



Solistaa Pharmaceuticals Private Limited

PRODUCT SPECIFICATION

NAME OF THE PRODUCT: IMMUNITY GUMMY

Specification No.	SPC-143	Reference	In-House	Page No.	1 of 8
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date:  12/09/23	
STP No.	STP-143†	Review Date	4/09-2024		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

Prepared By:

Sign:

Date:



11/09/2023

Quality Control

Reviewed By:

Sign:

Date:



11/09/2023

Quality Control

Reviewed By:

Sign:

Date:



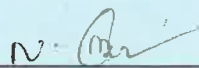
11/09/2023

Regulatory Affairs

Approved By:

Sign:

Date:



12/09/2023

Quality Assurance

† Follow the current version of the STP

F3QC062D22 – WEF – 05/02/2022

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QA	
Copy No.:	02
Sign/Date	12/09/23



Solistaa Pharmaceuticals Private Limited

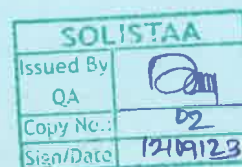
PRODUCT SPECIFICATION

NAME OF THE PRODUCT: IMMUNITY GUMMY

Specification No.	SPC-143	Reference	In-House	Page No.	2 of 8
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: DGM 12/09/23	
STP No.	STP-143†	Review Date	AUG-2024		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

A. In-Process Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Water content by KF A. Before Drying B. After Drying	For information only Not More Than 12.0% (% w/w)	In-House



**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: IMMUNITY GUMMY**

Specification No.	SPC-143	Reference	In-House	Page No.	3 of 8
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date:  12/09/23	
STP No.	STP-143†	Review Date	Aug-2024		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

B. In-Process Specification: (Bulk)

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Brownish red to dark brownish red colour, drop shaped with forest fruit flavoured gummy	In-House
2.	Identification: By HPLC: Elderberry extract Curcumin C ₃ complex	The Retention time of the major peak in the chromatogram of the sample preparation correspondence to that in the chromatogram of the standard preparation, as obtained in the assay.	In-House
3.	Average weight	3.00 g $\pm$ 10 % (2.70 g to 3.30 g)	In-House
4.	Uniformity of Weight	Individual weight of Gummy . does not deviate by more than $\pm$ 20 % from the average weight.	In-House
5.	Water content by KF	Not More Than 12.0% (% w/w)	In-House
6.	Assay: Each Gummy contains: By HPLC: Elderberry extract Curcumin C ₃ complex Thyme vulgaris* Moringa oleifera extract*	50 mg 50 mg 10 mg 10 mg Not Less Than 90.0% Not Less Than 90.0% Not Less Than 100% Not Less Than 100%	In-House



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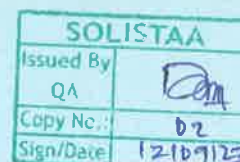
Specification No.	SPC-143	Reference	In-House	Page No.	4 of 8
Revision No.	01	Effective Date	12/09/2022	Assigned by/Date:  12/09/22	
STP No.	STP-143†	Review Date	12/09/2022		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

S. No.	Tests Parameters	Specification Limit	Reference for Test
7.	Microbiological Test a) Total aerobic Microbial count b) Total Yeasts and Molds Count c) <i>Enterobacteriaceae</i> d) <i>Listeria monocytogenes</i> e) <i>Salmonella species</i>	Not More Than 10000 cfu/g Not More Than 100 cfu/g Not More Than 100 cfu/g Absent in 25g Absent in 25g	In-House

Note:

cfu – colony forming unit

*- Calculation based on initial input



**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: IMMUNITY GUMMY**

Specification No.	SPC-143	Reference	In-House	Page No.	5 of 8
Revision No.	01	Effective Date	12-10-2023	Assigned by/Date:  12-10-2023	
STP No.	STP-143†	Review Date	AUG-2024		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

C. Finished Product – Release Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Brownish red to dark brownish red colour, drop shaped with forest fruit flavoured gummy	In-House
2.	Identification: By HPLC: Elderberry extract Curcumin C ₃ complex	The Retention time of the major peak in the chromatogram of the sample preparation correspondence to that in the chromatogram of the standard preparation, as obtained in the assay.	In-House
3.	Average weight	3.00 g $\pm$ 10 % (2.70 g to 3.30 g)	In-House
4.	Uniformity of Weight	Individual weight of Gummy does not deviate by more than $\pm$ 20 % from the average weight.	In-House
5.	Water content by KF	Not More Than 12.0% (% w/w)	In-House
6.	Assay: Each Gummy contains: By HPLC: Elderberry extract Curcumin C ₃ complex Thyme vulgaris* Moringa oleifera extract*	50 mg Not Less Than 90.0% 50 mg Not Less Than 90.0% 10 mg Not Less Than 100% 10 mg Not Less Than 100%	In-House

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Specification No.	SPC-143	Reference	In-House	Page No.	6 of 8
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STP No.	STP-143†	Review Date	AUG-2021		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

S. No.	Tests Parameters	Specification Limit	Reference for Test
7.	Microbiological Test: a) Total aerobic Microbial count b) Total Yeasts and Molds Count c) <i>Enterobacteriaceae</i> d) <i>Listeria monocytogenes</i> e) <i>Salmonella species</i>	Not More Than 10000 cfu/g Not more Than 100 cfu/g Not more Than 100 cfu/g Absent in 25g Absent in 25g	In-House
8.	Heavy Metals ^{+\$} a) Lead b) Copper c) Arsenic d) Tin e) Cadmium f) Mercury g) Methyl Mercury	Not More Than 2.5 ppm Not More Than 30.0 ppm Not More Than 1.1 ppm Not More Than 250.0 ppm Not More Than 1.5 ppm Not More Than 1.0 ppm Not More Than 0.25 ppm	FSSAI
9.	Total Aflatoxins ^{+\$} Aflatoxin B1 ^{+\$}	Maximum 20mcg/kg Maximum 10mcg/kg	FSSAI
10.	Pesticides ^{+\$}	Should comply	FSSAI

Note:

cfu – colony forming unit,

*- Calculation based on initial input

\$ -These tests will be performed for first commercial batch and will be repeated every 6 months. The requirements for these tests are as per the regulatory framework laid by FSSAI and Test performed at NABL accredited / FSSAI recognized laboratory.

+-This Test is not a part of Product Release.

Shelf life: 18 Months from the date of manufacturing.

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Revision No.	01	Effective Date	12-10-2023	Assigned by/Date: DM 12-10-23	
STP No.	STP-143†	Review Date	AUG - 2021		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

E. Finished Product – Stability Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Brownish red to dark brownish red colour, drop shaped with forest fruit flavoured gummy.	In-House
2.	Average weight	3.00 g $\pm$ 10 % (2.70 g to 3.30 g)	In-House
3.	Water content by KF	Not More Than 12.0% (% w/w)	In-House
4.	Assay: Each Gummy contains: By HPLC: Elderberry extract 50 mg Curcumin C ₃ complex 50 mg Thyme vulgaris* 10 mg Moringa oleifera extract* 10 mg	Not Less Than 90.0% Not Less Than 90.0% Not Less Than 100% Not Less Than 100%	In-House
5.	Microbiological Test: a) Total aerobic Microbial count b) Total Yeasts and Molds Count c) <i>Enterobacteriaceae</i> d) <i>Listeria monocytogenes</i> e) <i>Salmonella species</i>	Not More Than 10000 cfu/g Not More Than 100 cfu/g Not More Than 100 cfu/g Absent in 25g Absent in 25g	In-House

Note: cfu – colony forming unit, *- Calculation based on initial input



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STP No.	STP-143†	Review Date	10/9-2023		
Product Code	143	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

REVISION HISTORY:

Rev No.	Nature of revision in brief	Effective Date	DCR Reference
00	New Document	19/05/2023	CCRD23007
01	1. Microbiological Test parameters are modified as per current FSSAI (Food Products Standards and Food Additives) Amendment Regulation 2023. 2. In C. Finished Product Release Specification Aflatoxins is changed into Total Aflatoxins and Aflatoxin B1.	12/09/2023	CCMB23005