Warehousing - An excerpt from the GDP Audit Checklist

	Good Distribution Practice Checklist	checked*	EU GDP	EU GMP	WHO GDP	EN ISO 13485
7.	**Warehousing**					
7.1	**First documentation check**: Are the respective **storage conditions** adhered to? How are the required storage conditions checked? Are alarms triggered if, for example, temperature limits are exceeded or undercut? Is active counteraction taken if specific limits are overstepped? Is the procedure described in an SOP?		5.5	1.4ix, xv 1.8iii, iv, viii	9.1 9.8 9.16	6.3 6.4 7.5.5 7.6 8.2.1
	Tour (premises/warehouse): Are MPs stored separately from other products? Can the influence of other products be ruled out? Are MPs protected from the negative effects of light, temperature, humidity and other external factors? Are the required storage conditions adhered to?					
	Second documentation check: Request records on temperature and humidity measurements: • Are the values within the defined interval? • Were there deviations in the past? • What approach was taken? • Was this documented accordingly?					

* ✓ requirements met | – requirements not met | Ø not required | ✘ see comment

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7.2	**The following applies to refrigerated warehouses in particular:** **First documentation check**: Request the qualification documents of the storage rooms and the validation documents of the **temperature monitoring system**.		5.5	1.4viii, ix 1.8iii	9.4 9.20	6.3 7.6
	Was a summer and winter temperature mapping carried out?					
	Were deviations detected?					
	Were representative extreme values reached?					
	Have loggers been positioned in accordance with the results of a risk analysis?					
	Was the number and location of the monitoring loggers (temperature and humidity) determined by means of validation?					
	Is there a plan showing where the various loggers are located? Are loggers calibrated regularly?					
	Is this documented in the service and maintenance plan?					
	Tour (premises/warehouse): Ask to see loggers in the storage area: • Have they been placed according to the plan?					
	• Are the loggers clearly labeled and assigned?					
	Second documentation check: Request the logger calibration certificates: • Can the certificates be assigned to the installed loggers?					

* ✓ requirements met | – requirements not met | Ø not required | ✘ see comment

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	Good Distribution Practice Checklist	checked*	EU GDP	EU GMP	WHO GDP	EN ISO 13485
7.3	**The following applies to refrigerated warehouses in particular:** **First documentation check**: Can the documents provide traceable and complete evidence of compliance with the storage conditions relating to the **temperature** of the products? How long are temperature records stored?		9.4	1.4viii 1.8iii, viii	9.1 9.4 9.19	6.4 7.5.5 8.5.2
	Tour (premises/warehouse): Select a particular product and check the history of the product: • When, where and for how long was it stored?					
	Second documentation check: Request proof of the adherence to the storage temperature: • Were there several product movements? Request temperature records of all the places the product passed through (including IG area): • Can the temperature values be assigned to the measuring point near the product and the time without error?					

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