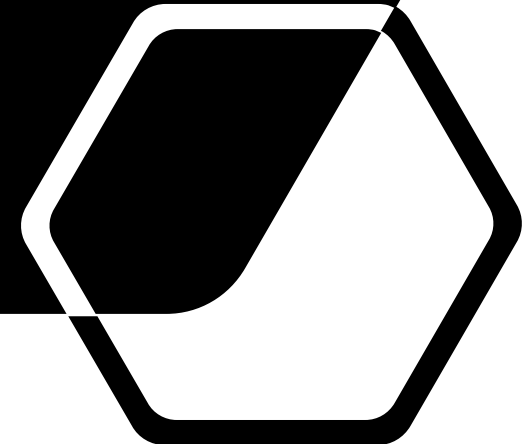
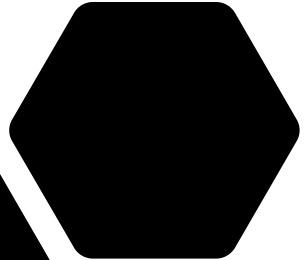


Cannabidiol monograph

Development 2016 – 2022

Boris Bañas, CBDepot.eu



No pharmacopoeia-
grade monograph
available for
Cannabidiol yet...

@JustFiveLines



Sub-pharmacopoeia- grade monograph from Germany

- DAC/NRF monograph C – 052 available since 2016
- "DAC" = Deutscher Arzneimittel Codex
- "NRF" = Neues Rezeptur-Formularium
- Small but significant changes published in 2020
- Yet no further clarification on presence of CBD analogs:
 - Cannabidivarin (CBDV)
 - Cannabidibutol (CBDB)

EDQM and US
Pharmacopoeial
forum have been
working on official
CBD monographs

The Pharmedropa reference number:

PA/PH/Exp. 11/T (21) 50 ANP

Published: 15 June 2022

Public deadline: 30 Sept 2022

US Reference number is (PF) 48(1).

The deadline for comments was March
31, 2022.

Comparing DAC 2016 & 2020 vs draft Ph.Eur. & USP

Parameter	DAC/NRF 2016/2, C – 052	DAC/NRF 2020/2, C – 052	PA/PH/Exp. 11/T (21) 50 ANP	USP draft
Origin	<i>C. sativa</i> L. or chemical synthesis	<i>C. sativa</i> L., synthesis or fermentation	Isolated from natural sources	<i>C. sativa</i> or synthesis
Identity	B. IR Spectroscopy (2.2.24) A. Melting point (2.2.60) C. Thin-layer chromatography	A. IR Spectroscopy (2.2.24) B. Thin-layer chromatography	A. IR Spectroscopy (2.2.24) B. Specific rotation (2.2.7): -128 to -135	N/A
Purity	1. Specific rotation (2.2.7): -129 to -135 2. Liquid chromatography (2.2.29) 98.0 – 102.0 % 3. Sulphated Ash (2.4.14) ≤ 0.1 %	1. Specific rotation (2.2.7): -129 to -135 2. Liquid chromatography (2.2.29) 98.0 – 102.0 % 3. Sulphated Ash (2.4.14) ≤ 0.1 %	1. Liquid chromatography (2.2.29) 98.0 – 102.0 % 2. Water content (2.5.32) ≤ 0.5 % 3. Sulphated Ash (2.4.14) ≤ 0.1 %	98.0 – 102.0 %
Impurities				
Specified impurities	A. Cannabinol B. D9THC C. D8THC (Reporting limit 0.05 %)	A. Cannabinol ≤ 0.10 % B. D9THC ≤ 0.10 % C. D8THC ≤ 0.10 %	A. Cannabidivarin ≤ 0.15 % B. Cannabidibutol ≤ 0.2 % C. Cannabinol ≤ 0.15 % D. D9THC ≤ 0.10 % E. CBD-HQ ≤ 0.15 % F. <i>Cannabichromene</i> G. <i>Cannabidiolic acid</i> H. <i>D9THC acid</i> F. G. H. (Ph.Eur. 2034, 5.10)	A. Cannabinol ≤ 0.15 % B. D9THC ≤ 0.10 % C. D8THC Not detected
Unspecified impurities	Each ≤ 0.10 %	Each ≤ 0.10 %	Each ≤ 0.10 %	Each ≤ 0.10 %
Sum of all impurities	≤ 0.5 %	≤ 0.5 %	≤ 0.8 %	≤ 2.0 %

Thank you for your attention

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