



a Sandoz company

Lek Pharmaceuticals d.d.

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Quality Unit API

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# CERTIFICATE OF ANALYSIS

Product LITHIUM CARBONATE Ph.Eur./BP

Lot No. B493882AC

| Parameters                                                                                 | Specifications               | Results |
|--------------------------------------------------------------------------------------------|------------------------------|---------|
| Assay                                                                                      | 98.5 - 100.5 %<br>Li(2)CO(3) | 99.4 %  |
| Manufacturing date                                                                         | 09.11.2018                   |         |
| Retest date                                                                                | 30.11.2023                   |         |
| Storage                                                                                    | In a well-closed container   |         |
| Complies with specification of PhEur                                                       |                              |         |
| The batch manufacturing and packaging was reviewed and found to be in compliance with cGMP |                              |         |

Date of approval 09.01.2019

Quality Unit

Breda Rode

*Handwritten signature* 25.01.2019



Lek Pharmaceuticals d.d.

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\* Not routinely tested. Test is performed according to approved testing frequency.

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Betr.: 200 kgs. netto LITHIUM CARBONAAT EP 9, EX LEK SLOVENIJE (UW ART. NO. 9200175),  
zoals geleverd met onze factuur No. 19101-9.116 d.d. 10.07.2019.



*Handwritten signature* "UTAG" B.V.



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# CERTIFICATE OF ANALYSIS

Product LITHIUM CARBONATE Ph.Eur./BP

Lot No. B493882AC

| Parameters                | Specifications               | Results   |
|---------------------------|------------------------------|-----------|
| Description               | white or almost white powder | conforms  |
| Identification: lithium   | lithium carbonate            | conforms  |
| Identification: carbonate | lithium carbonate            | conforms  |
| Appearance of solution    | clear and colourless         | conforms  |
| Arsenic                   | $\leq 2$ ppm                 | conforms  |
| Calcium                   | $\leq 200$ ppm               | conforms  |
| Chlorides                 | $\leq 200$ ppm               | conforms  |
| Magnesium                 | $\leq 150$ ppm               | conforms  |
| Sulphates                 | $\leq 200$ ppm               | conforms  |
| Heavy metals              | $\leq 20$ ppm                | conforms  |
| Iron                      | $\leq 20$ ppm                | conforms  |
| Potassium                 | $\leq 300$ ppm               | $< 5$ ppm |
| Sodium                    | $\leq 300$ ppm               | $< 5$ ppm |

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