

Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
**Drug Regulatory Authority of Pakistan**  
Division of Biological Evaluation & Research

**PRE-SUBMISSION SCREENING CHECKLIST FOR BIOLOGICAL REGISTRATION DOSSIER**

Note: Application shall be received for detailed evaluation if all the below mentioned documents are submitted.

- |   |                          |     |                          |    |             |
|---|--------------------------|-----|--------------------------|----|-------------|
| 1. Original Duly signed Covering letter and Form-5A, Form-5 or Form-5F        | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 2. Fee as per relevant SRO  | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 3. Copy of valid DSL/ DML (As Applicable)                                     | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 4. Evidence of valid Section & GMP Compliance of relevant section (For Local) | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 5. Valid legalized CoPP/ FSC & GMP (For Import)                               | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 6. Original or Notarized Copy of Valid Sole Agency Agreement (For Import)     | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 7. Evidence of Approval of formulation in RRA                                 | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 8. Evidence of already registered same formulation in Pakistan                | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 9. Dossier is properly annexed with binding & Page numbering                  | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |
| 10. Soft copy of dossier (USB)  | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | Page# _____ |

Remarks (if any)

---

---

---

---

Receive

Return back to the applicant for completion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature (Asst. Director)