**Guidelines/checklist for Form 5 Approved by Registration Board in 251st and 273rd meeting**

 **(For Form-5)**

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| **S #** | **Form 5** | **Procedure to be adopted**  |
|  | Name and address of the manufacturer (applicant) | - |
|  | Brand (Proprietary) name of Drug | - |
|  | The chemical name(s) and, as appropriate and available the established (generic) names and synonyms of the drug. | - |
|  | Strength of active ingredient(s) per unit, e.g. each tablet or 5 ml, etc. contains | - |
|  | Pharmacological group. | - |
|  | Recommended clinical use. | * Commitment to follow innovator brand or as approved by any reference regulatory authority (as approved in 249th meeting) and only such information shall be mentioned in medical literature/ patient information leaflet.
* This condition shall also be mentioned in registration letter.
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|  | Proposed route of administration. | * Commitment to follow innovator brand or as approved by any reference regulatory authority (as approved in 249th meeting) and only such information shall be mentioned in medical literature/ patient information leaflet.
* This condition shall also be mentioned in registration letter.
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|  | Proposed dosage. | * Commitment to follow innovator brand or as approved by any reference regulatory authority (as approved in 249th meeting) and only such information shall be mentioned in medical literature/ patient information leaflet.
* This condition shall also be mentioned in registration letter.
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|  | Proposed shelf life of the drug | As per commitment (max 2 years).  |
|  | Proposed storage conditions of finished product. | * Commitment to follow innovator brand or as approved by any reference regulatory authority (as approved in 249th meeting) and only such information shall be mentioned in medical literature/ patient information leaflet.
* This condition shall also be mentioned in registration letter.
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|  | Unit price of the drug, e.g. per tablet, per capsule, per 5ml, etc.  | - |
|  | In case of international availability, provide the following information, namely:- a. name of the drug; b. country where sold / registered; and c. name of company selling the drug or having registration to manufacture (include supporting documents/proof of International registration.  | - |
|  | Brand name(s) of drug available in Pakistan. | - |
|  | Name(s) of company(s) manufacturing in Pakistan. | - |
|  | Composition (actives & excepients) including statement of the quantitative composition, giving the weight or measure for each active substance used in the manufacture of the dosage form.  | Commitment for following:* Pharmaceutical product development (before sale of drug) in line with the compostion of innovator or any other generic approved by any reference regulatory authority. For excepients, equivalent alternates can be used.
* No banned excipient shall be used. All excipients are required to be of pharmaceutical grade and within safe limits.
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|  | Outline of method of manufacture.  | Flow chart is required  |
|  | Persons under whose direct supervision and control the drug is manufactured with the following details, namely:- a. total number of technical staff; and b. name, qualification and designation of the persons directly supervising the manufacture of the drug applied for registration, and any change shall be properly documented and record maintained by the manufacturer.  | As per information provided by the firm  |
|  | Name of equipment that will be used in the manufacture of the drug applied for registration | As per information provided by the firm according to the applied dosage form of the drug |
|  | Full descriptions of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product. | Commitment for complying Drug Specification Rules, 1978 and validaton of analytical methods (before sale of drug) to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.  |
|  | Name, qualification and designation of the persons who will be responsible for the quality control of the drug.  | As per information provided by the firm.  |
|  | Description of the equipment to be used for the quality control of the active raw material and the finished products. | As per information provided by the firm according to the applied dosage form of the drug.  |
|  | Labeling and prescribing information ( to be mentioned on the pack/leaflet) specimen or draft shall be submitted for the following class as of drugs, namely:- a. C.N.S. stimulants; b. drugs affecting uterine motility; c. drugs inhibiting hormonal production; d. hormones and other steroidal preparation excluding preparations for external and topical use; e. narcotic drugs as per Single Convention on Narcotic Drugs 1961; and f. psychotropic substances mentioned as per convention on psychotropic substances, 1971. (Specimen of label to be submitted as soon as production starts)  | * Commitment to follow innovator brand or as approved by any reference regulatory authority (as approved in 249th meeting) and only such information shall be mentioned in medical literature/ patient information leaflet.
* This condition shall also be mentioned in registration letter.
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|  | Facility of water processing with specifications.  | As per Licensing section’s approval / GMP report / information provided by thr firm |
|  | Environment control processing with details. | As per Licensing section’s approval / GMP report / information provided by thr firm |
|  | Type of container/packaging. | As per innovator / approved by any reference regulatory authority (as approved in 249th meeting).  |
|  | A copy of last Inspection Report conducted by the DRAP.  | - |
|  | Undertaking that the above given information is true and correct to the best knowledge and belief of Production Manager & Quality Control Manager. | -  |