



CATOCYANIC COMPLEX®

réf / rév.ind
DTC002B.a_dossier
technique catocyanic
complex GB

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AUTORISATIONS

	NOM	FONCTION	DATE
RÉDACTION	C. SOULIER	Responsable Développement	27/11/02
VERIFICATION	A. DE KERVASDOUE	Responsable Qualité	
APPROBATION	G. LAPLAIGE	Directeur Général	

HISTORIQUE DES RÉVISIONS

REVISION	DATE	DESCRIPTION DE LA MODIFICATION	PARAGRAPHERS CONCERNES
A	19/11/02	Création du document	Tous
B	27/11/02	Version anglaise	Tous

LISTE DE DIFFUSION

EXEMPLAIRE	DESTINATAIRE	LIEU
1.	C. SOULIER	Archives Dossiers Techniques
2.	Client FERLUX	NA



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1. Object of the document

The following document defines :

- composition
- product characteristics
- product specifications and associated Analytical methods

of the dry bilberry extract CATOCYANIC COMPLEX®.

2. Glossary :

TLC : Thin Layer Chromatography

ND : Not Determined

NC : Not Available

CFU : Colony Forming Units

UpH : pH units

3. Product name :

Product name	Source
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4. Description :

Characteristics	Specifications
Aspect	Fine powder
Color	Purple-red
Smell	Fruity
Taste	Astringent



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5. Characteristics

Tests	Specifications	Units	Method
Solubility in water	$S \geq 80$	%	FERLUX
pH solution at 1% w/w	5 ± 1	U pH	FERLUX
Loss on drying at 60°C	≤ 5	%	
Total ash	< 18	%	European Pharmacopeia IV edition

6. Product specifications :

Characteristics	Analytical Techniques	Specifications	Units
Color	Visual	Violet	-
Aspect	Visual	Fine powder	-
Smell	NC	Fruity	-
Taste	NC	Astringent	-
Total polyphenols calculated as Cyanidin chloride	FERLUX	> 40	mg/g
Catocyanic Complex content		> 18	%
Total aerobic microorganisms	European Pharmacopeia IV edition	$< 10^4$	CFU/ g
Yeast, mould		$< 10^2$	CFU/ g



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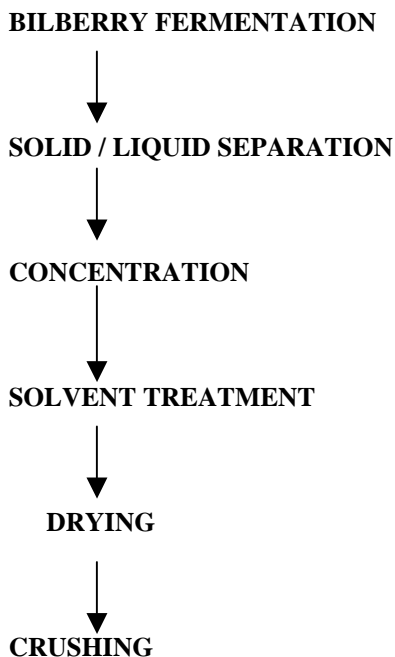
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7. Process data

7.5. Process Steps

7.6. Tests performed on the Active Ingredient (*Vaccinium myrtillus*)

Characteristics	Specifications	Analytical Technique
Organoleptic datas (taste, color)	Comply	European Pharmacopeia IV edition
Identification A	Comply	
Identification C	Comply	
Total ash	≤ 0.6%	
Impurities	< 2%	
Loss on drying	80% ≤ P ≤ 90%	
Radioactivity	≤ 50 bq/kg	FERLUX
Sugars	≥ 60.0 g/l	
Monomers	ND	ND



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7.7. Tests performed during manufacturing process

The quality of the product is guaranteed during the manufacturing process. In-process controls are duly performed.

Sugar content, density, granulometry and loss on drying are tested on the intermediate.

7.8. Tests performed on the finished product

Characteristics	Specifications	Analytical Techniques	
Organoleptic Characteristics			
Color	Purple-Red	FERLUX Internal method	
Odour	Fruity		
Aspect	Fine powder		
Analytical Characteristics			
Solubility in water	≥ 80%	FERLUX Internal method	
pH solution at 1% w/w	5 ± 1		
Loss on drying at 60°C	≤ 5%		
Total ash	≤ 18%	European Pharmacopeia IV edition	
Arsenic	≤ 1 ppm		
Granulometry	> 90µm		≥ 50%
	> 180µm		≥ 30%
	>355µm		≥ 35%
Quinic acid (TLC)	Comply		
Anthocyanosides (TLC)	Comply		
Total polyphenols calculated as Cyanidin chloride	≥ 40 mg/g		
Catocyanic Complex content	> 18 %	FERLUX Internal method	
Total aerobic microorganisms	<10 ⁴ CFU/g	European Pharmacopeia IV edition	
Yeast, mould	<10 ² CFU/g		

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8. Stability Data :

characteristics	Specifications	Deadline results	Units
Solubility	≥ 80	12 months	%
pH	5 ± 1	12 months	UpH
Loss on drying at 60°C	≤ 5	12 months	%
Total polyphenols calculated as Cyanidin chloride	≥ 40	12 months	mg/g

9. Storage conditions

Keep stored free from humidity, high temperature and light.