

| ADDITIONAL REQUIREMENT                                                         | EXPLANATION AND SIGNIFICANCE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
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| Hardness Limits                                                                | <p>Tablet hardness is a function of the pharmaceutical manufacturing process and is an appropriate tool to measure uniformity and consistency in products. It may have a bearing on breakage or crumbling of the tablets in shipment as well as uniformity from lot to lot and within a lot. Therefore tablet hardness represents another important control factor in assuring uniform and constant dosage for the patient.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Accelerated Aging Test                                                         | <p>In the large volume procurement of medical materiel, which may undergo lengthy and adverse transportation and storage, it is desirable to determine in advance whether a product that may be offered will remain stable for the required period of time. In addition, drug products generally have a deterioration rate which may vary with the product, the formulation, and the method of manufacture. In those instances where proof of stability is necessary because of a predetermined long shelf life or because deterioration has been experienced, it is necessary to establish standards prior to contracting. This serves to preclude the potential for administering/dispensing deteriorated medicaments. Compliance with this requirement contributes to longer shelf life and reduces the possibility of having deteriorated stock on hand that must be destroyed.</p> |
| Maximum Unrefrigerated Shipping Times for Items Requiring Refrigerated Storage | <p>Drug products which require refrigeration are sensitive to unrefrigerated conditions such as room temperature or elevated temperature. There are no established requirements which would limit the unrefrigerated shipping time from manufacturer to depots and</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |