



**CERTIFICATE OF ANALYSIS**  
**СЕРТИФИКАТ АНАЛИЗА**

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<b>PRODUCT NAME: DEXPAN PLUS CREAM IN LAMI TUBE /</b> <b>НАИМЕНОВАНИЕ ПРОДУКТА: ДЕКСПАН ПЛЮС В ТУБЕ ИЗ ЛАМИНИРОВАННОГО ПОЛИЭТИЛЕНА</b>			
<b>Batch No / Серия № :</b> B5FZ02		<b>Batch Size / Объем партии :</b> 1500 KG	
<b>AR No / Аналитический отчет № :</b> 1810F25004758		<b>Date of Analysis / Дата анализа:</b> 05.08.2025	
<b>Date of Mfg. / Дата производства:</b> Jul-25		<b>Date of Expiry / Годен до:</b> Jun-27	

No / №	Test / Показатель	Results / Результаты	Specifications / Спецификация
1	<b>Description / Описание</b>	White homogenous cream free from visible extraneous matter / Однородный крем белого цвета без видимых посторонних включений	White to off white homogenous cream free from visible extraneous matter / Однородный крем белого или почти белого цвета без видимых посторонних включений
2	<b>Identification / Подлинность</b>	Complies as prescribed / Соответствует требованиям	The retention time of the major peaks due to Dexpanthenol, Allantoin, methylhydroxy benzoate, propylhydroxy benzoate, phenoxyethanol, butylated hydroxy toluene and butylated hydroxy anisole in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation under assay. / Времена удерживания основных пиков, относящихся к декспантенолу, аллантину, метилгидроксibenзоату, пропилогидроксibenзоату, феноксиэтанолу, бутилгидрокситолуолу и бутилгидроксianизолу, на хроматограмме испытуемого раствора должны соответствовать пикам веществ на хроматограмме стандартного раствора при проведении количественного определения.
3	<b>Average net content / Средняя масса содержимого</b>	30g / 30г	Not less than 30 g / Не менее 30 г
4	<b>pH</b>	4.3	Between 3.0 and 7.0 / От 3,0 до 7,0
5	<b>Viscosity / Вязкость</b>	16200 centi poise / 16200сПз.	6000 to 30000 centi poise / От 6000 до 30000 сПз
6	<b>Uniformity of dosage units / Однородность дозирования</b>		
6.1	<b>Uniformity of dosage units for Dexpanthenol / Однородность дозирования декспантенола</b>	104.5% w/w / 104,5 % (м/м)	Not less than 90.0% w/w and not more than 110.0% w/w of the label claim / От 90,0% (м/м) до 110,0% (м/м) от заявленного содержания
6.2	<b>Uniformity of dosage units for Allantoin / Однородность дозирования аллантина</b>	99.1% w/w / 99,1% (м/м)	Not less than 90.0% w/w and not more than 110.0% w/w of the label claim / От 90,0% (м/м) до 110,0% (м/м) от заявленного содержания
6.3	<b>Acceptance value for Dexpanthenol / Критерии приемлемости для декспантенола</b>	3.8	The acceptance value (AV) should be less than or equal to 15.0 / Критерии приемлемости (AV) должен быть не более 15,0
6.4	<b>Acceptance value for Allantoin / Критерии приемлемости для аллантина</b>	0.6	The acceptance value (AV) should be less than or equal to 15.0 / Критерии приемлемости (AV) должен быть не более 15,0



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No / №	Test / Показатель	Results / Результаты	Specifications / Спецификация
<b>7</b>	<b>Assay / Количественное определение</b>		
7.1	Each 100 mg of Cream contains Dexpanthenol (5 mg) / Каждые 100 мг крема содержат декспантенол (5 мг)	104.5 % w/w / 104,5 % (м/м)	Not less than 90.0 % w/w and not more than 110.0 % w/w / Не менее 90,0% (м/м) и не более 110,0% (м/м) от заявленного содержания
7.2	Each 100 mg of Cream contains Allantoin (0.5 mg) / Каждые 100 мг крема содержат аллантиин (0,5 мг)	99.3 % w/w / 99,3 % (м/м)	Not less than 90.0 % w/w and not more than 110.0 % w/w / Не менее 90,0% (м/м) и не более 110,0% (м/м) от заявленного содержания
<b>8</b>	<b>Preservatives and antioxidants content / Содержание консервантов и антиоксидантов</b>		
8.1	Each 100 mg of Cream contains Phenoxyethanol (0.3 mg) / Каждые 100 мг крема содержат Феноксизтанол (0,3 мг)	0.307 % w/w 0,307 % (м/м)	Not less than 0.255 % w/w and not more than 0.345 % w/w / Не менее 0,255% (м/м) и не более 0,345% (м/м).
8.2	Each 100 mg of Cream contains Methylhydroxy benzoate (0.2 mg) / Каждые 100 мг крема содержат метилгидроксibenзоат (0,2 мг)	0.20 % w/w / 0,20% (м/м)	Not less than 0.17 % w/w and not more than 0.23 % w/w / Не менее 0,17% (м/м) и не более 0,23% (м/м).
8.3	Each 100 mg of Cream contains Propylhydroxy benzoate (0.02 mg) / Каждые 100 мг крема содержат пропилгидроксibenзоат (0,02 мг)	0.020 % w/w / 0,020% (м/м)	Not less than 0.017 % w/w and not more than 0.023 % w/w / Не менее 0,017 (м/м) и не более 0,023% (м/м).
8.4	Each 100 mg of Cream contains Butylated hydroxyl toluene (0.1 mg) / Каждые 100 мг крема содержат бутилгидрокситолуол (0,1 мг)	0.099 % w/w / 0,099 % (м/м)	Not less than 0.085 % w/w and not more than 0.115 % w/w / Не менее 0,085% (м/м) и не более 0,115% (м/м).
8.5	Each 100 mg of Cream contains Butylated hydroxyl anisole (0.01 mg) / Каждые 100 мг крема содержат бутилгидроксianизол (0,01 мг)	0.0097 % w/w / 0,0097 % (м/м)	Not less than 0.0085 % w/w and not more than 0.0115 % w/w / Не менее 0,0085% (м/м) и не более 0,0115% (м/м).



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<b>9</b>	<b>Microbial enumeration tests and tests for specific micro organisms /</b> <b>Микробиологическая чистота и испытания на специфические микроорганизмы</b>		
<b>9.1</b>	<b>Total aerobic microbial count /</b> <b>Общее содержание аэробных микроорганизмов</b>	Less than 10 cfu/gm / Менее 10 КОЕ/г	Not more than 100 cfu/gm / Не более 100 КОЕ/г
<b>9.2</b>	<b>Total combined yeasts and moulds /</b> <b>Общее содержание дрожжевых и плесневых грибов</b>	Less than 10 cfu/gm / Менее 10 КОЕ/г	Not more than 10 cfu/gm / Не более 10 КОЕ/г
<b>9.3</b>	<b>Pathodens /</b> <b>Патогенные микроорганизмы</b>		
<b>9.3.1</b>	<b>Staphylococcus aureus</b>	Absent per 1 g / Отсутствует в 1 г	Shall be absent per 1 g / Должен отсутствовать в 1 г
<b>9.3.2</b>	<b>P. aeruginosa</b>	Absent per 1 g / Отсутствует в 1 г	Shall be absent per 1 g / Должна отсутствовать в 1 г
<b>9.3.3</b>	<b>Salmonella</b>	Absent per 10 g / Отсутствует в 10 г	Shall be absent per 10 g / Должна отсутствовать в 10 г
<b>9.3.4</b>	<b>Escherichia coli</b>	Absent per 1 g / Отсутствует в 1 г	Shall be absent per 1 g / Должна отсутствовать в 1 г
<b>9.3.5</b>	<b>Bile tolerant gram negative bacteria/ Грамотрицательные бактерии устойчивые к желчи</b>	Absent per 1 g / Отсутствует в 1 г	Shall be absent per 1 g / Должны отсутствовать в 1 г

**Remarks / Примечания:** APPROVED (Sample Conforms to above Specification) / Примечание: ОДОБРЕНО (образец соответствует выше указанным спецификациям)

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Envelope Sent	Hashed/Encrypted	14-Aug-25   15:40
Certified Delivered	Security Checked	14-Aug-25   16:48
Signing Complete	Security Checked	14-Aug-25   16:59
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