Supplementary Table 3: Unit Sample Acceptance Table for dissolution following USP Monograph

<711>

|  |  |  |
| --- | --- | --- |
| Stage | NumberTested | Acceptance Criteria |
| s1 | 6 | Each unit is not less than Q + 5%. |
| Sz | 6 | Average of 12 units (S1 + Sz) is equal to or great than Q + 5%. |
| 53 | 12 | Average of 24 units (S1 + Sz + S3) is equal to or greater than Q. |

\* Reference: Guidance for Industry, Dissolution Testing of Immediate

Release Solid Oral Dosage Forms

**http:** *I* [/www.fda.go](http://www.fda.gov/)v /downloads /drugs /guidancecomplianceregulatoryin formation/guidances