GMP-Z Annex 9 – Bereiding van vloeistoffen, crèmes en zalven

Inleiding

De annex 'Bereiding van vloeistoffen, crèmes en zalven' uit de GMP-richtsnoeren is goed toepasbaar in de ziekenhuisapotheek.

GMP item	Gewijzigd richtsnoer GMP-Z	Toelichting
Zelfinspectie		
Principle Liquids, creams and ointments may be particularly susceptible to microbial and other contamination during manufacture. Therefore special measures must be taken to prevent any contamination.	**Principe** GMP	
1. The use of closed systems for processing and transfer is recommended in order to protect the product from contamination. Production areas where the products or open clean containers are exposed should normally be effectively ventilated with filtered air.	GMP	-
2. Tanks, containers, pipework and pumps should be designed and installed so that they may be readily cleaned and if necessary sanitised. In particular, equipment design should include a minimum of dead-legs or sites where residues can accumulate and promote microbial proliferation.	GMP	-
3. The use of glass apparatus should be avoided wherever possible. High quality stainless steel is often the material of choice for parts coming into contact with product.	GMP-Z: Voor kleinere bereidingen, zoals te doen gebruikelijk binnen de ziekenhuisfarmacie, kan gebruik worden gemaakt van glazen objecten.	De voorkeur die bestaat voor roestvrij staal boven glas berust op het risico van verwondingen door gebroken glas en van het voorkomen van glassplinters in het preparaat. Voor grotere vaten geldt ook in de ziekenhuisapotheek de voorkeur voor roestvrij staal, maar voor bereidingen van een geringe chargeomvang kan goed worden volstaan met kleine glazen objecten.
4. The chemical and microbiological quality of water used in production should be specified and monitored. Care should be taken in the maintenance of water systems in order to avoid the risk of microbial proliferation. After any chemical sanitisation of the water systems, a validated flushing procedure should be followed to ensure	GMP	-

that the sanitising agent has been effectively removed.		
5. The quality of materials received in bulk tankers should be checked before they are transferred to bulk storage tanks.	GMP	-
6. Care should be taken when transferring materials via pipelines to ensure that they are delivered to their correct destination.	GMP	-
7. Materials likely to shed fibres or other contaminants, like cardboard or wooden pallets, should not enter the areas where products or clean containers are exposed.	GMP	-
8. Care should be taken to maintain the homogeneity of mixtures, suspensions, etc. during filling. Mixing and filling processes should be validated. Special care should be taken at the beginning of a filling process, after stoppages and at the end of the process to ensure that homogeneity is maintained.	GMP	-
9. When the finished product is not immediately packaged, the maximum period of storage and the storage conditions should be specified and adhered to.	GMP	-

Literatuur:

Niet van toepassing.