الاختبارات المطلوب عملها

لجميع الأشكال الصيدلية طبقاً لمنظمة الصحة العالمية (بعد التعديل)

Dosage Form	Tests to be done
1-Tablets:	- Physical characters (appearance and color) - Average weight - Dissolution (or disintegration, if justified) -Water content -Hardness / Friability -Level of microbial contamination.
2-Capsules: **- Hard gelatin capsules:**	- Physical characters (appearance and color) -Average weight (of whole capsule and capsule content) -Brittleness -Dissolution (or disintegration, if justified) -Water content - Level of microbial contamination.
- Soft gelatin capsules	- Physical characters (appearance and color) -Average weight (of whole capsule and capsule content) -Dissolution (or disintegration, if justified) -Level of microbial contamination -PH -Leakage -Pellicle formation.
3-Emulsions:	-Physical characters (appearance and color) -Phase separation - PH - Viscosity -Level of microbial contamination -Mean size and distribution of dispersed globules
4-Oral Solutions & Suspensions:	- Physical characters (appearance and color) -Formation of precipitate -Clarity for solutions - PH -Viscosity -Extractables -Level of microbial contamination. -Additionally for suspensions: -Redispersibility -Rheological properties -Mean size -Distribution of particles should be considered. -Also;polymorphic conversion may be examined,if applicable

5-Powders & Granules for Oral Solutions or Suspensions:	- Physical characters (appearance and color) - Water content - reconstitution time. - Reconstituted products (solutions & suspensions) should be evaluated as described in "Oral solutions & Suspensions" above, after preparation according to the recommended labeling, through the maximum intended use period.
6-Metered-dose, Inhalers & Nasal Aerosols:	-Dose content uniformity -Labeled number of medication actuations per container meeting dose content uniformity, -Aerodynamic particle size distribution -Microscopic evaluation, -Water content -Leak rate -Level of microbial contamination -Valve delivery (shot weight) & extractables/ leachables from plastic & elastomeric components -Samples should be stored in upright & inverted/on-the-side orientations. -For suspension-type aerosols: Tthe appearance of the valve components & container's contents should be evaluated microscopically for large particles & changes in morphology of the drug surface particles, extent of agglomerates, crystal growth, as well as foreign particulate matter. These particles lead to clogged valves or non-reproducible delivery of a dose. Corrosion of the container or deterioration of the gaskets may adversely affect the performance of the drug product.
7-Nasal Sprays: Solutions & Suspensions:	-Clarity (for solutions) -level of microbial contamination -PH -Particulate matter, -Unit spray per container -Droplet &/or particle size distribution -Weight loss -Pump delivery -Microscopic evaluation (for suspensions) -Foreign particulate matter & extractables/ leachables from plastic & elastomeric components of the container -Closure - pump

8-Topical, Ophthalmic & Otic preparations:	- Included in this broad category: Ointments, creams, lotions, pastes, gels, solutions, Eye drops, & cutaneous sprays. -Topical preparations should be evaluated for: - Physical characters (appearance and color) -Clarity -Homogeneity -PH - Resuspendability (for lotions) -Consistency -Viscosity -Particle size distribution (for suspensions, when feasible) -Level of microbial contamination /sterility - Weight loss (when appropriate). - Evaluation of ophthalmic or otic products (e.g. creams, ointments, solutions & suspensions) should include the following additional attributes: -sterility (in case of otic products if antibiotics are present only) -particulate matter & extractable. - Evaluation of cutaneous sprays should include: -Pressure -Weight loss -Net weight dispensed -Delivery rate -Level of microbial contamination -Spray pattern -Water content -Particle size distribution (for suspensions) .
9-Suppositories:	-Softening range -Dissolution (at 37°C)
10-Small Volume Parenterals (SVPs):	- Color -Clarity (for solutions) -Particulate matter -PH -Sterility -Endotoxins.

	- Stability studies for powders for injection solution should include : -Monitoring for color -Reconstitution time - Water content Specific parameters to be examined at appropriate intervals throughout the maximum intended use period of the reconstituted drug product, stored under condition(s) recommended in labeling should include: -Clarity -Color -PH -Sterility -Pyrogen/ endotoxin -Particulate matter -The stability studies for suspensions for injection should include, in addition: -Particle size -Distribution -Redispersibility -Rheological properties -The stability studies for emulsion for injection should include, in addition: -Phase separation -Viscosity -Mean size -Distribution of dispersed phase globules
11-Large Volume Parenterals (LVPs):	-Color, -Clarity -particulate matter -PH -Sterility -Pyrogen/ endotoxin -Volume.
12-Transdermal Patches:	-In vitro release rates -Leakage -Level of microbial contamination/ sterility -Peel -Adhesive forces