

Drug Submission Screening Checklist for Aqueous Solutions

Table 1, Drug Product Information

Drug Product Information	Reference Information
Drug Product:	Reference Product:
Lot Number:	Lot Number:
Expiry Date:	Expiry Date:

Table 2, Routes of Administration

Test Parameter	Injectable	Inhalation	Nasal	Ophthalmic	Oral*	Otic
Description, colour, clarity, expiry	C	C	C	C	C	C
Drug Potency	NC	NC	NC	NC	NC	NC
Potency, preservative	NC	NC	NC	NC	NC	NC
Potency, salt, solvent	C	C	C	C	C	C
pH	C	C	C	C	C	C
Viscosity	C	C	C	C	C	C
Surface Tension	C	C	C	C	C	C
Specific Gravity	C	C	C	C	C	C
Antimicrobial Effectiveness Testing	NC	NC	NC	NC	NC	NC
Microbial Quality	N/A	N/A	NC	N/A	NC	NC

Test Parameter	Injectable	Inhalation	Nasal	Ophthalmic	Oral*	Otic
Partition Coefficient, where applicable	C	C	C	C	C	C
Sterility	NC	NC	C	NC	N/A	NC
Pyrogens, Endotoxin	NC	NC	N/A	N/A	N/A	N/A
Particulate Matter	NC	N/A	N/A	N/A	N/A	N/A
Foreign Matter	NC	NC	N/A	NC	N/A	NC
Fill Volume	NC	N/A	N/A	N/A	N/A	N/A
Uniformity of Mass	N/A	N/A	NC	N/A	NC	N/A
Osmolality, Osmolarity	C	C	C	C	N/A	C
Buffer Capacity	C	C	C	C	C	C
Droplet Size or Volume, Drug Content per Drop, Quantity per spray, as appropriate	N/A	C	C	C	N/A	C
Oral Drops Dose and Uniformity of Dose	N/A	N/A	N/A	N/A	C	N/A

C=comparative test; NC=non-comparative test; N/A=not applicable.

*orally administered solutions may be either aqueous or alcohol-based; all other solutions, regardless of the route of administration, must be aqueous.