

Certificate of Analysis

Productname: Riboflavinum
Number of analysis/Inspection Code: 1 / KEUR-185840B
Batchnumber: 20G16-F01-372712
Reference code / No.: 3936 / RIB2637HF
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Orange) yellow, crystalline powder	Conform		
Fermentation	According to Fermentation products Ph. Eur.	Conform		Data producer
Identification A	-115 - -135	Conform	°	Specific optical rotation
Identification B	Conform	Conform		TLC
Identification C	Conform	Conform		
Specific optical rotation	-115 - -135	-130	°	0,5% <i>m/V</i> 0.05M NaOH; dried
Absorbance	223, 267, 373, 444 nm	Conform	nm	
Absorbance ratio	0,31 - 0,33	0,33		E 373 / E 267
Absorbance ratio	0,36 - 0,39	0,39		E 444 / E 267
Related substances	Conform	Conform		HPLC
Impurity A	<=0,025	0,008	%	
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,2	n.d	%	
Impurity D	<=0,2	0,1	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,5	0,1	%	
Loss on drying	<=1,5	0,5	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Riboflavine	97,0 - 103,0	99,1	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

09/22/20

Expiration: 09-2023

Conclusion: APPROVED

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