Analysis Requirement

1. **Medicine:**
   - 1.1. Method of analysis.
   - 1.2. Certificate of analysis for the same submitted batch signed and stamped by the manufacturer.
   - 1.3. Chromatograms are required if the analysis is carried out by GC or HPLC Instrument.
   - 1.4. Pharmacopeial reference standard for all tests (Assay, Related substances, identification, dissolution and impurities tests) at least 100mg for each standard.
   - 1.5. Primary reference standard with its certificate of analysis if the reference standard is not available in the pharmacopeia.
   - 1.6. HPLC or GC column with its certificate in case if a chromatographic method is used (only new column will be accepted).
   - 1.7. Quantity of samples required as per attached list.
   - 1.8. Validation should be submitted for in house methods. If an in house method is used instead of available pharmacopeial monograph for the product, statistical comparison study should be submitted in addition to validation documents.
   - ***1.9. For pharmacopeial method, verification (specificity, precision and linearity) should be submitted.***
   - 1.10. The shelf life of submitted sample should not be less than 75%.
2. **Simple pharmaceutical products, Cosmetics and Food Supplements:**
   - 2.1. Method of analysis
   - 2.2. Certificate of analysis for the same submitted batch approved and stamped by the manufacturer.
   - 2.3. For simple pharmaceutical products validation for in house method should be submitted.
   - 1.11. HPLC or GC column with its certificate in case if a chromatographic method is used (only new column will be accepted).
   - 2.4. Working standard with its certificate (if needed).
   - 2.5. Chromatograms are required if the analysis is carried out by GC or HPLC Instrument.
   - 2.6. Quantity of samples required as per attached list.

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2.7. Composition formula showing the concentration and function of each component.
2.8. The shelf life of submitted Sample should not be less than 75%.

3. Paramedicals:

3.1. Certificate of analysis for the same submitted batch signed and stamped by the manufacturer.

3.2. Method of analysis.
3.3. Working standard with its certificate (if needed).
1.12. HPLC or GC column with its certificate in case if a chromatographic method is used (only new column will be accepted).
1.13. Quantity of samples required as per attached list.
1.14. The shelf life of submitted Sample should be not less than 75%.

NB:

1) Reference standards and samples that need to be stored at (2-8°C) should be submitted in a cool container
2) Reference standards and samples that need to be stored at (2-8°C) and need special shipment conditions (cool condition) a data logger should be submitted with them.

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