

## Supplementary Data

### Review and comparison of acceptance criteria for Senna and its preparations according to BP (2015 and 2020) and USP-NF (39-34 and 43-38)

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**Table 1:** Specifications and requirements of herbal monographs in pharmacopeias.

Pharmacopoeia	Monograph title	Foreign organ and elements	Loss on drying <sup>1</sup>	Total ash	Determination of insoluble ash	Contamination <sup>2</sup>
BP (2015-2020)	Pods of <i>C.acutifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	-
	Pods of <i>C. angustifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	-
	Senna liquid extract	-	-	-	-	-
	Senna leaflets from <i>C.acutifolia</i> and <i>C. angustifolia</i>	Max 4%	Max 12%	Max 12%	Max 2.5%	-
	Senna granules	-	Max 2%	-	-	-
		-	-	-	-	-

USP-NF (39-34 and 43-38)	Senna tablets from the powdered pericarp of senna Fruit, Alexandrian or Tinnevelly <sup>3</sup>					TAMC <sup>4</sup> : acceptance criterion 10 <sup>4</sup> CFU/g TYMC <sup>5</sup> : acceptance criterion 10 <sup>2</sup> CFU/g
	Dry extract of senna leaves (extracted by ethanol 50-80% )	-	Max 5%	-	-	
	Leaves of <i>C.acutifolia</i> and <i>C.angustifolia</i>	Max 8% of senna stems and max 2% of other elements	Max 12%	Max 12%	Max 3%	TBC <sup>6</sup> : CFU/g:10 <sup>5</sup> TYMC: CFU/g:10 <sup>3</sup> bile-tolerant gram-negative bacteria: CFU/g:10 <sup>3</sup>
	Senna fluid extract <sup>7</sup>	-	-	-	-	-
	Pods of <i>C.acutifolia</i> and <i>C.angustifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	TBC: CFU/g:10 <sup>5</sup> TYMC: CFU/g:10 <sup>3</sup> bile-tolerant gram-negative bacteria: CFU/g:10 <sup>3</sup>
	Senna oral solution	-	-	-	-	-
Sennosides powder or calcium salt of anthraquinone	-	Max 5%	-	-	heavy metals should be tested (Max 60 µg/g)	

glycosides from  
leaves or pods of  
*C.acutifolia* and  
*C.angustifolia*<sup>8</sup>

Sennoside tablets<sup>8</sup>

-

Max 5%

-

-

heavy metals should  
be tested  
(Max 60 µg/g)

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**Table 2:** Requirements for licensing Senna herbal parts and preparations according to two editions of BP and USP-NF.

Pharmacopoeia	Monograph title	Foreign organ and elements	Loss on drying <sup>1</sup>	Total ash	Determination of insoluble ash	Contamination <sup>2</sup>
BP (2015-2020)	Pods of <i>C.acutifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	-
	Pods of <i>C. angustifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	-
	Senna liquid extract	-	-	-	-	-
	Senna leaflets from <i>C.acutifolia</i> and <i>C. angustifolia</i>	Max 4%	Max 12%	Max 12%	Max 2.5%	-
	Senna granules	-	Max 2%	-	-	-
	Senna tablets from the powdered pericarp of senna Fruit, Alexandrian or Tinnevelly <sup>3</sup>	-	-	-	-	-
	Dry extract of senna leaves (extracted by ethanol 50-80% )	-	Max 5%	-	-	TAMC <sup>4</sup> : acceptance criterion 10 <sup>4</sup> CFU/g

TYMC<sup>5</sup>: acceptance  
criterion 10<sup>2</sup> CFU/g

USP-NF

TBC<sup>6</sup>: CFU/g:10<sup>5</sup>

(39-34 and 43-38)

TYMC: CFU/g:10<sup>3</sup>

Leaves of <i>C.acutifolia</i> and <i>C.angustifolia</i>	Max 8% of senna stems and max 2% of other elements	Max 12%	Max 12%	Max 3%	Bile-tolerant gram- negative bacteria: CFU/g:10 <sup>3</sup>
Senna fluid extract <sup>7</sup>	-	-	-	-	-
Pods of <i>C.acutifolia</i> and <i>C.angustifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	TBC: CFU/g:10 <sup>5</sup>

TYMC: CFU/g:10<sup>3</sup>

bile-tolerant gram-  
negative bacteria:  
CFU/g:10<sup>3</sup>

Senna oral solution - - - -

Sennosides powder  
or calcium salt of  
anthraquinone  
glycosides from  
leaves or pods of  
*C.acutifolia* and  
*C.angustifolia*<sup>8</sup> - Max 5% - -

Sennoside tablets<sup>8</sup> - Max 5% - -

heavy metals should  
be tested

(Max 60 µg/g)

heavy metals should  
be tested

(Max 60 µg/g)

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**Table 3:** Further requirements for licensing of Senna herbal parts and preparations according to two editions BP and USP-NF.

Pharmacopoeia	Monograph title	Foreign organ and elements	Loss on drying <sup>1</sup>	Total ash	Determination of insoluble ash	Contamination <sup>2</sup>
BP (2015-2020)	Pods of <i>C.acutifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	-
	Pods of <i>C. angustifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	-
	Senna liquid extract	-	-	-	-	-
	Senna leaflets from <i>C.acutifolia</i> and <i>C. angustifolia</i>	Max 4%	Max 12%	Max 12%	Max 2.5%	-
	Senna granules	-	Max 2%	-	-	-
	Senna tablets from the powdered pericarp of senna Fruit, Alexandrian or Tinnevelly <sup>3</sup>	-	-	-	-	-
	Dry extract of senna leaves (extracted by ethanol 50-80% )	-	Max 5%	-	-	TAMC <sup>4</sup> : acceptance criterion 10 <sup>4</sup> CFU/g TYMC <sup>5</sup> : acceptance criterion 10 <sup>2</sup> CFU/g
USP-NF (39-34 and 43-38)	Leaves of <i>C.acutifolia</i> and <i>C.angustifolia</i>	Max 8% of senna stems and max 2% of other elements	Max 12%	Max 12%	Max 3%	TBC <sup>6</sup> : CFU/g:10 <sup>5</sup> TYMC: CFU/g:10 <sup>3</sup> bile-tolerant gram-negative bacteria: CFU/g:10 <sup>3</sup>

Senna fluid extract <sup>7</sup>	-	-	-	-	-
Pods of <i>C.acutifolia</i> and <i>C.angustifolia</i>	Max 1%	Max 12%	Max 9%	Max 2%	TBC: CFU/g:10 <sup>5</sup> TYMC: CFU/g:10 <sup>3</sup> bile-tolerant gram-negative bacteria: CFU/g:10 <sup>3</sup>
Senna oral solution	-	-	-	-	-
Sennosides powder or calcium salt of anthraquinone glycosides from leaves or pods of <i>C.acutifolia</i> and <i>C.angustifolia</i> <sup>8</sup>	-	Max 5%	-	-	Heavy metals should be tested  (Max 60 µg/g)
Sennoside tablets <sup>8</sup>	-	Max 5%	-	-	Heavy metals should be tested (Max 60 µg/g)

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