

SOLUTIONS (LIQUIDS)

- Homogeneous liquid preparations which are formed from a mixture of at least two substances are called 'solutions'.
- Single-phase homogeneous systems prepared by dissolving one or more active substances in one or several solvent mixtures.
- It consists of solutions → solute + solvent phases.
- In general → phase is rarely found in the system + phase is mostly found in the system.

Classification of Solvents According to Their Solvents

- * Aqueous solutions
- * Dehydrated solutions
- * Alcoholic solutions
- * Hydroalcoholic solutions
- * Oily solutions

According to usage:

- Parenteral
- Ophthalmic
- Nasal
- Otic
- Collutory
- Gargle
- Enema
- Inhalation
- Spray
- Drop

Physical Stabilities of Solvents

Organoleptic Tests

In the early stages of the Stablite program a test panel should be established in terms of organoleptic tests.

Organoleptic tests are generally subjectively tested by a tester (operator, technician).

This person evaluates the product in terms of taste, image and smell and scores it numerically, descriptively or both.

Physical Stabilities of Solvents

Subjective appearance tests

Dubosque colorimetry yields numbers that match the Beer's law and is logarithmically proportional to concentration. In this respect, the decomposition can be simply expressed by first-order kinetics.

$$X = X_{\infty}[1 - \exp(-qt)]$$

X: Concentration of decomposition product.

q: Sabite

X: Repeatable.

t: Time


* This equality can be used to predict the worst appearance of the product.


Oral liquid dosage forms

Group	Test Attributes	In-process control	Release Testing	Stability Testing	Skip Testing
1	Organoleptical attributes <ul style="list-style-type: none"> • Description appearance • Odour 	x	x x	x x	
2	Physicochemical attributes <ul style="list-style-type: none"> • Identification • Uniformity of dosage units • Weight variations • Fill volume • Uniformity of fill) • Loss on mass • pH • Colour of solution • Clarity of solution • Viscosity Orals suspension <ul style="list-style-type: none"> • Particle size distribution • Redispersibility 	x x x x	x x x x x x x x x x	x x x x (x)	

Group	Test Attributes	In-process control	Release Testing	Stability Testing	Skip Testing
3	Chemical attributes <ul style="list-style-type: none"> • Assay • Impurities • Organic • Antimicrobial preservative content • Antimicrobial preservative decomposition • Antioxidant preservative content 		x x x	x x x x	
4	Microbial attributes <ul style="list-style-type: none"> • Microbial limits 		X	(x)	
5	Container closure system attributes <ul style="list-style-type: none"> • Interactions <ul style="list-style-type: none"> Extractables <ul style="list-style-type: none"> - rubber stopper - cap liner - plastic bottle 			(x)	x x x

Injections, Parenterals

Group	Test Attributes	In-process control	Release Testing	Stability Testing	Skip Testing
1	Organoleptical attributes <ul style="list-style-type: none"> • Description appearance 	x	x	x	
2	Physicochemical attributes <ul style="list-style-type: none"> • Identification • Uniformity of dosage units <ul style="list-style-type: none"> - Weight variations - Fill volume - Uniformity of fill) • Loss on mass • pH • Colour of solution • Particulate matters <ul style="list-style-type: none"> - clarity of solution • Osmolality  		x		
		x	x		
		x	x	x	
		x	x	x	
			x	x	
			x	(x)	

Group	Test Attributes	In-process control	Release Testing	Stability Testing	Skip Testing
3	Chemical attributes <ul style="list-style-type: none"> • Assay • Impurities <ul style="list-style-type: none"> - organic • Antimicrobial preservative content • Antimicrobial preservative decomposition • Antioxidant preservative content 		x x x x	x x x x x	
3	Microbial attributes <ul style="list-style-type: none"> • Microbial limits • Sterility  • Endotoxins • Pyrogens 		x x x x	(x)	
5	Container closure system attributes <ul style="list-style-type: none"> • Interactions • Extractables <ul style="list-style-type: none"> - rubber stopper - cap liner - plastic bottle • Functioning test 		x	(x) x	x x x