


**BATCH RELEASE CERTIFICATE
(FOR RUSSIA / BELARUS)**

| | |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Generic Name : Sennoside Tablets 13.5mg | |
| Brand Name : Senade | |
| *Lot / Packing Batch number : 484129 | **Manufacturing Batch number: NA |
| Importing Country : Russia | Customer : Dr.Reddy's Laboratories SA |
| Sales Order No. : 8455250/20 | Quantity released: 5845X25X20's |
| Marketing Authorization Number: N013745/01 (Product Registration No.) | |
| Name and address of Marketing Authorization Holder: | Cipla Ltd., Peninsula Business Park Lower Parel, Mumbai, India |
| Strength / Potency : Senna extract equivalent to 13.5 mg of Sennosides A & B as Calcium Salts. | Dosage form : Uncoated Tablets |
| Package size : 25X20's | Type of Pack : Blister |
| Mfg. Date : 11/2024 | Expiry date : 10/2027 |
| **Pack before : NA (Incase of products (Pellets / Tablets) packed in fibre / HDPE drums.) | |
| Name and address of Manufacturing site / Packaging site / Testing site | Simchem Pvt.Ltd. Plot No. 60-65, Tuem Industrial Estate, Tuem Pernem, Goa - 403512 India |
| Manufacturing Authorization Number / Licence or Certificate of GMP Compliance of a manufacturer | : GO/DRUGS/576/L |
| Results of analysis | : Certificate of analysis attached |
| Comments/remarks | : --- |

*Packing lot/ batch number should be mentioned.

**Write NA if not applicable

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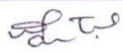

| | |
|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Generic Name : Sennoside Tablets 13.5mg | |
| Brand Name : Senade | |
| *Lot / Packing Batch number : 484129 | |
| Certification statement | : I hereby certify that the information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the mentioned site(s) in full compliance with the GMP requirements of the Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP and the Technical Agreement between Cipla and Dr. Reddy's Laboratories SA without deviation (or with deviations assessed as having no effect on the quality of the finished product. Details of any such deviations are appended). The batch is hereby released for supply to Dr. Reddy's Laboratories SA |
| Name and position/title and address of person authorizing the batch release | : Puja Kashalkar. Quality Assurance Executive. Simchem Pvt. Ltd. Plot No. 60-65, Tuem Industrial Estate, Tuem Pernem, Goa – 403512 India |
| Signature of person authorizing the batch release | :  |
| Date of signature | : 16.11.2024 |

CERTIFICATE OF ANALYSIS
СЕРТИФИКАТ АНАЛИЗА

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| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Product: SENADE TABLETS 13,5 mg | Продукт: СЕНАДЕ [®] , ТАБЛЕТКИ 13,5 мг |
| Batch No / Серия № : 484129 | Batch Quantity / Объем серии: 5845 packs / упаковок |
| AR No / Аналитический отчет № : ARF/219/2024 | Date of Analysis / Дата анализа: 16.11.2024 |
| Date of Mfg / Дата производства: 11/2024 | Date of Expiry / Годен до: 10/2027 |
| Analysis performed according ND / Анализ проведен по НД: П N013745/01-180522, amend No. 1 dated 09.07.2024 / П N013745/01-180522, изм. № 1 от 09.07.2024 | |

| № | Test / Показатель | Result / Результаты | Specification / Норма |
|-----|--------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Description / Описание | Complies / Соответствует | Flat circular tablets from brown to dark-brown with bevelled edges and disseminations. It has CIPLA monogram embossed on one side and central break-line on the other. / Плоские круглые таблетки со скошенными краями от коричневого до темно-коричневого цвета с вкраплениями. На одной стороне таблетки выдавлено слово «CIPLA», на другой - линия разлома. |
| 2 | Identification / Подлинность | | |
| 2a) | Anthraquinone glycosides / Антрахиноновые гликозиды | Complies / Соответствует | Ammoniacal solution turns a reddish colour / Окрашивание аммиачного раствора в красный цвет. |
| 2b) | Methyl Parahydroxybenzoate (HPLC)/ Метилпарагидроксibenzoат (ВЭЖХ) | Complies / Соответствует | Retention time of the principle peak in the chromatogram of the sample solution should corresponds to the retention time of the principle peak in the chromatogram of the Methyl Parahydroxybenzoate standard solution (refer test «Methyl Parahydroxybenzoate») / Время удерживания основного пика на хроматограмме испытуемого раствора должно соответствовать времени удерживания основного пика на хроматограмме стандартного раствора метилпарагидроксibenzoата (раздел «Метилпарагидроксibenzoат»). |
| 3 | Average weight / Средняя масса | 191.02mg / 191,02мг | 189.99 mg ±7.5% / 189,99 мг ±7,5% |

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| Remarks : The Product conforms to ND/ Примечание: Продукт соответствует требованиям НД | Conclusion : APPROVED / Заключение: ОДОБРЕНО |
| Checked by QC In-Charge / Документ проверен ОКК:  | Approved by QA In-Charge / Документ одобрен ООК:  |
| Date / Дата: 16.11.2024 | Date / Дата: 16.11.2024 |



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CERTIFICATE OF ANALYSIS
СЕРТИФИКАТ АНАЛИЗА

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| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Product: SENADE TABLETS 13,5 mg | Продукт: СЕНАДЕ[®], ТАБЛЕТКИ 13,5 мг |
| Batch No / Серия № : 484129 | Batch Quantity / Объем серии: 5845 packs / упаковок |
| AR No / Аналитический отчет № : ARF/219/2024 | Date of Analysis / Дата анализа: 16.11.2024 |
| Date of Mfg / Дата производства: 11/2024 | Date of Expiry / Годен до: 10/2027 |
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| № | Test / Показатель | Result / Результаты | Specification / Норма |
|---|----------------------------------------------------------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4 | Uniformity of weight / Однородность по массе | Complies / Соответствует | 18/20 tablets NMT $\pm 7.5\%$ / 18/20 не более $\pm 7,5\%$ 2/20 tablets NMT $\pm 15\%$ / 2/20 не более $\pm 15\%$ |
| 5 | Loss on drying / Потеря в массе при высушивании | 2.2% | NMT 6.0 % / Не более 6,0 % |
| 6 | Dissolution / Растворение | 78-97% | NLT 70 % (Q) of sennosides in 120 minutes Не менее 70 % (Q) сеннозидов через 120 мин |
| 7 | Uniformity of Dosage units / Однородность дозирования | AV = 5.9 | The acceptability index for n = 10 $AV \leq L1$. In the case where the value of AV exceeds L1, a test is carried out on the following 20 samples. For n = 30 $AV \leq L1$. All values of xi must satisfy the inequality: $ M-xi \leq 0,01 \times L2 \times M$. $L1 = 15,0; L2 = 25,0$. Показатель приемлемости для n=10 $AV \leq L1$. В случае, если значение AV превышает L1, проводят испытание на следующих 20 образцах. Для n=30 $AV \leq L1$. Все значения xi должны удовлетворять неравенству: $ M-xi \leq 0,01 \times L2 \times M$. $L1 = 15,0; L2 = 25,0$. |
| 8 | Assay (Spectrophotometry) / Количественное определение (Спектрофотометрия) | 14.05mg/tab / 14,05мг/таб | From 12.15 to 15.53 mg (from 90.0 to 115.0 %) of sennosides calculated as sennoside B in one tablet. / От 12,15 до 15,53 мг (от 90,0 до 115,0 %) сеннозидов в пересчете на сеннозид В в одной таблетке. |

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| Remarks : The Product conforms to ND/ Примечание: Продукт соответствует требованиям НД | Conclusion : APPROVED / Заключение: ОДОБРЕНО |
| Checked by QC In-Charge / Документ проверен ОКК:  | Approved by QA In-Charge / Документ одобрен ОКК:  |
| Date / Дата: 16.11.2024 | Date / Дата: 16.11.2024 |

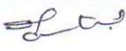
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CERTIFICATE OF ANALYSIS
СЕРТИФИКАТ АНАЛИЗА

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| Product: SENADE TABLETS 13,5 mg | Продукт: СЕНАДЕ[®], ТАБЛЕТКИ 13,5 мг |
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| № | Test / Показатель | Result / Результаты | Specification / Норма |
|-------|----------------------------------------------------------------------------------------------|--------------------------------|--------------------------------------------------------------------|
| 9 | Content of Methyl parahydroxybenzoate(HPLC)/ Содержание метилпарагидроксибензоата (ВЭЖХ) | 0.043mg/tab 0,043мг/таб | 0.028 – 0.056 mg/tab. / От 0,028 до 0,056 мг/таб. |
| 10 | MICROBIAL LIMIT TEST/ Микробиологическая чистота | | |
| 10 a) | Total Aerobic microbial count / Общее число аэробных микроорганизмов | 40 | Not more than 10 ⁴ cfu/ g / Не более 10 ⁴ /г |
| 10 b) | Total combined yeast and mould count / Общее число плесневых и дрожжевых грибов | <10 | Not more than 10 ² cfu/ g / Не более 10 ² /г |
| 10 c) | Bile tolerant gram-negative bacteria/ Устойчивые к действию желчи грамотрицательные бактерии | Absent /Отсутствуют | Not more than 10 ² / g / Не более 10 ² /г |
| 10 d) | Staphylococcus aureus | Absent /Отсутствуют | Absent in 1 g / Отсутствие в 1 г |
| 10 e) | Escherichia coli | Absent /Отсутствуют | Absent in 1 g / Отсутствие в 1 г |
| 10 f) | Salmonella | Absent / Отсутствуют | Absent in 10 g / Отсутствие в 10 г |

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| Remarks : The Product conforms to ND/ Примечание: Продукт соответствует требованиям НД | Conclusion : APPROVED / Заключение: ОДОБРЕНО |
| Checked by QC In-Charge / Документ проверен ОКК:  | Approved by QA In-Charge / Документ одобрен ООК:  |
| Date / Дата: 16.11.2024 | Date / Дата: 16.11.2024 |


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CERTIFICATE OF ANALYSIS
СЕРТИФИКАТ АНАЛИЗА

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| Product: SENADE TABLETS 13,5 mg | Продукт: СЕНАДЕ®, ТАБЛЕТКИ 13,5 мг |
| Batch No / Серия № : 484129 | Batch Quantity / Объем серии: 5845 packs / упаковок |
| AR No / Аналитический отчет № : ARF/219/2024 | Date of Analysis / Дата анализа: 16.11.2024 |
| Date of Mfg / Дата производства: 11/2024 | Date of Expiry / Годен до: 10/2027 |
| Analysis performed according ND / Анализ проведен по НД: П N013745/01-180522, amend No. 1 dated 09.07.2024 / П N013745/01-180522, изм. № 1 от 09.07.2024 | |

| № | Test / Показатель | Result / Результаты | Specification / Норма |
|----|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11 | Package / Упаковка | Package / Упаковка - 20 tablets in a blister made of PVC/PE/PVDC film and aluminum foil, 25 blisters with 25 patient information leaflets in a carton. / По 20 таблеток в блистер из пленки поливинилхлоридной (полиэтиленовой/ поливинилденхлоридной) и алюминиевой фольги, по 25 блистеров в картонную пачку с вложением 25 инструкций по применению. | Package / Упаковка - 20 tablets in a blister made of three-layer PVC/PE/PVDC film and aluminum foil. 2 or 3 blisters and a patient information leaflet in a carton. 20 tablets in a blister made of PVC /PE/PVDC film and aluminum foil, 25 blisters with 25 patient information leaflets in a carton. / По 20 таблеток в блистер из пленки трехслойной (ПВХ/ПЭ/ПВДХ) и алюминиевой фольги. По 2 или 3 блистера вместе с инструкцией по применению в картонную пачку. По 20 таблеток в блистер из пленки поливинилхлоридной (полиэтиленовой / поливинилденхлоридной) и алюминиевой фольги, по 25 блистеров в картонную пачку с вложением 25 инструкций по применению. |
| 12 | Labeling / Маркировка | According to ND / В соответствии с НД | |
| 13 | Storage conditions / Условия хранения | In a dry place, at temperature below 25 °C. / В сухом месте при температуре не выше 25 °C. | |
| 14 | Shelf life / Срок годности | 3 years / 3 года | |

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| Remarks : The Product conforms to ND/ Примечание: Продукт соответствует требованиям НД | Conclusion : APPROVED / Заключение: ОДОБРЕНО |
| Checked by QC In-Charge / Документ проверен ОКК:  | Approved by QA In-Charge / Документ одобрен ООК:  |
| Date / Дата: 16.11.2024 | Date / Дата: 16.11.2024 |

FMQC003-15-09

Authorized By (QA Head)
Sign & Date: *[Signature]* 06/11/2024

MASTER FORMAT

| | | | | |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|-----------------------------|----------|--------|
| SIMCHEM PVT. LTD. PLOT No. 60-65, TUEM INDUSTRIAL ESTATE, TUEM , PERNEM, GOA - 403512, INDIA. | Title PACK STOCK INSPECTION CHECKLIST -EXPORT | Ref. Doc. No. QA/048 | Page No. | 1 of 2 |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|-----------------------------|----------|--------|

Previous Product Name: Senade Tablet Previous Batch No. 484128 Line No. : I, II
 Product Name: Senade Tablet 570.000 Kgs
 *EXPORT/LOCAL: 8455250/20 Batch No. : 484129 Batch size: 3000000 Nos
 Mfg. Date: 11/2024 Exp. Date: 10/2027 Date of inspection: from 08.11.24 to 08.11.24

Keys: = complies/OK NA = Not Applicable
 = No defects are observed X = Does not comply

| Sr. No. | DEFECTS | SHIPPER NUMBER | | | | | | |
|---------|-----------------------------------------------------------------|----------------|---------|-----------|--------|----------|--------|-------------------|
| | | 01 | 16 | 23 | 36 | 48 | 59 | |
| 1. | Shipper Top / Bottom Taping | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| 2. | Shipper Overprinting / Labeling | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| 3. | Packer Name | Shivani | Ptadnya | Rajashree | Ankita | Sandeeta | Sonal | |
| 4. | Shipper Fill Value (100 x 25 x 20's) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓* | *(45 x 25 x 20's) |
| 5. | Bundling Quality / Pouch Quality | NA | NA | NA | NA | NA | NA | |
| 6. | Outer Carton Overprinting | NA | NA | NA | NA | NA | NA | |
| 7. | Inner Carton Serialization | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| 8. | Cracked/half tablet/Broken tablets edges. | - | - | - | - | - | - | |
| 9. | Missing Leaflet | - | - | - | - | - | - | |
| 10. | Blister Overprinting / Smudging Embossing | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| 11. | Missing units/Extra units | - | - | - | - | - | - | |
| 12. | Broken/chipping/ molted Tablets | - | - | - | - | - | - | |
| 13. | Spot/ Powder In Blister / Tablets. | - | - | - | - | - | - | |
| 14. | sticking / Picking | - | - | - | - | - | - | |
| 15. | Sealing/foil/ pinhole/ forming defects | - | - | - | - | - | - | NA 08.11.24 |
| 16. | Blister /Wrinkles / Improper Knurling/ Torn pocket | - | - | - | - | - | - | |
| 17. | Foreign Product/Foreign/ extraneous Material | - | - | - | - | - | - | |
| 18. | Wrong appearance/different shape of tablets/blister | - | - | - | - | - | - | |
| 19. | Colour of tablets | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| 20. | ** Other defect | - | - | - | - | - | - | |
| 21. | Total Defects | - | - | - | - | - | - | |
| 22. | Total replaced Units | NA | NA | NA | NA | NA | NA | |
| 23. | Shipper weight of each shipper after inspection (kilogram/gram) | 21.140 | 21.070 | 21.140 | 20.980 | 21.080 | 10.500 | |

Authorized By (QA Head)
Sign & Date: [Signature] 08.11.2023

MASTER FORMAT

| | | | | |
|--------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------|----------|--------|
| SIMCHEM PVT. LTD. PLOT No. 60-65, TUEM INDUSTRIAL ESTATE, TUEM , PERNEM, GOA - 403512, INDIA. | Title | PACK STOCK INSPECTION CHECKLIST -EXPORT | | |
| | Ref. Doc. No. | QA/048 | Page No. | 2 of 2 |

| | | | | | | | | |
|------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--|----------------------------|
| Done By | Snehal | Snehal | Snehal | Snehal | Snehal | Snehal | | |
| Checked By | [Signature] 08.11.24 | [Signature] 08.11.24 | [Signature] 08.11.24 | [Signature] 08.11.24 | [Signature] 08.11.24 | [Signature] 08.11.24 | | NA [Signature] 08.11.24 |

*(For export mention the export order no.)

FINAL INSPECTION CHECKLIST:

| | | | |
|--------------------------------|--------------------|--------------------------------------|------|
| Total shippers packed in Batch | 58 Full + 01 Loose | Total shippers checked in batch | 06 |
| Total Quantity packed | 5845 X 25 X 20'S | % of Pack Stock carried out on batch | 100% |

| | |
|---------------------------------------------------------------------------------------------------|----|
| Defect Observed | - |
| ** If any Other defect observed | - |
| Nature Of Defect Observed (Critical, Major, Minor) | - |
| Action Plan For Defect | NA |
| Corrective Action And Preventive Action (CAPA) (If Applicable For Details Enter CAPA Number) | NA |
| Decision For Further Pack Stock Inspection | NA |
| Total Replaced Unit Blister/Carton/Shipper | NA |

Certified By: [Signature] 08.11.24
(Packing Officer)

Rechecked By: [Signature] 09.11.24
(QA Officer)

Approved By: [Signature] 09.11.2024
(Quality Assurance Head / Executive)