Question Bank for BP603T: Herbal Drug Technology (Unit V)

Course Code: BP603T

Subject: Herbal Drug Technology (Theory)

Unit: V - General Introduction to Herbal Industry and Schedule T – Good Manufacturing Practice

Institution: SNS College of Pharmacy and Health Sciences

Prepared by: [Your Name], Professor of Pharmacognosy

This question bank is designed for Semester VI students of the B. Pharm program, aligned with the syllabus of BP603T (Herbal Drug Technology) as per the Pharmacy Council of India regulations. The questions cover Unit V, focusing on the herbal drugs industry, its scope and prospects, plant-based industries and institutions in India, and Schedule T – Good Manufacturing Practice (GMP) for Indian systems of medicine. Questions are categorized based on Bloom's Taxonomy levels (Knowledge, Application, Analysis) and include Two-Mark, Five-Mark, and Ten-Mark questions. Each question is accompanied by an answer and a rubric for evaluation.

Two-Mark Questions

Objective: Test basic recall and understanding of key concepts (Knowledge level).

1. **What is the scope of the herbal drugs industry in India?**

   Answer: The herbal drugs industry in India focuses on manufacturing herbal medicines, cosmetics, and nutraceuticals, driven by demand for natural products.

   Rubric:

   - 2 marks: Mentions manufacturing and demand for natural products.
   - 1 mark: Mentions only manufacturing or demand.
   - 0 marks: Incorrect or no response.

2 **Name two future prospects of the herbal drugs industry.**

   Answer: Global market expansion and increased research in herbal formulations.

   Rubric:

   - 2 marks: Names two prospects correctly.
   - 1 mark: Names one prospect correctly.
   - 0 marks: Incorrect or no response.

3 **What is Schedule T in the context of Indian systems of medicine?**

   Answer: Schedule T outlines Good Manufacturing Practices (GMP) for Ayurvedic, Siddha, and Unani (ASU) drug manufacturing in India.

   Rubric:

   - 2 marks: Defines Schedule T with GMP and ASU context.
   - 1 mark: Defines without GMP or ASU context.
   - 0 marks: Incorrect or no response.

4 **Name two objectives of Schedule T GMP.**

   Answer: Ensure product quality and maintain hygiene in manufacturing.

   Rubric:

   - 2 marks: Names two objectives correctly.
   - 1 mark: Names one objective correctly.
   - 0 marks: Incorrect or no response.

5 **What is the role of the Central Council for Research in Ayurvedic Sciences (CCRAS)?**

Answer: CCRAS conducts research and promotes Ayurvedic medicine development in India.

Rubric:

- 2 marks: Mentions research and Ayurveda promotion.
- 1 mark: Mentions only research or promotion.
- 0 marks: Incorrect or no response.

6 **Name two plant-based industries in India.**

Answer: Himalaya Wellness and Dabur India Ltd.

Rubric:

- 2 marks: Names two industries correctly.
- 1 mark: Names one industry correctly.
- 0 marks: Incorrect or no response.

7 **What is the purpose of Standard Operating Procedures (SOPs) in Schedule T?**

Answer: SOPs ensure consistent and standardized manufacturing processes for ASU drugs.

Rubric:

- 2 marks: Mentions consistency and standardization.
- 1 mark: Mentions purpose without specifics.
- 0 marks: Incorrect or no response.

8 **What is the significance of documentation in Schedule T GMP?**

Answer: Documentation ensures traceability and compliance with quality standards in ASU drug manufacturing.

Rubric:

- 2 marks: Mentions traceability and compliance.
- 1 mark: Mentions only traceability or compliance.
- 0 marks: Incorrect or no response.

9 **Name two infrastructural requirements under Schedule T.**

Answer: Adequate working space and proper storage areas.

Rubric:

- 2 marks: Names two requirements correctly.
- 1 mark: Names one requirement correctly.
- 0 marks: Incorrect or no response.

10 **What is the role of the National Medicinal Plants Board (NMPB)?**

Answer: NMPB promotes cultivation and conservation of medicinal plants in India.

Rubric:

- 2 marks: Mentions cultivation and conservation.
- 1 mark: Mentions only cultivation or conservation.
- 0 marks: Incorrect or no response.

11 **What is meant by health and hygiene in Schedule T GMP?**

Answer: Health and hygiene ensure a clean manufacturing environment and worker safety to prevent contamination.

Rubric:

- 2 marks: Mentions clean environment and contamination prevention.
- 1 mark: Mentions only environment or hygiene.
- 0 marks: Incorrect or no response.

12 **Name two types of machinery required under Schedule T.**

Answer: Tablet compression machine and mixing vessels.

Rubric:

- 2 marks: Names two machinery types correctly.
- 1 mark: Names one machinery type correctly.
- 0 marks: Incorrect or no response.

13 **What is the primary goal of the herbal drugs industry?**

Answer: To produce safe, effective, and high-quality herbal products for healthcare.

Rubric:

- 2 marks: Mentions safety, efficacy, or quality.
- 1 mark: Mentions goal without specifics.
- 0 marks: Incorrect or no response.

14 **Name two institutions involved in medicinal plant research in India.**

Answer: Central Institute of Medicinal and Aromatic Plants (CIMAP) and Indian Institute of Integrative Medicine (IIIM).

Rubric:

- 2 marks: Names two institutions correctly.
- 1 mark: Names one institution correctly.
- 0 marks: Incorrect or no response.

15 **What is the importance of storage areas in Schedule T GMP?**

Answer: Storage areas prevent contamination and preserve the quality of raw materials and finished products.

Rubric:

- 2 marks: Mentions contamination prevention and quality preservation.
- 1 mark: Mentions only contamination or quality.
- 0 marks: Incorrect or no response.

16 **What is the role of quality control in Schedule T GMP?**

Answer: Quality control ensures raw materials and finished ASU drugs meet safety and efficacy standards.

Rubric:

- 2 marks: Mentions safety and efficacy standards.
- 1 mark: Mentions quality control without specifics.
- 0 marks: Incorrect or no response.

17. **Name two components of Schedule T GMP.**

Answer: Health and hygiene, and documentation and records.

Rubric:

- 2 marks: Names two components correctly.
- 1 mark: Names one component correctly.
- 0 marks: Incorrect or no response.

18. **What is the significance of the AYUSH Ministry in the herbal industry?**

Answer: The AYUSH Ministry regulates and promotes the development of ASU medicines in India.

Rubric:

- 2 marks: Mentions regulation and promotion.
- 1 mark: Mentions only regulation or promotion.
- 0 marks: Incorrect or no response.

19. **What is the purpose of working space in Schedule T GMP?**

Answer: Working space ensures efficient and contamination-free manufacturing of ASU drugs.

Rubric:

- 2 marks: Mentions efficiency and contamination prevention.
- 1 mark: Mentions only efficiency or contamination.
- 0 marks: Incorrect or no response.

20. **Name two challenges faced by the herbal drugs industry in India.**

Answer: Regulatory compliance and raw material standardization.

Rubric:

- 2 marks: Names two challenges correctly.
- 1 mark: Names one challenge correctly.
- 0 marks: Incorrect or no response.

Five-Mark Questions

Objective: Assess application of concepts and ability to explain processes or principles (Application level).

1. **Explain the present scope of the herbal drugs industry in India.**
   Answer: The herbal drugs industry in India is thriving due to: 1) Growing demand for natural products in healthcare and cosmetics. 2) Export potential to global markets. 3) Support from AYUSH Ministry for ASU drugs. 4) Increased consumer awareness of herbal benefits. For example, companies like Himalaya and Patanjali produce herbal medicines and nutraceuticals, contributing to economic growth and employment.
   Rubric:
   - 5 marks: Explains four aspects of scope with examples.
   - 3-4 marks: Explains three aspects with partial details.
   - 1-2 marks: Brief scope with minimal detail.
   - 0 marks: Incorrect or no response.
2. **Discuss the future prospects of the herbal drugs industry in India.**
   Answer: Future prospects include: 1) Expansion into global markets due to demand for natural products. 2) Innovation in novel herbal formulations like phytosomes. 3) Increased R&D investment for evidence-based products. 4) Government initiatives like AYUSH Mission for promotion. For example, standardized herbal exports (e.g., turmeric-based products) are expected to grow, but challenges like quality control must be addressed.
   Rubric:
   - 5 marks: Discusses four prospects with examples or challenges.
   - 3-4 marks: Discusses three prospects with partial details.
   - 1-2 marks: Brief prospects with minimal detail.
   - 0 marks: Incorrect or no response.

3 **Describe the objectives of Schedule T GMP for ASU drugs.**

Answer: Schedule T GMP aims to: 1) Ensure consistent quality of ASU drugs. 2) Maintain hygiene and safety during manufacturing. 3) Prevent contamination of products. 4) Promote compliance with regulatory standards. 5) Enhance consumer trust through traceability. These objectives ensure safe and effective herbal medicines, aligning with global standards.

Rubric:

- 5 marks: Describes four objectives with details or examples.
- 3-4 marks: Describes three objectives with partial details.
- 1-2 marks: Brief objectives with minimal detail.
- 0 marks: Incorrect or no response.

4 **Explain the role of plant-based industries in India with examples.**

Answer: Plant-based industries produce herbal medicines, cosmetics, and nutraceuticals using medicinal plants. Roles: 1) Economic contribution through production and exports. 2) Employment generation in rural areas. 3) Promotion of sustainable cultivation. Examples: Himalaya Wellness manufactures herbal skincare, while Dabur produces Chyawanprash. These industries drive the herbal sector’s growth and global presence.

Rubric:

- 5 marks: Explains three roles with two examples.
- 3-4 marks: Explains two roles with one example.
- 1-2 marks: Brief role with minimal detail.
- 0 marks: Incorrect or no response.

5 **Discuss the infrastructural requirements under Schedule T GMP.**

Answer: Infrastructural requirements include: 1) Adequate working space for manufacturing processes. 2) Separate storage areas for raw materials and finished products. 3) Proper ventilation and lighting to prevent contamination. 4) Designated areas for quality control testing. For example, a clean room for tablet production ensures hygiene. These requirements maintain product quality and safety.

Rubric:

- 5 marks: Discusses four requirements with examples or details.
- 3-4 marks: Discusses three requirements with partial details.
- 1-2 marks: Brief requirements with minimal detail.
- 0 marks: Incorrect or no response.

6 **Explain the role of institutions involved in medicinal and aromatic plant research in India.**

Answer: Institutions promote research and development of medicinal plants. Roles: 1) Developing standardized herbal formulations (e.g., CIMAP's work on menthol). 2) Conserving biodiversity (e.g., NMPB's cultivation programs). 3) Training professionals in herbal technology. 4) Collaborating with industries for product development. For example, IIIM Jammu researches anti-cancer herbal drugs, enhancing the herbal industry's scientific base.

Rubric:

- 5 marks: Explains four roles with examples.
- 3-4 marks: Explains three roles with partial details.
- 1-2 marks: Brief role with minimal detail.
- 0 marks: Incorrect or no response.

7 **Describe the importance of health and hygiene in Schedule T GMP.**

Answer: Health and hygiene in Schedule T GMP ensure: 1) A contamination-free manufacturing environment. 2) Worker safety through proper attire and training. 3) Product safety for consumers. 4) Compliance with regulatory standards. For example, regular sanitization of equipment prevents microbial contamination in ASU drugs, maintaining quality and trust.

Rubric:

- 5 marks: Describes four importance points with examples.
- 3-4 marks: Describes three points with partial details.
- 1-2 marks: Brief importance with minimal detail.
- 0 marks: Incorrect or no response.

8 **Explain the significance of documentation and records in Schedule T GMP.**

Answer: Documentation ensures: 1) Traceability of raw materials and processes. 2) Compliance with regulatory standards. 3) Quality control through batch records. 4) Accountability in case of defects. For example, maintaining batch manufacturing records for an Ayurvedic syrup ensures recall if needed. Proper records enhance transparency and consumer safety in ASU drug production.

Rubric:

- 5 marks: Explains four significance points with examples.
- 3-4 marks: Explains three points with partial details.
- 1-2 marks: Brief significance with minimal detail.
- 0 marks: Incorrect or no response.

9 **Discuss the machinery and equipment requirements under Schedule T GMP.**
Answer: Machinery requirements include: 1) Mixing vessels for uniform blending of herbal extracts. 2) Tablet compression machines for solid dosage forms. 3) Drying equipment for raw materials. 4) Packaging machines for product safety. For example, a granulator ensures consistent tablet production. These machines ensure efficiency, quality, and compliance in ASU drug manufacturing.
Rubric:

- 5 marks: Discusses four requirements with examples or details.
- 3-4 marks: Discusses three requirements with partial details.
- 1-2 marks: Brief requirements with minimal detail.
- 0 marks: Incorrect or no response.

10 **Explain the role of Standard Operating Procedures (SOPs) in Schedule T GMP.**
Answer: SOPs in Schedule T GMP: 1) Standardize manufacturing processes for consistency. 2) Ensure worker training and safety. 3) Facilitate quality control and compliance. 4) Reduce errors in production. For example, an SOP for cleaning equipment prevents cross-contamination in ASU drug production. SOPs enhance efficiency and regulatory adherence.
Rubric:

- 5 marks: Explains four roles with examples or details.
- 3-4 marks: Explains three roles with partial details.
- 1-2 marks: Brief role with minimal detail.
- 0 marks: Incorrect or no response.

Ten-Mark Questions

Objective: Evaluate critical thinking and ability to analyze and synthesize information (Analysis level).

1. **Analyze the present scope and future prospects of the herbal drugs industry in India, with reference to challenges and opportunities.**

Answer: The herbal drugs industry's present scope includes: 1) Production of ASU medicines, cosmetics, and nutraceuticals. 2) Growing domestic and export markets. 3) Government support via AYUSH. Future prospects: 1) Global demand for natural products. 2) Innovation in formulations (e.g., phytosomes). 3) R&D for evidence-based drugs. Opportunities: Consumer preference for herbal products, biodiversity. Challenges: 1) Raw material standardization. 2) Regulatory compliance. 3) Competition from synthetic drugs. Solutions: Adopting GMP, enhancing research (e.g., CIMAP), and promoting exports. The industry's growth potential is high but requires quality focus.

Rubric:

- 8-10 marks: Analyzes scope, three prospects, challenges, and solutions with examples.
- 5-7 marks: Analyzes scope or two prospects with partial details.
- 2-4 marks: Brief analysis with minimal detail.
- 0-1 marks: Incorrect or incomplete response.

2 **Evaluate the role of plant-based industries and institutions in advancing the herbal drugs sector in India, with examples.**

Answer: Plant-based industries like Himalaya Wellness and Dabur produce herbal medicines, cosmetics, and nutraceuticals, contributing to: 1) Economic growth via exports. 2) Employment in rural areas. 3) Sustainable cultivation. Institutions like CIMAP and CCRAS advance the sector through: 1) Research on medicinal plants (e.g., CIMAP's work on menthol). 2) Standardization of formulations. 3) Training professionals. Strengths: Industry-institution collaboration, biodiversity. Weaknesses: Limited funding, slow technology transfer. Examples: Dabur's Chyawanprash, CCRAS's AYUSH-64. Enhanced collaboration can drive global competitiveness.

Rubric:

- 8-10 marks: Evaluates roles of both, three contributions, strengths, weaknesses, and examples.
- 5-7 marks: Evaluates one group or two contributions with partial details.
- 2-4 marks: Brief evaluation with minimal detail.
- 0-1 marks: Incorrect or incomplete response.

3 **Critically analyze the components of Schedule T GMP and their impact on the quality of ASU drugs in India.**

Answer: Schedule T GMP components include: 1) Infrastructural requirements (e.g., working space, storage). 2) Machinery and equipment (e.g., tablet presses). 3) Health and hygiene (e.g., sanitization). 4) SOPs and documentation. Impact: 1) Ensures consistent quality (e.g., standardized Ayurvedic tablets). 2) Prevents contamination. 3) Enhances consumer trust. Strengths: Regulatory compliance, safety. Weaknesses: High implementation costs, inconsistent enforcement. Solutions: Subsidies for small manufacturers, regular audits. Schedule T strengthens the ASU drug industry but needs uniform adoption for global standards.

Rubric:

- 8-10 marks: Analyzes four components, impact, strengths, weaknesses, and solutions.
- 5-7 marks: Analyzes three components or partial impact.
- 2-4 marks: Brief analysis with minimal detail.
- 0-1 marks: Incorrect or incomplete response.

4 **Evaluate the significance of Schedule T GMP in ensuring the safety and efficacy of ASU drugs, with a focus on infrastructural and documentation requirements.**
Answer: Schedule T GMP ensures ASU drug safety and efficacy through: 1) Infrastructural requirements like separate storage areas to prevent contamination (e.g., raw material segregation). 2) Adequate working space for efficient production. 3) Documentation for traceability (e.g., batch records). 4) Quality control via SOPs. Significance: 1) Enhances product safety. 2) Ensures consistent efficacy. 3) Meets regulatory standards. Challenges: High setup costs, limited awareness among small manufacturers. Solutions: Training programs, financial support. Schedule T aligns ASU drugs with global quality norms, boosting market trust.
Rubric:

- 8-10 marks: Evaluates significance, three requirements, challenges, and solutions with examples.
- 5-7 marks: Evaluates two requirements or partial significance.
- 2-4 marks: Brief evaluation with minimal detail.
- 0-1 marks: Incorrect or incomplete response.

Note: This question bank is based on the BP603T syllabus for Unit V, focusing on the herbal drugs industry and Schedule T GMP. Questions are designed to align with Bloom's Taxonomy, ensuring a progressive assessment of knowledge, application, and analysis. Faculty are encouraged to use these questions for sessional exams, assignments, or classroom discussions to enhance student understanding of herbal drug technology.