

## Certificate of Analysis

**Product name:** **Novata B pastilles**

**Batch number / Weight:** **22J11-B10-223012 / 5 KG**

**Analysed according to:** **Ph.Eur.11.0**

**Number of analysis / Inspection Code** **22J11-B10 / INS-22-9527**

**Reference Code / No.:** **V01252 / 0026032725**

Tests	Requirement	Result	Unit	Standard remark
Protocol number		2178/S/1022		
Appearance	Yellow-white, fatty pellets or flakes	Conform		
Appearance melted substance	Clear / slightly yellow or slightly yellowish liquid	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Alkaline impurities	Conform	Conform		
Melting point	32,5 - 36,5	34,2	°C	
Acid value	<=0,5	0,17		
Hydroxyl value	20 - 30	26,3		
Iodine value	<=3,0	1,37		
Peroxide value	<=3,0	1,10		
Saponification value	221 - 244	232,0		
Sulphated ash	<=0,2	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:  
Dominika Soltysik  
Qualified Person

16-01-2023

Expiration: 10-05-2024

Conclusion: APPROVED

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