

**BHARATI VIDYAPEETH**  
**(DEEMED TO BE UNIVERSITY), PUNE, INDIA**  
**PhD Entrance Test – 2022**  
**SECTION-II: Drug Regulatory Affairs - 50 Marks**

<b>1)</b>	<b>GMP &amp; GLP guidelines</b> - The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for Ayurvedic, Siddha and Unanni medicines (Schedule T).
<b>2)</b>	<b>ICH Guidelines for stability, analytical method validation</b>
<b>3)</b>	<b>Drug registration process &amp; types - Preparation of CTD Document as per ICH</b>
<b>4)</b>	<b>Documentation, Audits &amp; Inspections:</b> Master formula record, Batch packaging records, Standard operating procedure, Certificate of analysis, validation protocols, Stability protocol, Maintenance of records in Pharmaceutical industry.  Audit types – Internal audit, external audit, regulatory audit.  General process of audit planning.
<b>5)</b>	<b>Clinical trials Rules and Medical device rules:</b> Indian Regulations
<b>6)</b>	<b>Herbal Products:</b> Quality, safety and legislation for herbal products in India and USA

<b>References:</b>		
<b>1</b>	Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals	
<b>2</b>	Common Technical documents (ICH guidelines).	
<b>3</b>	WHO GMP guidelines	
<b>4</b>	Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.	
<b>5</b>	How to practice GLP by PP Sharma, Vandana Publications	
<b>6</b>	FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008	
<b>7</b>	<a href="http://www.who.int">www.who.int</a>	
<b>8</b>	<a href="http://www.ich.org">www.ich.org</a>	
<b>9</b>	<a href="https://cdsco.gov.in">https://cdsco.gov.in</a>	
<b>10</b>	<a href="http://www.fda.gov">www.fda.gov</a>	

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