



GMP+ B10 Laboratory testing



Art.	Description	Possible items for attention	Freq.	Interpretation Category 1	Interpretation Category 2	Interpretation Category 3
02 NORMATIVE REFERENCES						
2.1	GMP+ documents					
2.1	Does the company comply with the requirements specified in the A documents?	See A1, A2, A3 and A4	3			
2.2	Legal compliance					
2.2	Does the participant comply with community legislation, national legislation and good manufacturing practice?		3			
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03 ORGANISATION AND QUALITY POLICY						
3.1	Quality system					
3.1	Does the participant have a quality system that complies with the requirements of this GMP+ standard? (S)		3			
3.2	Organisational diagram					
3.2	Is there an organisational chart to show how the participant fits into the organisation of the business? (S)	Independence with respect to any activities related to the production and trading of feeds / feed raw materials # Quality controller direct access to management # Internal audit carried out by independent and competent auditor	3		No organisational chart. Independence not demonstrable by way of, for example, signed management statement # No direct access to directors # Insufficient knowledge	Unclear organisational chart # Not independent
3.3	Management of the quality system					
3.3	Is there a procedure in which authority is regulated with respect to the modification / changing of the quality system and has the controller been appointed? (S)		3		No procedures.	Procedures incomplete. No controller
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04 DOCUMENTATION						
4.1	Records					
4.1	Have all parts of the quality system been established and put to use? (S/M)		3			
4.2	Manual					
4.2	Does the company have a manual / is it demonstrably up to date? (S/M)		3		No up to date manual	
4.3	Date and authorisation					
4.3	Are the procedures and instructions dated and authorised by a competent person? (S)		3		No dating or authorisation of instructions and procedures: cat. 2/3 depending on the seriousness (auditor assessment). For analysis instructions more likely cat. 2 than for procedures	
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05 ACCOMODATION						
5.1	Environment					
5.1	Are there no environmental factors which influence the correctness and accuracy of the analyses? (M)		3		This includes, for example: vibration-free setting up of the balance, good storage, clean glasswork, clean working area / dust from production: cat. 2/3 (auditor assessment)	
5.2	Access regulation					
5.2	Does the laboratory have access arrangements which are approved by management? (S)	sample storage is secure against unauthorised access # data is secure # third parties may only enter the laboratory in the presence of laboratory personnel	3		Sample storage is freely accessible in the absence of laboratory personnel # Laboratory is freely accessible in the absence of laboratory personnel	# Computer data not protected with a password.
5.3	Facilities					
5.3	Are the necessary facilities available and are they adequate in relation to the objectives of the quality system (S/M)	The GMP+ standard states for which sections measures must be taken.	3		No sample storage	
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06 PERSONNEL						
6	Personell					

6	Do the personnel have sufficient knowledge and skills for the tasks they are given? (S/M)	Tasks, responsibilities and authority recorded in writing and made known # Procedure available to ensure that the personnel are informed of changes to instructions and procedures. # Personnel are sufficiently trained and given refresher training and this is recorded	3		No demonstrable work experience or diploma. No job description available # No procedure available. Personnel not demonstrably informed. # Insufficient training or refresher training, no training programme, no record in personnel dossier of training cat. 2/3 (auditor assessment)	# No procedure available by which personnel are demonstrably informed.
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07 EQUIPMENT						
7.1	Items to be recorded					
7.1	Have the items related to equipment and tools which have an influence on the analyses been recorded? (M)	Inventory of available equipment # Maintenance system with a report of the frequency and nature of the maintenance work including calibration, adjustment and validation. Statement of competent person # The suitability for use of the equipment which determines quality and the measures taken for the validity of analysis results if the equipment deviates.	3	# No recording of maintenance system # No recording of suitability for use of equipment	No equipment inventory list # Unsatisfactory maintenance: Cat. 2/3 (depending on seriousness) # Incomplete recording: Cat. 2/3 (depending on seriousness)	
7.2	Logbook					
7.2	Is there a logbook available for each piece of equipment recording the data specified in section 6.1 and is equipment which does not function properly quarantined (M)		3		Working with equipment which does not function properly	No logbook at the equipment or unclear entries in logbook
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08 SAMPLES, STANDARDS, REF -AUXILIARY M.						
8.1	Specifications					
8.1	Are the specifications of the desired quality of the standards, reference and auxiliary materials recorded? (M)		3		Specifications not recorded or not complied with	Specifications incomplete
8.2	Check					
8.2	Is there a check on receipt of standards, reference and auxiliary materials of whether what has been received is what was ordered? (S)		3			No or incomplete reception check

8.3	List of authorised suppliers					
8.3	Is there, on the basis of insight into quality and reliability, a list of permitted suppliers and is the suitability for use of critical standards, reference and auxiliary materials checked in accordance with the procedure drawn up for this purpose (S/M)		3		No procedure for checking usability	No list of suppliers, no knowledge of the quality of suppliers (certificates)
8.4	Identification					
8.4	Are standards, reference and auxiliary materials clearly identified and provided with an expiry date and storage conditions? (S)		3		No expiry date or working with chemicals which are beyond their expiry date	
8.5	Precautionary measures					
8.5	Are there instructions available with precautionary measures to prevent unfavourable influence on the analysis results in all stages of the process and are these instructions complied with? (M)		3		No instructions	No instructions but there are precautionary measures in practice
8.6	Instructions					
8.6	Are instructions available covering receipt, storage life and destruction of samples and standard, reference and auxiliary materials? (S)		3		No instructions	No instructions but there are precautionary measures in practice
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09 INSTRUCTIONS						
9.1	Instructions and description					
9.1	Are there instructions for the operation of the equipment, the handling of samples and the carrying out of analyses? (M)	The performance features of the used methods should be documented. # The GMP+ standard states what should be recorded as a minimum in a test instruction.	3		No instruction for the calibration of equipment, calibration criteria unsatisfactory # Incomplete instruction: Cat. 2/3 (depending on seriousness)	Incomplete instruction: Cat. 2/3 (depending on seriousness)
9.2	Familiarity with the instructions					
9.2	Are the employees aware of the current instructions and is work done in accordance with these instructions? (m)		3		Not demonstrable	
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10 REGISTRATION, REPORTING AND ARCHIVING						

10.1	Registration					
10.1	Does the registration of data meet the requirements of this GMP+ standard? (S/M)	The GMP+ standard states for which data there should be a clear record.	3			
10.2	Reporting					
10.2	Are the results reported by a competent person on behalf of the participant and does the report contain all the prescribed data? (S/M)	The GMP+ standard states which data the report should contain.	3		Lack of identity of analysis results, confirmation results, control samples	Missing date for sample receipt, applied method of testing, name of laboratory worker and authorisation, reported particularities
10.3	Archiving					
10.3	Is all the data required to be able to reconstruct how a result was arrived at kept for at least 2 years? (S/M)	The GMP+ standard states which data should be kept for at least 2 years.	3		No archiving of data	There is archiving but less than 2 years
10.4	Protection of data					
10.4	Is there proper protection of information against unauthorised retrieval and/or modification? (S)		3		Protection against retrieval or modification by third parties is unsatisfactory	
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11 QUALITY CONTROL PLAN AND INTERN AUDIT						
11.1	Quality control plan					
11.1	Has a quality control plan been drawn up and the results compared to the internal company requirements? (S/M)	The GMP+ standard states which sections the quality control plan should at least contain.	3		No quality control plan or not demonstrably implemented	
11.2	Records					
11.2	Are the results of the quality control plan recorded in forms developed for this purpose and have the shortcomings which have been observed examined and rectified? (S/M)	The GMP+ standard states which information must be recorded.	3		No demonstrable records	
11.3	Frequency					
11.3	Is the internal audit carried out once per year?		3		No internal audit or last internal audit was more than a year ago	Implementation of internal audit is behind schedule
11.4	Reporting					

11.4	Are the results, evaluation and actions taken reported to management? (S/M)		3			No reporting to management, management does not take its final responsibility seriously
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12 PEER GROUP TESTING						
12.1	Participation					
12.1	Has there been participation in a peer group test for each operation where possible on the basis of proficiency testing? (M)		3		No participation in peer group testing	
12.2	Administration					
12.2	Are the results of the peer group testing administered per operation for at least 3 years? (M)	The GMP+ standard states how the results must be shown.	3		No statistical recording of results, no administrative system	Administrative results less than 3 years
12.3	Instigation of testing					
12.3	Is an examination set up if the results of the peer group test deviate and is the problem solved and correctly administered? (M)	The GMP+ standard states on the basis of which norms the result of a peer group test is non-standard.	3		No actions with respect to deviations	
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13 CONTRACTING OUT TO OTHER LABORATORIES						
13	Contracting out to other laboratories					
13	Are analyses contracted out to laboratories which are certified as GMP+ or equivalent and is this clearly stated in the report to the client? (S)		3	GMP operation contracted out to a non-GMP-certified or equivalent laboratory	no report of contracting out on report to customer	
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14 COMPLAINTS PROCEDURE						
14	Complaints procedure					
14	Is there a system for recording and handling complaints? (S)		3		No complaints procedure	
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15 CONTROL OF THE TEST AND CAL. RESULTS						
15	Quality control of the testing and calibration results					

15	Does the laboratory have procedures to monitor the validity of the tests carried out and calibrations and is the registration of data such that trends are noticed? (M)	There should be a periodic evaluation of the analysis methods used and the monitoring method.	3			
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16 SEROLOGICAL CLASSIFICATION FOR SALMONELLA						
16	Serological classification for Salmonella					
16	Does the laboratory comply with the additional requirements?		3			