responsible for executing the chosen method of manufacture on an ongoing basis to supply commercial need.

BATCH SIZE

Since 1990, the FDA has required that exhibit batches intended to support an ANDA submission comprise a minimum of 100,000 finished dosage units or 10% of the batch size intended for commercial production, whichever is greater [5]. The original basis for establishment of this standard is somewhat arbitrary; however, it has since proven to be an appropriate benchmark for scale-up operations.

DEVELOPMENT REPORTS OR LOGS

Generic drug firms prepare formal development reports for each product. Development reports outline the rationale for formulation development, summarize all the experimental batches made and what was concluded from the results obtained on them, explain what changes were made in the formulation during development, and list the processing parameters that were used for each batch.

A possible aid in the preparation of a Development Report is the use of a Development Log. A log is maintained for each project, showing the receipt of all raw materials, including samples for preliminary testing, testing done, experimental batches made, conclusions drawn, manufacturing and testing of the submission batches, and biostudy sampling. References to laboratory notebooks and other documentation are included. An example of a idealized Product Development Log is shown in Table 7.2. In larger R&D groups, which may have several projects ongoing

TABLE 7.2
Product Development Log for Profitabilamine Tablets, 1 mg code Number: P0022

Date	Action	Notebook References
01/07/97	Received raw material sample from Cornucopia Fine Chemicals	
01/14/97	Received technical dossier from Cornucopia Fine Chemicals	
01/28/97	Completed sample testing; material acceptable	RDP0022-1, pp. 1–10
01/31/97	Ordered 1.0 kg raw material from Cornucopia	
02/18/97	Material received from Cornucopia receiving number 97B055-P	
02/19/97	QA sample of 97B055-P received by laboratory	
02/20/97	Preliminary raw material analytical method approved	
03/06/97	97B055-P released by R&D laboratory	RDP0022-1, pp. 11–20
03/07/97	Experimental batch X005-C prepared in pilot lab; samples to R&D laboratory	
03/21/97	Dissolution of batch X005-C profile similar to brand batch 97XYZ09; uniformity and all other tests acceptable	RDP0022-1, pp. 25–35
03/25/97	Hardness. Thickness and weight specification report approved	
04/02/97	Master #P0022-1 for 100,000 tablet batch size approved	