1.0 Purpose

The purpose of this procedure is to define the process for determining particle size and relative quantity.

2.0 Scope

This procedure applies to raw material and finished product samples for which there is a specification for the percentage of particles that will pass through a screen of a specified size. This procedure does not apply to materials intended for use in pharmaceuticals.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Analysts to follow this procedure.

3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.

3.3 It is the responsibility of QC Laboratory Management and/or Analytical Development to keep this procedure aligned with current practices.

4.0 Definitions

4.1 **QC** – Quality Control

4.2 **ASTME** – American Society of Tool Manufacturing Engineers

4.3 **NIST** – National Institute of Standards and Technology

4.4 **ISO** – International Organization for Standardization

5.0 References

5.1 USP<786>, monograph, Particle Size Distribution Estimation by Analytical Sieving

5.2 D-724-F1, Form, Particle Size Test Ticket

6.0 Procedure

6.1 Perform the procedure using form D-724-F1 Particle Size Test Ticket.

6.2 All sieves used must be traceable to ASTME, NIST, or ISO 3310-1 specifications and have a placard with the specified gauge.

6.3 Verify that the sieves used have the correct gauges specified for the material.

6.4 Inspect sieve to verify that there are no broken, bent, or missing wires in the mesh. Replace sieve if any damage if found.

6.5 When more than one gauge of sieve is being used place in order of coarsest (top) to finest (bottom). Pre-weigh each sieve and document their initial weights.

6.6 Weigh each test sieve to the nearest 0.1 g. Record Weight.

6.7 Weigh a representative portion of the test material and document the initial sample weight.

6.7.1 Sample size is dependent upon the density of the powder or granule, and the diameter of test sieves being used, typically between 25 – 100 grams.

6.7.2 If the test material is prone to picking up or losing significant amounts of water with varying humidity, the test must be carried out in an appropriately controlled environment.

6.7.3 If the test material is known to develop an electrostatic charge, careful observation must be made to ensure that such charging is not influencing the

analysis. An antistatic agent, such as colloidal silicon dioxide and/or aluminum oxide, may be added at a 0.5 percent (m/m) level to minimize this effect.

6.7.4 Agglomerations may be manually broken apart without pressing sample through the screen.

6.8 Place an accurately weighed quantity of test specimen on the top (coarsest) sieve, and replace the lid. Agitate the nest of sieves for 5 minutes. Then carefully remove each from the nest without loss of material. Reweigh each sieve, and determine the weight of material on each sieve. Determine the weight of material in the collecting pan in a similar manner

6.9 Calculate the %weight of a particle size by:

6.9.1 Subtract the pre-weight of the sieve from the final sieve containing sifted sample.

6.9.2 Divide the difference in by the original sample tare weight then multiply by 100. The result is the % weight by particle size.

6.9.3 Report % weight as the percentage of the initial sample weight.

6.9.4 Calculations can be repeated for each gauge screen as needed.

6.10 Alternatively, weigh the amount passed through the sieve directly and report the percentage passed as a percentage of the initial sample weight.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New	-	-
1	01/26/12	Updated SOP.	-	-
2	02/23/13	Reformatted SOP.	13-114	B. Johns
3	02/06/15	Biennial review. Update SOP format. Expanded calculation description.	15-0144	B. Johns
4	04/10/17	Expanded sieve standardization traceability. Excluded pharmaceutical materials. Changed responsibilities. Added USP <786> reference.	17-0394	B. Johns
5	07/20/20	Added definition and changed responsibilities.	CC-20-0517	J. Maignan
6	06/09/22	Updated to reflect current practice and align with USP.	CC-22-0266	J. Sassman
7	01/30/23	Updated to add reference to new form D-724-F1. Created new form D-724-F1 that can accept up to three tests per page.	CC-23-0053	J. Nicholson

ION LABS	Particle Size Test Ticket		
	Form: D-724-F1	**CCR No:** CC-23-0053	**Revision:** 0

SOP #: D-724 Balance ION #: _____ Cal due: _____

Date: _____ Humboldt Shaker ION #: _____ Cal due: _____

Paste Weigh Tapes Below

Sample Number:		Reference Number:		
mple Weight (g):		Release Specification:		
Sieve Size	**Weight (g)**	**Final Weight (g)**	**Final % On**	**Pass / Fail**
			=IF(A10="","",((C10-B10)/B8)*100)	
			=IF(A11="","",((C11-B11)/B8)*100)	
			=IF(A12="","",((C12-B12)/B8)*100)	

Sample Number:		Reference Number:		
mple Weight (g):		Release Specification:		
Sieve Size	**Weight (g)**	**Final Weight (g)**	**Final % On**	**Pass / Fail**
			=IF(A17="","",((C17-B17)/B15)*100)	
			=IF(A18="","",((C18-B18)/B15)*100)	
			=IF(A19="","",((C19-B19)/B15)*100)	

Sample Number:		Reference Number:		
mple Weight (g):		Release Specification:		
Sieve Size	**Weight (g)**	**Final Weight (g)**	**Final % On**	**Pass / Fail**
			=IF(A24="","",((C24-B24)/B22)*100)	
			=IF(A25="","",((C25-B25)/B22)*100)	
			=IF(A26="","",((C26-B26)/B22)*100)	

_____ _____

Performed By/Date Reviewed By/Date