QPLAB

Cannabis Sample Request

Company:		N	ame:		Contact:			_ Date	e/time:		Sign:
Proposal code and/or PO			QPL			QPLAB transpor	rt 🗆	□ No □ Yes Est.date/week:			
Stage			 Development In Process Control Validation Stability Study Batch release 				Formulation		Dry Flower Fresh Flower Oil Extract Other:		
Shipping conditions			□ 15°C to 25°C □ 2°C to 8°C □ \leq -15°C				Storage conditio	ons 🗆	$\Box 15^{\circ}C \text{ to } 25^{\circ}C \Box 2^{\circ}C \text{ to } 8^{\circ}C \Box \leq -15^{\circ}C$		
Email(s) to receive results			Contact				Observations				
Batch number Sampl		ole ID	Gross weight	t (g) Tare (g)	Tests to apply			Specifications		QPLAB sample nº	
					□ 1 □ 2 □ 3 □ 4A □ 4B □ 5 □ 6A □ 6B □ 6C □ 7 □ 8A □ 8B □ 9 □ 10 Other:			From the request table			
					□ 1 □ 2 □ 3 □ 4A □ 4B □ 5 □ 6A □ 6B □ 6C □ 7 □ 8A □ 8B □ 9 □ 10 Other:			From the request table			
				□ 1 □ 2 □ 3 □ 4A □ 4B □ 5 □ 6A □ □ 6C □ 7 □ 8A □ 8B □ 9 □ 10 Other:				From the request table			
				□ 1 □ 2 □ 3 □ 4A □ 4B □ 5 □ 6A □ 6B □ 6C □ 7 □ 8A □ 8B □ 9 □ 10 Other:			From the request table				
							4A □ 4B □ 5 □ 6A □ 6B] 8B □ 9 □ 10		From the request table		
					□ 1 □ 2 □ 3 □ 6C □ 7 □ 8 Other:		□ 4B □ 5 □ 6A □ 0 □ 9 □ 10		From the request table		
					□ 1 □ 2 □ 3 □ 6C □ 7 □ 8 Other:		□ 4B □ 5 □ 6A □ 0 □ 9 □ 10	6B	From the request table		
Destination: Arriv		Arriva	I (date/time): Received by:				Storage (date/time): Sigr		Sign:		
		□Compliant □Non-complia	ant Quantity (Number, Amount)		per, Amount)		Compliant □ n-compliant		Shipping conditions		npliant □ Non-compliant t available

Sample (Name, Batch)	□Non-compliant	Quantity (Number, Amount)	Non-compliant	Snipping conditions	Not available
Transport identification	Name: D	ocument#:	Storage	□ 15°C to 25°C □ 2°C to	o 8°C □ ≤ -15°C
Additional Documentation:	□ Fiscal declaration (AT) □ Cu □ Purchase Order □ Transpor □ Not available	ustody of goods	Observations		
Verified by:	Date:	The verific	ation must be signed by the controlled	d substances responsible perso	on.

Tests and specification table:

Test #	Description	Method	Specifications (only applied for Batch Release			
Test #1 Identification	Identification A Visual exam.	EP 3028	Complies with monograph			
Sample 10gr (or with other tests) (note 1)	Identification B Microscopic exam	EP 3028 (2.8.23)	Complies with monograph			
	Identification HPLC	EP 3028 (2.2.29)	Complies with monograph			
Test #2 Cannabinoids	Assay Total THC and total CBD	EP 3028 (2.2.29)	± 10% of label claim.			
Sample 10gr (note 1)	Total CBN	EP 3028 (2.2.29)	≤ 1.0 %			
	Loss on Drying	EP 3028 (2.2.32)	≤ 12.0% w/w			
Test #3 Mycotoxins	Aflatoxins	EP 1433 (2.8.18)	≤ 2 μg/kg (ppb) - Aflatoxin B1 ≤ 4 μg/kg (ppb) - Aflatoxins B1+B2+G1+G2			
Sample 20gr	Ochratoxin A	EP 1433 (2.8.22)	≤ 20 µg/kg (ppb)			
T			4A API	4B Medicinal Product		
Test #4 Heavy Metals Sample 10g	As, Cd, Pb, Hg	EP 3028 (2.4.27)	Arsenic - informative Cadmium \leq 1.0 ppm Lead \leq 5.0 ppm Mercury \leq 0.1 ppm	Arsenic $\leq 0.2 \text{ ppm}$ Cadmium $\leq 0.3 \text{ppm}$ Lead $\leq 0.5 \text{ppm}$ Mercury $\leq 0.1 \text{ ppm}$		
Test #5 - Pesticides Sample 40g	Ph. Eur. list	EP 1433 (2.8.13)	Complies with monograph.			
	Method Description	6A EP 5.1.4	6B EP 5.1.8.B	6C EP 5.1.8.C		
	ТАМС	≤ 10 ² CFU/g	≤ 10⁴ CFU/g	≤ 10⁵ CFU/g		
Test #6	TYMC	≤ 10 ¹ CFU/g	≤ 10 ² CFU/g	≤ 10 ⁴ CFU/g		
Microbial purity Sample 55g	Bile-tolerant gram-negative bacteria	Absent/g	≤ 10² CFU/g	≤ 10⁴ CFU/g		
	E. coli (note 2)	Absent/g	Absent/g	Absent/g		
	Salmonella (note 2)	Absent/25g	Absent/25g	Absent/25g		
	S. aureus (note 2)	Absent/g	Absent/g	Absent/g		
	P. aeruginosa (note 2)	Absent/g	Absent/g	Absent/g		
Test #7 Total Ash Sample 5g		EP 1433 (2.4.16)	≤ 20%			
Test #8 Identification C	8A - TLC	EP 3028 (2.8.25) Equivalent to HPTLC	Complies with the R components of intere	Rf values for the standards of sts		
Sample 10g	8B - HPTLC	EP 3028 (2.8.25)				
Test #9 Foreign Matter Sample 50g	N/A	EP 3028 (2.8.2)	Max. 2%; if the herbal drug is to be prescrib patients, it does not contain any seeds an whole herbal drug does not contain any le more than 1.0 cm in length.			
Test #10 - Terpenes Sample 10g	N/A	Internal Method	Informative			

Note 1 - These tests can still be performed according to DAB 2018. Please specify in the request form.

Note 2 - If samples are selected for batch release purposes, the microorganism identifications will be performed as soon as detected. In any other stage, customers will be asked about the need to perform these identifications.



Prior delivery:

- Send the requisition form and expected delivery date to <u>samples@qplab.eu</u>. Requisition form is available on QPLAB's site.
- QPLAB team will confirm availability to receive samples.

Transport requisition:

- QPLAB can perform sample transportation.
- To request transportation, please send an email requiring transportation with the requisition (FOR00135) to <u>samples@qplab.eu</u>. Requisition form is available on QPLAB's site.
- The team will organize the transportation according to routes and confirm the date with the customer.

Sample Preparation:

- Print page 1;
- Identify samples (batch, sample ID, stage, storage conditions, formulation) and choose the tests and specifications to apply to each sample;
- Weigh the empty sample-container Tare (g);
- Pack the sample inside the container and weigh Gross weight (g);
- Transportation of a total amount higher than 1 Kg, requires communication a minimum of 72 hours earlier to the origin and destination local authorities. A copy of that communication must be received at QPLAB before sample delivery.

Transport:

- Samples transportation is a customer's responsibility unless requested to QPLAB;
- Transportation must be environmentally monitored;
- Transportation must incur contamination and maintain the sample's integrity;

QPLAB Transport:

- On the transportation date, the customer will receive an email with the estimated time of arrival and driver's name/contact;
- Driver will check samples and fill in appropriate documentation, at the time of arrival;
- A real-time location link will be provided during sample's transportation;
- Transportation report will be sent with picking and dropoff activities and temperature/humidity conditions;

Samples reception:

- Cannabis-based substances must be hand-delivered to QPLAB-authorized staff.
- If samples are unacceptable (ie. missing documentation, not properly labeled, not hand delivered) the customer will be informed to pick up samples. After 15 days samples will be destroyed and costs incurred to the customer.
- The customer will receive a summary of the internal sample conference.

Delivery Information:

- Samples must be delivered to:
 - Name: QPLAB Pharma Services (Laboratory)
 - Address: Teclabs FCUL Campo Grande 1749-016 Lisboa, Portugal
 - Monday to Friday 9h00 to 12h00 and 14h00 to 18h00
 - Out of office hours please contact (+351) 919634758