

	<b>CERTIFICATE OF ANALYSIS FINISHED PRODUCT</b>	SPECIFICATION No.: 194/KJ/1
	<b>HydroVag vaginal pessaries</b>	Page: 1/1

<b>LOT NO.</b>		19421003	
<b>PRODUCTION DATE</b>		2021-01	
<b>EXPIRY DATE</b>		2024-01	
TEST	METHOD	REQUIREMENTS	RESULTS
1. Form and characteristic	Ph. Eur. Monograph 1164 In-house method IPL-293	Egg-shaped pessaries in white or light yellow color	Egg-shaped pessaries in white
2. Uniformity of mass	Ph. Eur. 2.9.5 In-house method IPL-177	1.5 – 1.7 g	1.6 g
3. Time of disintegration*	Ph. Eur. 2.9.2 Contract manufacturer document	Less than 60 minutes	6 minutes 44 second
4. pH	Ph. Eur. 2.2.3 In-house method IPL-4	3.8 – 4.5	4.1
5. Microbiological examination	Ph. Eur. 2.6.12; 2.6.13 In-house method IPL-146	Not more than 10 <sup>2</sup> aerobic microorganisms in 1g Not more than 10 <sup>1</sup> yeasts and moulds in 1g Absence in 1g: <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> and <i>Candida albicans</i>	15 aerobic microorganisms in 1g < 10 yeasts and moulds in 1g Absence in 1g: <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> and <i>Candida albicans</i>

\* test performed by a contract manufacturer

<b>IMMEDIATE PACKAGING</b>	Blister made of PVC/PE foil containing 7 globules
<b>STORAGE AND TRANSPORT CONDITIONS</b>	Store at temperature 15 - 25°C (at room temperature)
<b>THE LOT COMPLIES WITH THE SPECIFICATION REQUIREMENTS</b>	
08.02.2021	<b>Bożena Moskała</b> <i>B. Moskała</i> Kierownik Działu Kontroli Jakości
<b>DATE</b>	<b>QC MANAGER SIGNATURE</b>