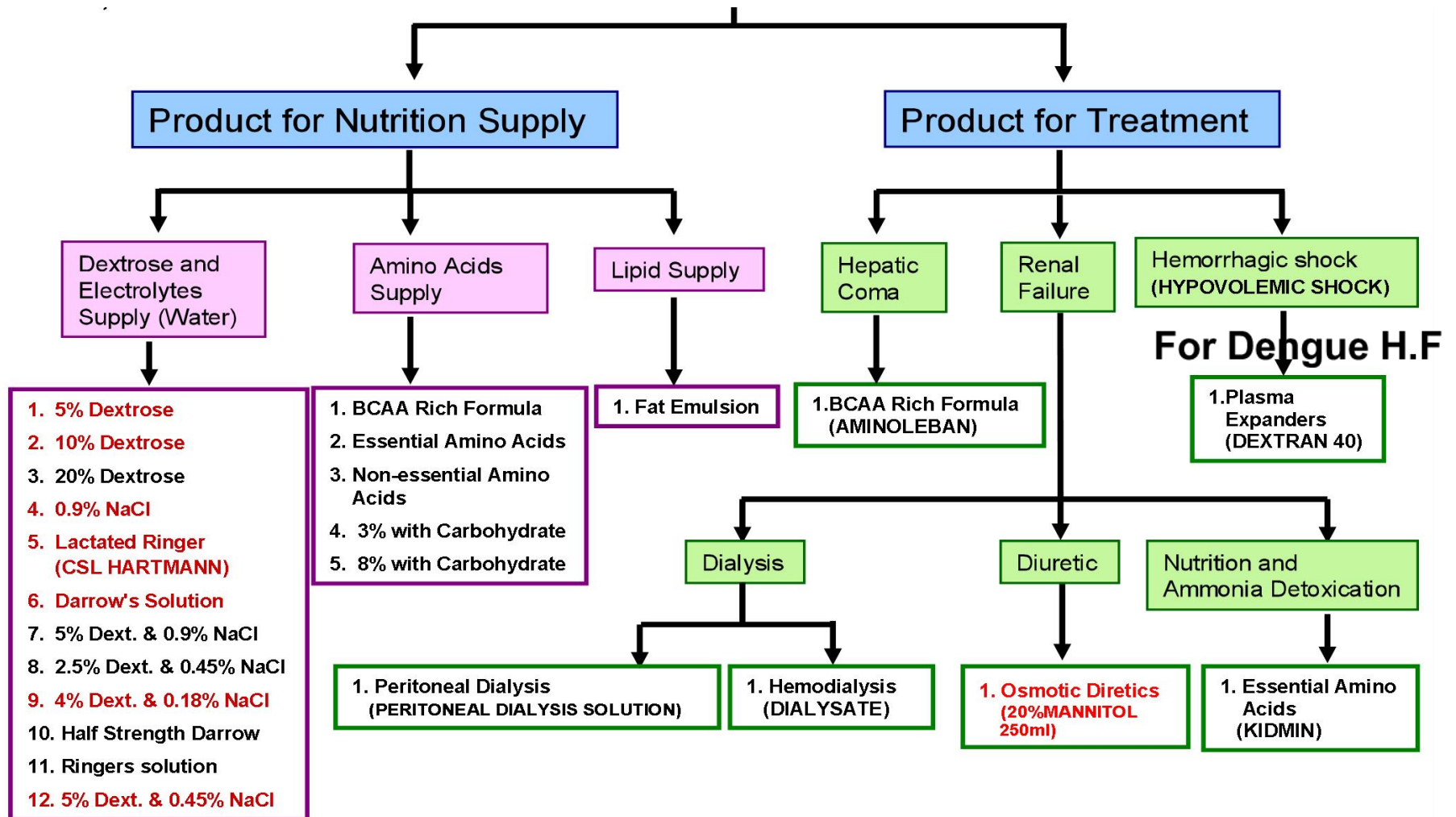


Project to set up Intravenous Solutions Manufacturing Plant in Sri Lanka

Nov. 27, 2017

Intra Venous Solutions



Sterilization by heat

This can be achieved by autoclaving, by exposing articles to dry heat in hot air ovens or boiling.

Autoclaving

Autoclaves can sterilize anything that can withstand a temperature of 121°C for 30 minutes.

A pressure cooker used in homes for cooking purposes can also be used as a makeshift autoclave.

The containers having clinical material are subjected to heat treatment in the autoclave after which these are emptied and washed and put back into service.

Only autoclaves designed for laboratory work and capable of dealing with a mixed load should be used. Porous load and bottle fluid sterilizers are rarely satisfactory for laboratory work. There are two varieties of laboratory autoclaves:

WHO PHARMACOPOEIA : STEAM STERILIZATION

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Introduction | General notices | Monographs | Methods of analysis | IR Spectra | Reagents | Suppl. information

sometimes for routine control of individual cycles. Periodic revalidation is recommended.

Heating in an autoclave (steam sterilization)

Exposure of microorganisms to saturated steam under pressure in an autoclave achieves their destruction by the irreversible denaturation of enzymes and structural proteins. The temperature at which denaturation occurs varies inversely with the amount of water present. Sterilization in saturated steam thus requires precise control of time, temperature, and pressure. As displacement of the air by steam is unlikely to be readily achieved, the air should be evacuated from the autoclave before admission of steam. This method should be used whenever possible for aqueous preparations and for surgical dressings and medical devices.

The recommendations for sterilization in an autoclave are 15 minutes at 121-124 °C (200 kPa).¹ The temperature should be used to control and monitor the process; the pressure is mainly used to obtain the required steam temperature. Alternative conditions, with different combinations of time and temperature, are given below.

¹ 1 atm = 101 325 Pa

Temperature (°C)	Approximate corresponding pressure (kPa)	Minimum sterilization time (min)
126-129	250 (~2.5 atm)	10
134-138	300 (~3.0 atm)	5

Minimum sterilization time should be measured from the moment when all the materials to be sterilized have reached the required temperature throughout. Monitoring the physical conditions within the autoclave during sterilization is essential. To provide the required information, temperature-monitoring probes should be inserted into representative containers, with additional probes placed in the load at the potentially coolest parts of the loaded chamber (as established in the course of the validation programme). The conditions should be within ±2 °C and ±10 kPa (±0.1 atm) of the required values. Each cycle should be recorded on a time-temperature chart or by other suitable means.

Aqueous solutions in glass containers usually reach thermal equilibrium within 10 minutes for volumes up to 100 mL and 20 minutes for volumes up to 1000 mL.

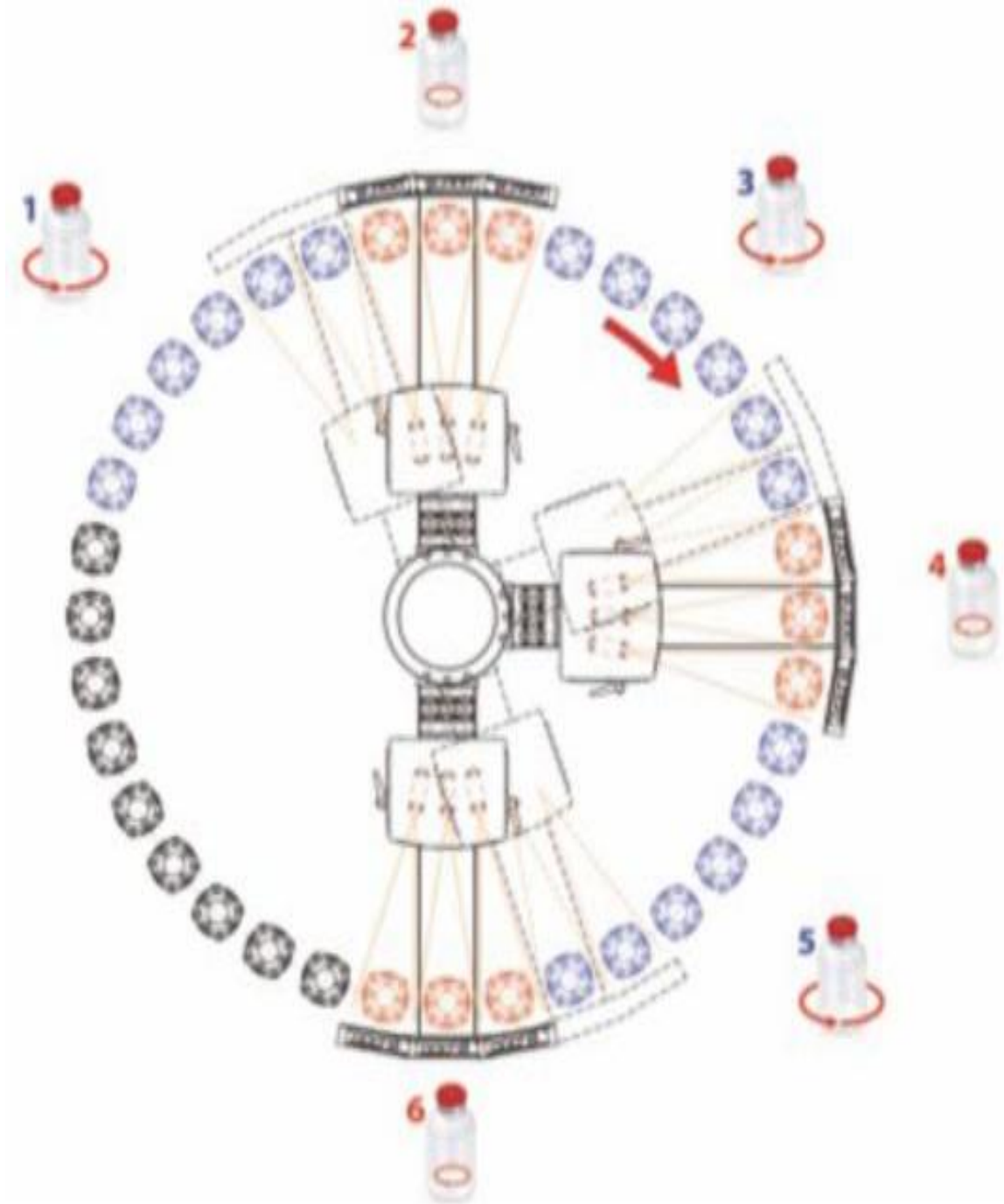
Porous loads, such as surgical dressings and related products, should be processed in an apparatus that ensures steam penetration. Most dressings are

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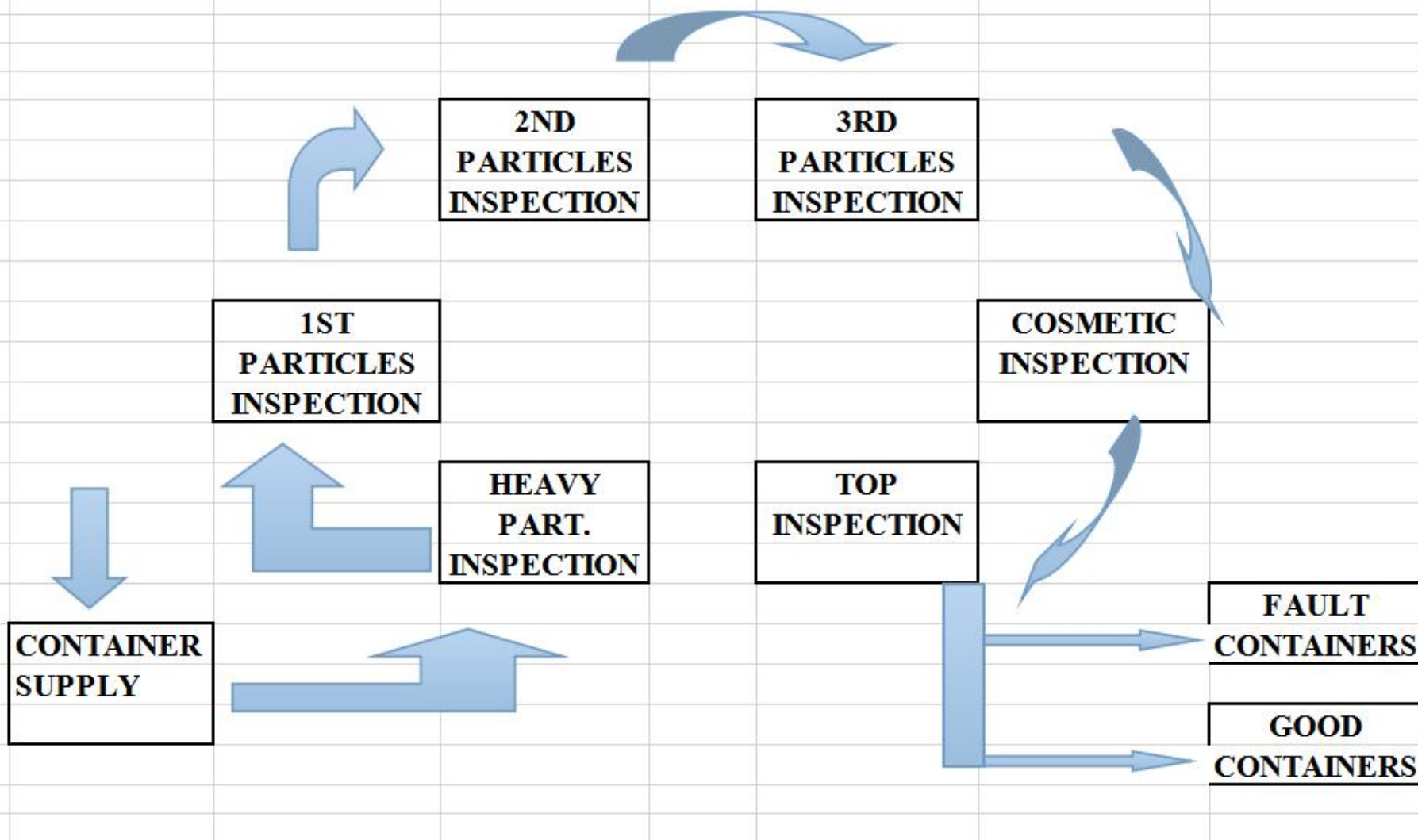
Inspection phases:

- 1. Spinning phase**
- 2. First particle inspection**
- 3. Spinning phase**
- 4. Second particle inspection**
- 5. Spinning phase**
- 6. Second particle inspection**



	Automatic leak detection and optical inspection machine for polypropylene bottles composed of:
1	Automatic Inspection Machine mod. LYNX 150, basic equipment 1. (ex-works)
2	Standard safety guards according to application CE norms
3	Electrical cabinet in painted carbon steel fixed on the machine
4	Standard No 2 fans and fillers ventilation system on electrical cabinet
5	Standard machine top cover made in plastic material
6	Standard machine feels
7	Standard machine corrousel manual high adjustment
8	Standard machine main motorization with Syncro motor
9	Control unit and automation (industrial PC and touchscreen panel)
10	JOG mode
11	Machine "Emergency stop" button on machine front side on HMI
12	Machine "Emergency stop" button on machine back side
13	Set of change parts in PVC for one basic container size
14	Extra cost for machine with neck handling bading conveyor
15	First particles inspection station completed with cameras and illuminators
16	Second particles inspection station completed with cameras and illuminators
17	Third particles inspection station completed with cameras and illuminators
18	Fill level inspection (executed in one of the three particles inspection stations)
19	Meniscus floating particles inspection unit
20	Machine unloading form standard conveyor belt (bottles laying down)
21	Software in compliance with 21CFR part 11
22	"GF Help troubleshooting system
23	Remote assistance software
24	UPS integrated unit (only for machine PC safe shut down)
25	Recommended spare parts for 1-year operation (max. 2000 working hours)
26	IQ-OQ Validation Documentation Package
27	Packing (wooden crate and protection bag)
28	FAT :GF qualified engineers available for 3 days including 1 Knopp test
29	Start-up, training, commissioning of all mechanical formats and 1 Knapp Test**
30	Integrated module for leak detection with vacuum decay system
31	Leak module set of change parts for basic container size
32	Certified software for self-test and verification on each leak head
33	Recommended spare parts for 1-year operation (max. 2000 working hours) .
34	IQ-OQ validation documentation package for leak module
18	Extra packing costs

OPERATING DIAGRAM EXAMPLE



1. Site Plan

- 1 - MAIN FACTORY BUILDING
- 2 - UTILITY BUILDING
- 3 - G.F. - OFFICE/ STAFF CANTEEN/ REST ROOM FOR EXPECTS / EMERGENCY ROOM/ TOILET
F.F. - ENGINEER'S REST ROOM
- 4 - WARE HOUSE
- 5 - QA/ QC BUILDING
- 6 - ANIMAL HOUSE
- 7 - EXPLOSIVE MATERIAL STORAGE ROOM
- 8 - DEEP WELL
- 9 - WASTE WATER TREATMENT PLANT
- 10A - TOILET 1 (MAIN TOILET)
- 10B - TOILET 2
- 11 - STORAGE TANK
- 12 - POWER STATION
- 13 - INCENERATOR
- 14 - GUARD ROOM
- 15 - GARBAGE
- 16 - COOLING TOWER

