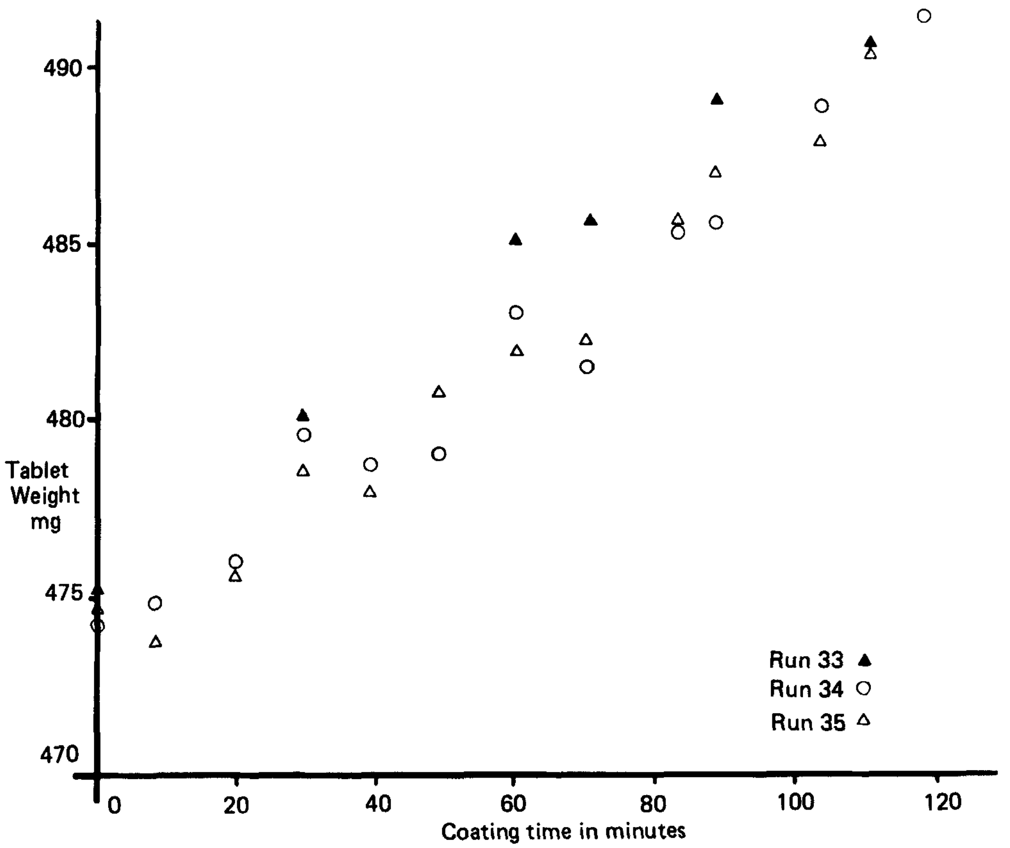
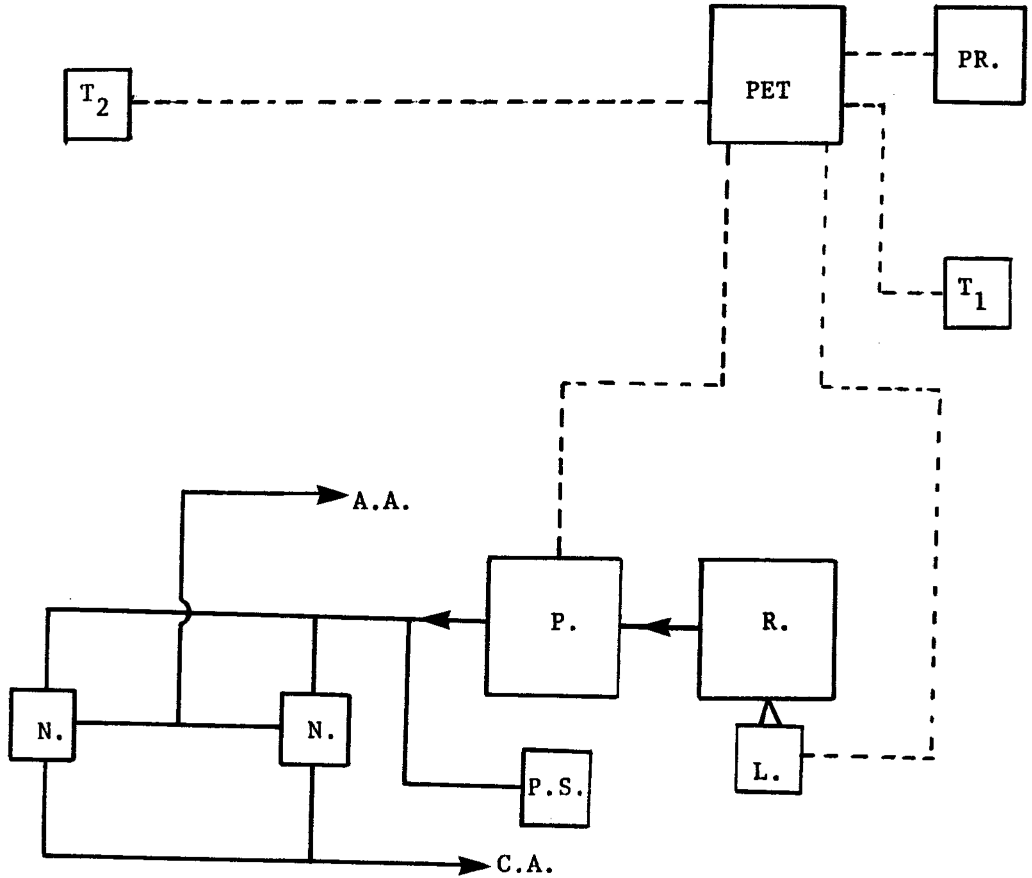


FIGURE 5

Tablet core increase in weight during film coating on model 75 Accela-Cota.

These parameters were measured every 5 seconds and displayed on the VDU. They were recorded every minute and every five minutes the spray flow rate was calculated and recorded.

When a pre-determined quantity of coating suspension has been applied a batch completed sign is flashed onto the VDU, the pump is automatically switched off and a summary of the processing parameters recorded on the printout. Based on this programme three runs (numbers 33-35), were completed in the model 75 Accela-Cota using one Schlick nozzle[24]. Placebos engraved MSD and coating suspension made to the same formulations as shown



A.A.	Atomising Air
C.A.	Control Air
P.	Peristaltic Pump
R.	Reservoir
N.	Nozzle
P.S.	Pressure Switch
PR.	Printer
PET	Pet Commodore Computer
T_1	Inlet air temperature probe
T_2	Exhaust air temperature probe
L.	Load Cell
----	Command and Signal loops.

FIGURE 6

Model 350 Accela-Cota Aqueous coating set up using Schlick nozzles and a peristaltic pump.

TABLE 4

Results from two runs in an unsealed model 350 Accela-Cota. Runs 36 and 37.

Load kg	Number of tablets	Weight of core (mean) mg	Inlet air temperature °C Range	Outlet air temperature °C Range	Spray rate g.p.m. Range	Coating time minutes	Increase in core weight mg	Weight of film coat as percentage of applied film coat	Loss per cent
356	750,000	475	65 - 81	44 - 48	265-312	180	11.2	88.9	11.1
356	750,000	475	65 - 79	41 - 46	350-550	110	10.9	92.4	7.6

in sections A and B were used. The results are summarised in Table 3 and the increase in weight of the core is shown in figure 5. Using the classification chart shown in Table 1 tablets from these three batches (33-35) were of +10 quality. Mean coating time to apply 10 mg of coat was 80 minutes.

This process and control programme (schematically represented in figure 6) was then used to coat two batches of 737,000 tablets (350 kg) on a model 350 Accela-Cota.

The first batch (run 36) used only one nozzle and took three hours. The flow rate was roo slow and the tablet appearance was +1 to +2 range on the classification chart. This experiment was repeated (Run 36) using two nozzles. The results are summarized in Table 4. However, problems were experienced because the flow rate was too fast for the size of the container which required refilling every 9-11 minutes. The coating time was reduced to 110 minutes and the tablet quality was in the +5 to +7 range.

DISCUSSION

A. Equipment

As a result of the initial experiments on the Accela-Cota model 10 the following criticisms of the test rig could be made:-

1. The turbo flow meters are unsuitable for measuring the flow of air in the exhaust duct due to the high concentration of dried film coating particles. It is necessary to measure inlet drying air and exhaust air to test for leakage in the system and therefore a differential pressure method (pitot tube) was investigated, found to be satisfactory, and fitted on the exhaust duct.
2. The method of measuring the spray rate by using a load cell is unsatisfactory. A number of readings are required before an average result is obtained.
3. The Co-Tab Unit and spraying system were difficult to control and adjust. In later experiments an alternative

system using a Schlick nozzle and peristaltic pump was used. This was developed in parallel with further experiments using the Co-Tab Unit.

4. The input fan has a maximum output of 300 c.f.m. This was replaced with one capable of up to 600 c.f.m.
5. The input plenum for the drying air was modified to direct the hot air directly into the coating pan.
6. A large amount of air was drawn into the pan from the room causing displacement of the spray and turbulence within the pan. This resulted in poorly coated tablets and a large amount of coating deposited on the pan wall. This was eliminated by sealing the unit.
7. One report suggested that cold air was drawn in through the tablet bed at the point above the exhaust plenum. This plenum was extended to eliminate this possibility. However, if the casing is completely sealed during the coating cycle this would not be possible.

The Schlick nozzle, used in runs 30-37 was a model 932/7-1 supplied by Orthos Engineering of Market Harborough. This replaced the Walther spray gun resulting in a much smaller and neater set-up inside the coating pan. This is especially useful in the model 10 Accela-Cota where the volume of space available is very limited. The nozzle is fitted with a cleanout needle which in the event of failure in the atomising air automatically closes and prevents any dripping of the liquid onto the tablets in the pan. This gun can be easily adjusted to provide a much wider spray angle and it was demonstrated that one of these nozzles could replace two Walther spray guns in the Manesty model 75 Accela-Cota. In the model 350 two nozzles of this type were used.

The spray system used did not allow re-circulation of the coating suspension and to maintain the flow rate the nozzle is pressurized with liquid resulting in a small pressure build-up in the feed line to the nozzle. To safeguard against excessive pressure a pressure switch was fitted to this tube set to operate at 5 psi. If this was exceeded the pump automatically stopped. A diagrammatic layout of this process is shown in figure 6. The coating system is linked through the PET computer to a printer which prints a batch record for each batch of tablets coated.

In these experiments problems were experienced with the dew point recording of the exhaust air and the air flow measurements in the inlet and exhaust ducts.

Originally it was thought that the dew point readings would give sensitive control on the spray rate but the variation in the readings for apparently identical conditions (greater than 20 per cent in several experiments) have led us to temporarily discount this method. The dew point hygrometer used requires careful adjustment to provide reliable readings. It is not robust and this is a disadvantage from the production viewpoint.

Difficulties were experienced with the measurement of the air flow rates in the exhaust and inlet ducts. We had purchased two insertion turbine flow meters designed to measure the velocity of the air. These are required to be accurately positioned in a straight section of the duct at a point at least 10 diameters downstream from any bend or restriction and at least 5 diameters upstream from any similar obstruction or bend. This is to ensure a fully developed velocity profile at the insertion meter.

These meters are very sensitive to dust particles in the air and it was found that they were unsuitable for use in the exhaust duct. This meter was replaced by a pitot tube which gave satisfactory results. Difficulties with transferring these measuring sensors to the duct system for the larger Accela-Cotas and measuring a transverse profile has meant that we have not developed a system for measuring the air flow for the model 75 and model 350 Accela-Cotas. Difficulties were also encountered in measuring and recording consistently the rotational fan speed (due to the problem of positioning the sensor) and the coating drum drive torque (the instrument was unreliable).

The tablet bed temperature was measured accurately and reliably using an infra red pyrometer but was discarded as a method of control in favour of using the exhaust air temperature measured in the exhaust plenum or ductwork before the extract fan. This is necessary as 85 per cent of the power used by the fan is transferred to the exhaust air in the form of heat and measurement after the fan would give spurious results. The problem with measuring the tablet bed temperature is the position of the sensor and reconciling its position with the need to reduce any opening in the front of the Accela-Cota to a minimum. As good results were obtained using the exhaust air temperature we decided to discard the tablet bed temperature method of assessing the tablet quality during processing.

Several problems were highlighted during the coating of two batches on the model 350.

1. The load cell required recalibration to permit much larger quantities of film coating to be applied before completion of the programme.
2. The nozzle - pump configuration required modification to permit better adjustments within the coating pan.
3. Individual nozzle feed from the pump may be better for more consistent application of the film.

In the experiments conducted on the model 75 Accela-Cota the rate of utilisation of the spray film coat recovered as a percentage of weight increase in the core tablet weight was 91.4, 96.3 and 91.0 per cent. For the two trials on the 60 inch Accela-Cota the corresponding recovery was 88.9 and 92.4 per cent.

B. Coating.

Table 2 is a summary of all the results obtained using the model 10 Accela-Cota and shows how changes in one or more of the independent variables effect the dependent variables. In all cases the tablet bed surface temperature is lower than the exhaust air temperature even though the sensor was mounted in the exhaust plenum before the exhaust fan. There are two possibilities which would explain this difference:-

1. Some air is by-passing the tablet bed and entering the plenum without any of its heat content being transferred to the tablets or spray.
2. The temperature at the liquid solid interface on the tablet surface is lower due to the latent heat of evaporation of water being utilised to dry the film coating spray. This air then mixes with air in the plenum which has by-passed the bed and the total mixture registers a rise in temperature.

Where the tablet quality is acceptable the surface bed temperature and the exhaust air temperature are in close agreement and this suggests efficient use of the inlet air heat content. Where exceptions exist the spray rate was in excess of 50 gpm. Generally in cases where there is a large differential in these two temperatures the tablets were unacceptable. In these instances the tablets were becoming too wet and inefficient heat transfer was taking place.

It is shown that with three borderline exceptions tablets could not be coated satisfactorily with a spray rate of in excess of 50 gpm. In these experiments it is interesting to note that the air flow rate was at a maximum. We concluded therefore that the maximum spray rate was 50 gpm. Significantly the temperature of the inlet air was not critical providing that it was above a minimum of 50°C for the spray rate of 20 to 30 gpm and 60°C for the 30 to 50 gpm. Air volume on the inlet side was also not so critical as we were able to coat tablets at a level of 27-32 c.f.m. However, these results were not reproducible.

The effect of varying the atomising pressure is shown in runs 20-21. It would appear that 50 psi was the borderline condition above this satisfactory spray patterns could be maintained.

Originally it was considered that the dew point measurement would be a useful parameter for controlling the spray rate. However during the experiments wide fluctuations in readings were experienced as an examination of the results in Table 2 will show.

One aspect which is not clearly demonstrated in the results is the effect of sealing the pan. The effect was twofold:

1. The amount of air drawn in through the inlet duct increased significantly. In Run 05 which was a repeat of Run 04, the only change made was the sealing of the unit.
2. It could be readily observed through the front of the pan that in the unsealed situation the spray was displaced from the centre of the tablet bed to an area at the rear of the pan. This resulted in excess material adhering to the pan walls and baffles.

From these results we concluded that for optimum coating conditions in an aqueous system:-

- Reduce all leakages to a minimum.
- Link the spray rate to the exhaust air temperature and set this to operate between 35 and 50^{o}C.
- Link the exhaust temperature to the inlet temperature with a control loop. This would reduce the temperature of the inlet air if the spray rate reached the maximum and the maximum exhaust temperature specified was being exceeded.
- It was decided to omit the measurement of the inlet air flow due to variations in the shapes of the ducts and the problems associated with ensuring a fully developed

transverse velocity profile. Further work is required before a universal method can be recommended.

CONCLUSIONS

From these experiments it can be seen that improvements have been made to the aqueous film coating process using the Manesty Accela-Cota. Computer programmes have been written and linked to a number of sensors to automatically control the coating cycle. In-process recording of the critical coating parameters has been achieved and provides comprehensive documentation for each batch of tablets processed. The new nozzles and pumping system has provided a more elegantly coated tablet.

This system can be extended to complete the control loop by linking the inlet air temperature and air flow to the computer. To include automatic loading and unloading requires certain modifications to the Accela-Cota and these are at present being considered by Manesty Machines. A prototype fitted with an automatic emptying system will be built early in 1982.

A number of unknowns remain which require further investigation. These include the evaluation of air flow meters and their ability to measure reliable velocity profiles in irregular shaped ducts with regard to the effect on the aqueous coating process. The problem of measurement of humidity of the exhaust air and its relationship to the spray rate remains unresolved as well as the determination of the weight of the film coat. This is especially critical where small tablets are being coated and the quantity of film applied is very small.

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