Production Screen Extruder 35

The Caleva Extruder 35 is a cost effective screen extruder ideal for many pharmaceutical and other formulations.

It is designed to produce low pressure extrudate at high capacity and to generate as little heat as possible.

The amount of heat generated is a function of the product characteristics as well as the operating parameters used.

It is suitable for product development, pilot plant and full scale production.

Use:	Laboratory or Development:	☑	Pilot plant:	☑	Production:	☑
Operating capacity:	Up to 180 kg per hour (product dependant)					
Minimum batch size:	Approximately 500 g					

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General Description

Extrusion:	Extrusion is required as a step prior to spheronization. For pharmaceutical products either a gear or screen (basket) extruder is generally recommended. Both of these extruder types are suitable for pharmaceutical products in terms of product quality and capacity of production. Both also have the advantage of minimum heat production during the extrusion process.
Production capacity:	Product capacity is dependent on both operational parameters and the characteristics of the formulation being extruded. These items are outside the control of Caleva and therefore production rates cannot be guaranteed. However, Caleva will work with you to ensure that you get the optimum production capacity from the equipment that you have. Trials have shown that the Extruder 35 is capable of extruding up to about 3 kg per minute. With different formulations, screens and process parameters, figures both in excess of, and less than, this amount had been achieved. This figure is given as a reasonable guide only and are not guaranteed.
Minimum batch size:	From a single batch of about 0.5 kg to continuous production.
Document package:	Full pharmaceutical industry qualification documentation packages are available as options if required.
Materials certificates:	Certified copies of original mill certificates for all product contact parts are available as an option if required.
Availability / Delivery time	The actual delivery date will depend on the level of work that we have at the time of order. In general if we do not have a suitable machine in stock then delivery will be between 8 and 16 weeks. Please contact us for an exact delivery date when the required specifications are known.

Main Uses

- The Extruder 35 is designed for full production use but can also be used for product development and pilot scale production.
- The working capacity is suited to the Caleva floor standing production spheronizers with 380, 500 or 700 mm diameter drums.
- The most convenient working rate will depend on the size of the spheronizer and the batch residence time in the spheronizer as this is generally the rate determining step in the production of pellets by extrusion and spheronization.
- Extruder 35 Small quantities (from about 0.5 kg) can be extruded during development work.
- A working rate could be up to 180 kg/hour making the Extruder 35 ideal for production work.
- Easy to dismantle and clean, the Extruder 35 uses a limited amount of floor space whilst being a powerful production machine.

Standard Design Configuration

Important note on configuration	This brochure contains information about the standard floor standing Extruder 35 models but Caleva can work with you according to your specific needs. Some options are given in this quotation but please discuss with us any specific needs that you might have. It is often possible in the early stages of design that changes can be incorporated at low or no additional cost.
Size	Approximately 500 mm d x 750 mm w x 1000 mm h depending on actual specification.
Weight	Approximately 120 kg depending on specification.
Material	Cabinet is 304 stainless steel.
Contact parts	316 stainless steel and polycarbonate.
Standard extrusion screen	150mm diameter with holes 1mm diameter x 1mm deep. May be exchanged for other sizes if required. A wide range of screen hole sizes are available. Please contact us for details.
Product feed	Manual, loaded through top loading aperture placed at a convenient height for manual loading. Automatic, the Caleva Extruder 35 screen extruder can be supplied with an optional automated product feed from a 20 litre “flexi-wall” loading bin. The automated loading feature is not essential but can be a useful option.

Safety	All Caleva equipment is designed to the high safety standards. Safety cut-out switches are fitted as standard and the machine cannot be operated if all the safety covers are not in place. We would not recommend any purchaser to take the responsibility to purchase any extruder without full safety covers and associated cut-out switches.
Technical data	2.2 kW AC motor. Motor speed infinitely variable (within a fixed range).
Utility requirements	**Electrical supply** 400 VAC, 50 Hz or 460 VAC, 60 Hz 3 ph 5.5 A. Other voltages are available on request
Operation and controls	Front panel mounted controls comprising ***stop***, ***start, emergency stop, power connected indicator***, ***motor running indicator***, and a ***variable speed control*** with a ***digital display of rotation speed.*** Other configurations are available. Contact us for details
Roller speed	From 50 to 150 rpm (infinitely variable). The speed range can be set (within limits) to suit the product and required production rate.
Standard documentation supplied	• Installation and operation Manual. • Parts list. • CE declaration of conformity • Completed quality control check sheet.

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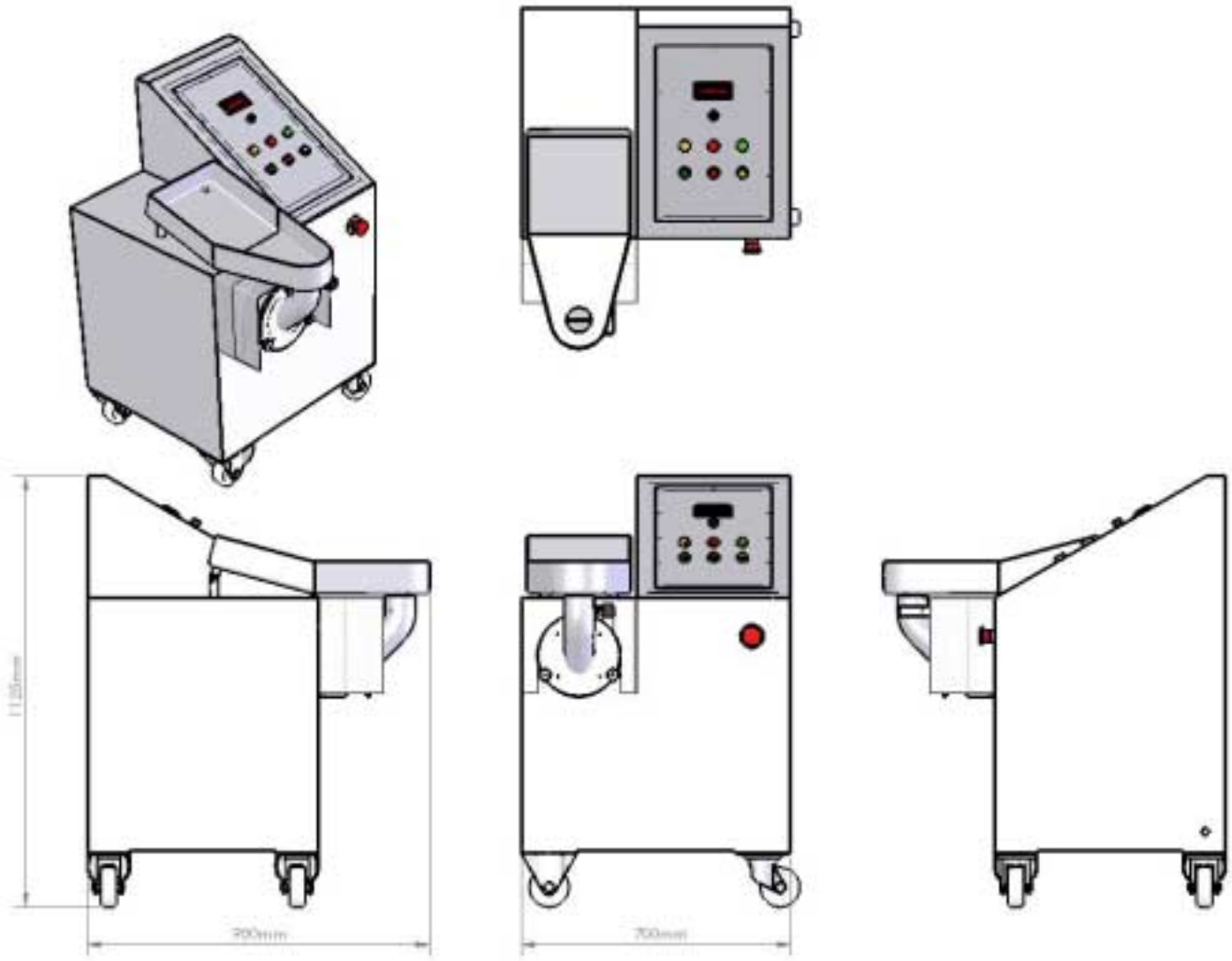
General Arrangement Diagram



Options Overview

All machines are supplied with a 150mm diameter extrusion screen. Additional screens are available as extras. Amongst the options available are:

- There are no required options. The Extruder 35 is fully functional as supplied.
- Screens with apertures from 0.5mm to 2.0 mm can be supplied.
- Customer specific apertures in 0.1 mm increments can be supplied as required.
- Although we can make screens with very small apertures or apertures larger than 2.0 mm diameter, we do not currently recommend aperture sizes below 0.5mm or above 2.0 mm in diameter.
- Replacement screens of different designs can be supplied as needed.
- Additional collection bins can be supplied to collect product as it is discharged from the machine.

See also: Recommendations, in the following pages……..

Training and Validation Options

Installation/commissioning/training at the customer site	
	Includes installation, commissioning and training at customer site of up to one day, but does not include IQ/OQ which is separately chargeable. The customer will provide local transport for the Caleva technician if required. The customer will supply all consumable products required according to further discussion. Trained electricians will be provided by the customer if required (generally not required). Installation does not include any alteration to the customer site and does not include installation of any electrical services. The customer will be responsible for the unpacking and location of the machines at the use site. This is not included in the quotation. If more than one item is purchased then training can be completed together for other equipment with considerable savings in cost. Contact us for details.
Factory acceptance test at Caleva UK site	
	We make our own quality check before the extruder is shipped (a copy is supplied to the customer) and thus a separate FAT is not normally necessary but can be completed with the customer if required. The customer will be responsible for all his or her expenses incurred in getting to and from the Caleva site.
Customer training at the Caleva site (overseas customers)	
	Training is recommended if extrusion and spheronization is a relatively new technique to the company or if new staff would benefit from it. Contact us for details. Customers from outside the UK will be collected at any London main airport and transferred to Bournemouth, accommodation and all meals for one trainee whilst in Bournemouth, UK. Transport to and from the Caleva site is included. Any extras (such as phone calls etc.) at hotel are for guest's account. One night bed & breakfast in London hotel before return flight to home country can be included if requested. Up to two days training (as required) at the Caleva site on customer's own equipment prior to shipment. Transport to and from the customer's own country to London Main airport is not included and is for the customer's account. If more than one item is purchased then training can be completed together with considerable savings in cost. Contact us for details.
Validation and IQ/OQ documentation package	
	Recommended if required for regulatory purposes.
	At Caleva site:
	The IQ/OQ package completed at the Caleva site by us. The customer can attend if he or she wished to do so at their own cost. An additional set of blank documents will be provided to allow the customer to re-do the IQ/OQ in their own facility if required.
	At customer site:
	IQ/OQ and installation completed at the customer site as part of the training (that is charged

	separately). The cost shown is a cost for the IQ/OQ in addition to the costs for installation and training.
	***Note**: there may be additional country-specific charges depending on location. Contact us for details.*
Material certificates (included in IQ/OQ package)	
	Certified copies of mill certificates for product contact parts These are included if the IQ/OQ package is purchased. They are offered as an option if the certificates are required but not the full IQ/OQ.
	Caleva certificate confirming that copies of the mill certificates are held by Caleva if copies of the original certificates are not required.

Upgrades and Accessories

Automatic product feeder	
	Single screw volumetric "flex-wall" feeder including 35 lt hopper. In 316 or 304 stainless steel. Cost according to detailed specification according to customer requirement.
Rear cooling plate	
	With some formulations the extrusion process benefits if heat is removed or added to the extrusion chamber. This option builds into the rear of the extrusion chamber a water chamber so that a supply of hot or cold water can be pumped through the rear of the extrusion chamber adding or removing heat.
Digital ammeter	
	A digital ammeter will be positioned on the control panel giving a digital display of current being used. Not required if data display module is chosen see below.
Data display module	
	The instrument will digitally display on the control panel the amps being used during the operation and the temperature of the product as it exits a selected point on the extrusion screen
Knurled extrusion rollers	
	Some users prefer to have knurled surfaces to the extrusion rollers. These can be offered if requested as a non-standard option. The cost shown is an additional cost if knurled rollers are requested in place of the standard smooth rollers.
Additional roller assembly unit with knurled rollers	
	Additional roller assembly unit complete with knurled rollers
Datastor™ data capture system	
	With this option the extruder can be connected (5 m max cable) to any available USB port your own bench top or laptop computer. If an extruder or spheronizer is connected to a USB port on the PC then, with minimal additional operator intervention, the following data is recorded: • Power usage • Operating speed in rpm • Product temperature The software can recognize and monitor up to two machines working independently at the same time. Results are stored and the software allows the printing of a one page summary of all relevant data that can be printed as a permanent record. A PC is not supplied in this option as most users prefer to supply their own. We can supply a suitable PC with the Datastor software preloaded if required please let us know if you wish us to quote.

Consumables

Additional screens

Screens

Caleva drill rather than punch or laser cut holes as the quality of the individual hole is improved. The quality and consistency of the holes is important to ensure a regular extrudate to obtain the best possible consistency and highest usable yield in pellet production.

Additional screens available

Hole diameter

Note that Caleva only offers drilled holes. We do not offer laser cut or punched screens. As both these other options lead to inferior and variable hole shapes and can lead to less consistent extrudate which can affect usable yield.

Different hole pitch

Screens are offered as standard capacity. Some holes sizes are offered as high capacity screens (greater open area). High capacity screen have more holes per unit area and thus are able to increase the hourly throughput. However high-capacity screens are not as physically robust as standard screens.

Description

Full height screens

Hole size 0.5 mm diameter, Open area % = 16.5

Hole size 0.6 mm diameter, Open area % = 20

Hole size 0.7 mm diameter, Open area % = 20

Hole size 0.8 mm diameter, Open area % = 21

Hole size 0.9 mm diameter, Open area % = 20

Hole size 1.0 mm diameter, Open area % = 22.5.
(This is the Caleva standard screen)

Hole size 1.1 mm diameter, Open area % = 21

Hole size 1.2 mm diameter, Open area % = 19

Hole size 1.3 mm diameter, Open area % = 18

Hole size 1.4 mm diameter, Open area % = 16.5

Hole size 1.5 mm diameter, Open area % = 15

Hole size 2.0 mm diameter, Open area % = 10

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High capacity full height screens

Hole size 0.7 mm diameter, Open area % = 32

Hole size 0.8 mm diameter, Open area % = 28.7

Hole size 0.9 mm diameter, Open area % = 26

Low capacity full height screen – for tough products

Hole size 0.8 mm diameter, Open area % = 14

Replacement roller bushes

FDA approved polymer bushes for extruder rollers. Per set of 6

Companion Equipment

Production Spheronizer

The production line would normally consist of four principle machines: -

1. A mixer granulator not supplied by Caleva. It is assumed that the customer has a means of producing a granulation suitable for extrusion and spheronization. If additional advice is required then Caleva would be prepared to discuss this requirement with the customer and offer advice.

2. A Caleva Extruder production extruder (with manual or automatic loading as an option). Caleva could offer a gear extruder or a screen (basket) extruder. These extruders are designed for pharmaceutical production and produce extrudate with different properties. This offer is for such a production screen extruder.

3. A production Spheronizer The extruder 35 in this offer is suitable for any of the following production spheronizers:-
    a. A Caleva Spheronizer 380 (production capacity approximately 50 kg/hour) or,
    b. A Caleva Spheronizer 500 (production capacity approximately 100 kg/hour) or,
    c. A Caleva Spheronizer 700 (production capacity approximately 150 kg/hour).

4. Fluid bed equipment for drying and coating not supplied by Caleva. It is assumed that the customer has a suitable fluid bed or other type of drier as well as suitable coating equipment if this is necessary.

In addition, a set of sieves would normally be required.

Details of the actual product requirements would need to be discussed in detail with the customer but the current offer is given as to what we believe is a suitable proposal based on the information that we have.

Recommended Spares

There is a recommended spares kit that is suitable for customers outside the UK. The Extruder 35 is a production machine and is designed for continuous work. However if production machines are out of action whilst waiting for spares then the financial implications can be significant. All eventualities cannot be foreseen but the spares kit below is recommended as a suitable kit that could be held to cover for possible breakages and losses.

Please contact us if further advice or clarification is needed.

Recommended spare parts kit	
	A complete kit containing the following:- Slim Ferroguard Safety Interlock Extruder 35 Shaft Bearing Universal Input Control Transformer 208V To 600AC Motor, + NMRV75 Gearbox 15 Contactor 24v DC Coil 4 No Relay 3 Pole 11 Pin/24v Ac Coil Sensor 3 Wire Proximity Npn Dome Nut S/S M10 4PCO Mini plug in relay Pressure Roll Bush Three Phase 415AC -24Vdc Power Supply 10A Safety Relay Inverter 2.2kW Transformer 200-600VAC voltage input 100VA 110VAC output E35 Manual Product Cover (Water Jacket) E35 Roller Drive Arm Washer Screen Extruder Nut

Recommendations[1]

There are no required options.

The basic equipment as offered is fully functional. If you require any advice regarding the options or wish us to make any recommendations based on your planned use then please contact us.

The machines can be supplied as offered and this offer is believed to be suitable for the intended use. However this is information based on our best knowledge and belief. It is important that the attached specifications are discussed in detail between the customer and Caleva to determine if modifications are recommended.

The design of the machine can be modified to be suitable for your facilities, product flow and production plan. Please discuss your actual needs with us so that we can ensure that the equipment that we offer is exactly according to your requirements. This option is recommended so that discussions can then be completed and final specification and costs can be agreed.

Additional screens

A range of screens are available with different hole sizes and % open area. Initially we would recommend that two additional screens are ordered if the machine is to be used in production. This option (two additional screens) is ***highly recommended***.

IQ/OQ before shipment

Installation can be provided at customer site if required but is not considered necessary for this equipment. Installation charges are listed in Training and Validation Options on next page. This option is ***recommended*** if required for regulatory purposes.

Training at Caleva site

Training in the use of the equipment at the customer site or at our site in the UK prior to shipment is available. This option is ***suggested*** if extrusion and spheronization is a new technique for the user.

[1] ***Strongly recommended:*** We consider that this option is a "must" for most cases unless you have specific reasons why this option is not needed.
Highly recommended: Most users would consider this option as something that they would want.
Recommended: We consider that it is sensible to purchase these options.
Suggested: We suggest that you consider these options according to circumstances. Please contact us for any advice.