



**INSPECTION OF MANUFACTURER/REPACKER – COSMETICS/HOUSEHOLD URBAN PESTICIDES /TOYS AND CHILD CARE ARTICLES (TCCAs)**

INSPECTION AGENDA		
Presence of all Key Personnel	<p><b><u>Opening Meeting</u></b></p> <ul style="list-style-type: none"> <li>● Introduction from FDA Lead Inspector</li> <li>● Discussion of Scope, Inspection Plan</li> <li>● Attendance Sheet</li> <li>● Company Introduction and Overview</li> <li>● Design and Lay-out Review prior to Site Inspection</li> </ul>	GMP Cosmetics Team
Company Key Person Assigned	<p><b><u>Site Inspection</u></b></p> <p><b>QUALITY MANAGEMENT SYSTEM</b></p> <ul style="list-style-type: none"> <li>● Quality Manual</li> <li>● Suppliers of materials/ accreditation</li> <li>● Site Master File</li> </ul> <p><b>PERSONNEL</b></p> <ul style="list-style-type: none"> <li>● Organizational Chart/ number of personnel</li> <li>● Qualification</li> <li>● Responsibilities</li> <li>● Training/records</li> </ul> <p><b>PREMISES</b></p> <ul style="list-style-type: none"> <li>● Location</li> <li>● Plant Construction &amp; Design</li> <li>● Changing rooms and facilities</li> </ul>	



	<ul style="list-style-type: none"><li>● Toilets</li><li>Defined areas<ul style="list-style-type: none"><li>➤ Materials receiving.</li><li>➤ Material Sampling</li><li>➤ Incoming goods and quarantine.</li><li>➤ Starting materials storage.</li><li>➤ Weighing and dispensing.</li><li>➤ Processing.</li><li>➤ Storage of bulk products.</li><li>➤ Packaging.</li><li>➤ Quarantine storage before final release of products.</li><li>➤ Storage of finished products.</li><li>➤ Loading and unloading.</li><li>➤ Laboratories.</li><li>➤ Equipment washing.</li><li>➤ Wall, Ceiling &amp; Floor</li><li>➤ Drains</li><li>➤ Air Intakes and Exhausts</li><li>➤ Lighting &amp; Ventilation</li><li>➤ Laboratories</li><li>➤ Storage Areas</li></ul></li><li>● Cleaning and Maintenance of facilities</li><li>● Water System (Lay-out, Monitoring / records)</li></ul> <p><b>EQUIPMENT</b></p> <ul style="list-style-type: none"><li>● Design and Construction</li><li>● Installation and Location</li></ul>	
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