
	<b>FINISHED PRODUCT SPECIFICATION</b>	<b>194/KJ/2</b>
	<b>HydroVag vaginal pessaries</b>	Strona: 1/2
<b>MEDICAL DEVICE</b>		

<b>QA</b>	<b>IMPLEMENTED</b>
Effective date: 2021-11-04	Signature: 

**1. SHELF LIFE** – 36 months

**2. STORAGE AND TRANSPORT CONDITIONS**


Store at room temperature (15 - 25°C)

**3. REQUIREMENTS**

PARAMETER	METHOD	REQUIREMENT	
		RELEASE	SHELF LIFE
1. Appearance	Visual method IPL-281	egg-shaped pessaries in white or light yellow color	egg-shaped pessaries in white or light yellow color
2. Uniformity of mass	Ph. Eur. 2.9.5. IPL-177	1.52 – 1.68 g not more than 2 of the individual masses deviate from the average mass by more than 5% and none deviates by more than 10%	1.52 – 1.68 g not more than 2 of the individual masses deviate from the average mass by more than 5% and none deviates by more than 10%
3. Disintegration time*	Ph. Eur. 2.9.2.	not more than 60 minutes	not more than 60 minutes
4. pH	Ph. Eur. 2.2.3. IPL-26	3.8 – 4.5	3.8 – 4.5
5. Microbial contamination: - aerobic microbial contamination count in 1 g - combined yeasts/moulds contamination count in 1 g - presence in 1 g: <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> <i>Candida albicans</i>	Ph. Eur. 2.6.12.; 2.6.13. IPL-146	not more than 2x10 <sup>2</sup> CFU/g  not more than 2x10 <sup>1</sup> CFU/g  absent absent absent	not more than 2x10 <sup>2</sup> CFU/g  not more than 2x10 <sup>1</sup> CFU/g  absent absent absent
*test performed by a contract laboratory			
6. Unit packaging	The product is packed in an PVC / PE blister, peel off type. The outer packaging is a cardboard box with a print containing: information leaflet and a blister with 1 pessary or 1 blister with 7 pessaries, or 2 blisters with 7 pessaries.		

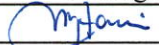


**4. SAMPLING**

According to Quality Control procedures

	<b>FINISHED PRODUCT SPECIFICATION</b>	<b>194/KJ/2</b>
	<b>HydroVag vaginal pessaries</b>	Strona: 2/2
<b>MEDICAL DEVICE</b>		

### 5. LIST OF CHANGES

Short description of changes	<ul style="list-style-type: none"> <li>- change of the name for parametr form and characteristics into appearance</li> <li>- removal of incorrect records regarding „In-house methods” for those parameters, that are tested according to Ph. Eur. methods</li> <li>- change of the format for requirements for the parameters: uniformity of mass and microbial contamination (acc. to Ph. Eur.)</li> <li>- change of the index for parameter pH</li> <li>- introduce of the method number for microbial contamination</li> </ul>
Change control	253/2020, 383/2021
Previous version of the specification (code, edition number)	194/KJ/1

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Signature			
Date	03.11.2021	03.11.2021	03.11.2021