Otsuka Pharmaceutical India Private Limited

Batch Test Summary Report

Ref SOP No. CO/CQA/017

Storage Conditions	30°C ± 2°C and 75% RH ± 5% RH	Total Storage Duration	24 Months
Product Name	Paracetamol Infusion (1% w/v)	Fill Volume & Container	100 ml Fill Volume in NPVC Bag
Batch No.	2194009	Batch Size	1500 Lit.
Mfg. Date	2019-10	Exp. Date	2021-09
Study Started On	19/10/19	Study Status	Study Completed
Manufacturing Plant	MF02	Manufacturing Line No.	Line No. 06
API Manufacturer Name	Paracetamol - Farmson Pharmaceuticals Gujarat Pvt. Ltd	API Manufacturer Lot No./ A.R. No.	Paracetamol - 2R1900424
Any Additional Information	NA		

Sr. No.	Storage Period in number of months		0 (Initial)	3 months	6 months	9 months	12 months	18 months	24 months
	Expected withdrawal date		---	19/01/20	19/04/20	19/07/20	19/10/20	19/04/21	19/10/21
	Actual withdrawal date		---	20/01/20	20/04/20	21/07/20	19/10/20	19/04/21	19/10/21
	Tests	Specification							
1.0	Description	The solution should be clear and colourless. Practically free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless, Free from visible particles
2.0	pH	Between 4.50 and 6.50	5.88	5.62	5.37	5.42	5.15	5.55	5.36
3.0	Light absorption	The absorbance of sample should be not more than 0.04 at 500 nm	0.01	0.04	0.00	0.02	0.00	0.00	0.00
4.0	Related Substances (By HPLC)								
4.1	4-Amino phenol	Not More Than 0.1 %	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
4.2	4-Chloroacetanilide	Not More Than 10 ppm	Not Detected	0.00	0.00	0.00	0.00	0.00	0.00
4.3	Any other impurity	Not More Than 0.25 %	0.02%	0.01%	0.02%	0.01%	0.01%	0.01%	0.01%
5.0	Bacterial Endotoxins	Not More Than 2.0 EU per ml	Less Than 2.0 EU per ml	---	---	---	Less Than 2.0 EU per ml	---	Less Than 2.0 EU per ml
6.0	Particulate Matter For ≥ 10 µm For ≥ 25 µm	Not More Than 6000 particles per container Not More Than 600 particles per container	80.0 6.70	---	---	---	266.7 13.3	---	250.0 0.0
7.0	Assay								
7.1	Assay of Paracetamol (By HPLC)	Not less than 90.0% and not more than 110.0% of Label Claim (Label Claim: 10 mg/ml)	98.4	102.8	96.4	97.5	96.4	99.0	100.3
7.2	Assay of Sodium chloride (By Titration)	Between 95.0% and 105.0% of the Label Claim (Label claim: 7 mg/ml)	98.1	99.0	99.4	99.0	99.0	100.5	100.8
7.3	Content of Sodium Metabisulphite (By HPLC)	Between 10.0% and 110.0% of the Label Claim (Label Claim: 0.15 mg/ml)	72.6	47.2	57.4	47.2	37.3	41.8	26.9
8.0	Sterility Test	It should be sterile	Sterile	---	---	---	Sterile	---	Sterile
9.0	Osmolality	Between 240 and 350 mOsm/kg	290	296	292	285	295	291	299
10.0	Water Vapor Permeability Test	Not More Than 5.00%	NA	0.00%	0.00%	0.17%	0.33%	0.41%	0.49%
11.0	Correction Factor 30°C/35%RH	Not More Than 5.00%	NA	0.00%	0.00%	0.44%	0.86%	1.07%	1.27%
12.0	Any significant change observed	Yes/ No	NA	No	No	No	No	No	No
13.0	Remarks	(Passes / Fails)	Passes	Passes	Passes	Passes	Passes	Passes	Passes

NA: Not Applicable.

Current Specification No. : FP/QC/035f

Verified By CQA Officer/Executive Sign & Date	09/11/21
Approved By CQA Executive/Manager Sign & Date	09/11/21

Otsuka Pharmaceutical India Private Limited

Product Stability Summary Sheet

Ref SOP No.: CO/CQA/017

Product Name:	**Paracetamol Infusion (1% w/v)**
Fill Volume and Container:	**100 ml Fill Volume in Non PVC Bag**

Sr. No.	Storage period and condition	Batch No.
		2194009
00	**Initial**	Complies
01	**3 months 30°C**	Complies
02	**6 months 30°C**	Complies
03	**9 months 30°C**	Complies
04	**12 months 30°C**	Complies
05	**18 months 30°C**	Complies
06	**24 months 30°C**	Complies

Conclusion:

The stability study are conducted for **Paracetamol Infusion (1% w/v) - 100 ml Fill Volume in Non PVC Bag** on one Batch No. – 2194009 for 24 months at 30°C ± 2°C and 75% ± 5% RH. The results of above stability study at 30°C till now are complying with the pre-defined acceptance criteria and hence it is concluded that at this stage the **product is stable** when manufactured according to the master formula.

Signature : B

Name : Arkaprava Banerjee

Designation : Senior Process Incharge - Stability

Date : 09/11/21

Otsuka Pharmaceutical India Private Limited

Product Stability Summary Sheet

Ref SOP No.: CO/CQA/017

Product Name:	**Paracetamol Infusion (1% w/v)**
Fill Volume and Container:	**100 ml Fill Volume in Non PVC Bag**

Special Note:

01 Stability study tests are conducted on one Batch No. – 2194009 for 24 months at the interval of 3 months for the first year (0 (initial), 3, 6, 9 and 12 months) and 18 and 24 month at 30°C ± 2°C and 75% ± 5% RH.

02 Test for Description, pH, light absorption, Related substances of 4-Amino phenol, 4-Chloroacetanilide and Any other impurity, Assay of Paracetamol, Sodium Chloride and Content of Sodium Metabisulphite and Osmolality are performed at initial time and each stage of stability study and Water Vapor Permeability test is performed at each stage of stability study at above-mentioned condition.

03 Test for Particulate Matter, Bacterial Endotoxins and Sterility test are performed at initial time 12 months and 24 months

Signature : _____

Name : Arkaprava Banerjee

Designation : Senior Process Incharge - Stability

Date : 09/11/21

Otsuka Pharmaceutical India Private Limited

Batch Test Summary Report

Ref SOP No. CO/CQA/017

Storage Conditions	30°C ± 2°C and 75% RH ± 5% RH	Total Storage Duration	24 Months
Product Name	Paracetamol Infusion (1% w/v)	Fill Volume & Container	100 ml Fill Volume in NPVC Bag
Batch No.	2194010	Batch Size	1500 Lit.
Mfg. Date	2019-10	Exp. Date	2021-09
Study Started On	19/10/19	Study Status	Study Completed
Manufacturing Plant	MF02	Manufacturing Line No.	Line No. 06
API Manufacturer Name	Paracetamol - Farmson Pharmaceuticals Gujarat Pvt. Ltd	API Manufacturer Lot No./ A.R. No.	Paracetamol - 2R1900424
Any Additional Information	NA		

Sr. No.	Storage Period in number of months		0 (Initial)	3 months	6 months	9 months	12 months	18 months	24 months
	Expected withdrawal date		---	19/01/20	19/04/20	19/07/20	19/10/20	19/04/21	19/10/21
	Actual withdrawal date		---	20/01/20	20/04/20	21/07/20	19/10/20	19/04/21	19/10/21
	Tests	Specification							
1.0	Description	The solution should be clear and colourless. Practically free from visible particles	The solution is clear and colourless. Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless, Free from visible particles
2.0	pH	Between 4.50 and 6.50	5.94	5.48	5.47	5.25	5.31	5.29	4.94
3.0	Light absorption	The absorbance of sample should be not more than 0.04 at 500 nm	0.00	0.03	0.00	0.02	0.02	0.00	0.00
4.0	Related Substances (By HPLC)								
4.1	4-Amino phenol	Not More Than 0.1 %	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
4.2	4-Chloroacetanilide	Not More Than 10 ppm	Not Detected	0.00	0.00	0.00	0.00	0.00	0.00
4.3	Any other impurity	Not More Than 0.25 %	0.03%	0.01%	0.02%	0.01%	0.01%	0.01%	0.00%
5.0	Bacterial Endotoxins	Not More Than 2.0 EU per ml	Less Than 2.0 EU per ml	--	---	---	Less Than 2.0 EU per ml	---	Less Than 2.0 EU per ml
6.0	Particulate Matter For ≥ 10 µm For ≥ 25 µm	Not More Than 6000 particles per container Not More Than 600 particles per container	6.70 3.30	---	---	---	223.3 3.3	---	773.3 43.3
7.0	Assay								
7.1	Assay of Paracetamol (By HPLC)	Not less than 90.0% and not more than 110.0% of Label Claim (Label Claim: 10 mg/ml)	98.4	101.0	97.3	97.4	96.4	99.1	97.8
7.2	Assay of Sodium chloride (By Titration)	Between 95.0% and 105.0% of the Label Claim (Label claim: 7 mg/ml)	98.1	99.8	98.6	99.0	99.0	99.7	100.0
7.3	Content of Sodium Metabisulphite (By HPLC)	Between 10.0% and 110.0% of the Label Claim (Label Claim: 0.15 mg/ml)	72.9	47.5	65.6	46.7	37.4	39.7	25.6
8.0	Sterility Test	It should be sterile	Sterile	--	---	---	Sterile	---	Sterile
9.0	Osmolality	Between 240 and 350 mOsm/kg	289	296	292	287	292	290	293
10.0	Water Vapor Permeability Test	Not More Than 5.00%	NA	0.00%	0.00%	0.16%	0.32%	0.40%	0.48%
11.0	Correction Factor 30°C/35%RH	Not More Than 5.00%	NA	0.00%	0.00%	0.42%	0.83%	1.04%	1.25%
12.0	Any significant change observed	Yes/ No	NA	No	No	No	No	No	No
13.0	Remarks	(Passes / Fails)	Passes	Passes	Passes	Passes	Passes	Passes	Passes

NA: Not Applicable.

Current Specification No. : FP/QC/035f

Verified By CQA Officer/Executive Sign & Date	09/11/21
Approved By CQA Executive/Manager Sign & Date	09/11/21

Otsuka Pharmaceutical India Private Limited

Product Stability Summary Sheet

Ref SOP No.: CO/CQA/017

Product Name:	**Paracetamol Infusion (1% w/v)**
Fill Volume and Container:	**100 ml Fill Volume in Non PVC Bag**

Sr. No.	Storage period and condition	Batch No.
		2194010
00	**Initial**	Complies
01	**3 months 30°C**	Complies
02	**6 months 30°C**	Complies
03	**9 months 30°C**	Complies
04	**12 months 30°C**	Complies
05	**18 months 30°C**	Complies
06	**24 months 30°C**	Complies

Conclusion:

The stability study are conducted for **Paracetamol Infusion (1% w/v) - 100 ml Fill Volume in Non PVC Bag** on one Batch No. – 2194010 for 24 months at 30°C ± 2°C and 75% ± 5% RH. The results of above stability study at 30°C till now are complying with the pre-defined acceptance criteria and hence it is concluded that at this stage the **product is stable** when manufactured according to the master formula.

Signature : _____

Name : Arkaprava Banerjee

Designation : Senior Process Incharge - Stability

Date : 09/11/21

Otsuka Pharmaceutical India Private Limited

Product Stability Summary Sheet

Ref SOP No.: CO/CQA/017

Product Name:	**Paracetamol Infusion (1% w/v)**
Fill Volume and Container:	**100 ml Fill Volume in Non PVC Bag**

Special Note:

01 Stability study tests are conducted on one Batch No. – 2194010 for 24 months at the interval of 3 months for the first year (0 (initial), 3, 6, 9 and 12 months) and 18 and 24 month at 30°C ± 2°C and 75% ± 5% RH.

02 Test for Description, pH, light absorption, Related substances of 4-Amino phenol, 4-Chloroacetanilide and Any other impurity, Assay of Paracetamol, Sodium Chloride and Content of Sodium Metabisulphite and Osmolality are performed at initial time and each stage of stability study and Water Vapor Permeability test is performed at each stage of stability study at above-mentioned condition.

03 Test for Particulate Matter, Bacterial Endotoxins and Sterility test are performed at initial time 12 months and 24 months

Signature : _____

Name : Arkaprava Banerjee

Designation : Senior Process Incharge - Stability

Date : 09/11/21

Otsuka Pharmaceutical India Private Limited

Batch Test Summary Report

Ref SOP No. CO/CQA/017

Storage Conditions	30°C ± 2°C and 75% RH ± 5% RH	Total Storage Duration	24 Months
Product Name	Paracetamol Infusion (1% w/v)	Fill Volume & Container	100 ml Fill Volume in NPVC Bag
Batch No.	2194011	Batch Size	1500 Lit.
Mfg. Date	2019-10	Exp. Date	2021-09
Study Started On	19/10/19	Study Status	Study Completed
Manufacturing Plant	MF02	Manufacturing Line No.	Line No. 06
API Manufacturer Name	Paracetamol - Farmson Pharmaceuticals Gujarat Pvt. Ltd	API Manufacturer Lot No./ A.R. No.	Paracetamol - 2R1900424
Any Additional Information	NA		

Sr. No.	Storage Period in number of months		0 (Initial)	3 months	6 months	9 months	12 months	18 months	24 months
	Expected withdrawal date		---	19/01/20	19/04/20	19/07/20	19/10/20	19/04/21	19/10/21
	Actual withdrawal date		---	20/01/20	20/04/20	21/07/20	19/10/20	19/04/21	19/10/21
	Tests	Specification							
1.0	Description	The solution should be clear and colourless. Practically free from visible particles	The solution is clear and colourless. Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles	The solution is clear and colourless,Free from visible particles
2.0	pH	Between 4.50 and 6.50	5.95	5.67	5.60	5.38	5.40	5.39	5.05
3.0	Light absorption	The absorbance of sample should be not more than 0.04 at 500 nm	0.01	0.04	0.01	0.02	0.00	0.00	0.00
4.0	Related Substances (By HPLC)								
4.1	4-Amino phenol	Not More Than 0.1 %	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
4.2	4-Chloroacetanilide	Not More Than 10 ppm	Not Detected	0.00	0.00	0.00	0.00	0.00	0.00
4.3	Any other impurity	Not More Than 0.25 %	0.02%	0.01%	0.02%	0.01%	0.01%	0.01%	0.00%
5.0	Bacterial Endotoxins	Not More Than 2.0 EU per ml	Less Than 2.0 EU per ml	---	---	---	Less Than 2.0 EU per ml	---	Less Than 2.0 EU per ml
6.0	Particulate Matter For ≥ 10 µm For ≥ 25 µm	Not More Than 6000 particles per container Not More Than 600 particles per container	26.70 0.00	---	---	---	506.7 6.7	---	903.3 83.3
7.0	Assay								
7.1	Assay of Paracetamol (By HPLC)	Not less than 90.0% and not more than 110.0% of Label Claim (Label Claim: 10 mg/ml)	97.4	100.0	98.2	97.4	96.5	99.1	97.8
7.2	Assay of Sodium chloride (By Titration)	Between 95.0% and 105.0% of the Label Claim (Label claim: 7 mg/ml)	97.2	99.0	99.4	99.8	100.6	99.7	100.0
7.3	Content of Sodium Metabisulphite (By HPLC)	Between 10.0% and 110.0% of the Label Claim (Label Claim: 0.15 mg/ml)	72.7	48.4	60.8	46.7	37.2	35.5	33.1
8.0	Sterility Test	It should be sterile	Sterile	---	---	---	Sterile	---	Sterile
9.0	Osmolality	Between 240 and 350 mOsm/kg	284	297	289	288	287	288	290
10.0	Water Vapor Permeability Test	Not More Than 5.00%	NA	0.00%	0.00%	0.16%	0.32%	0.39%	0.65%
11.0	Correction Factor 30°C/35%RH	Not More Than 5.00%	NA	0.00%	0.00%	0.42%	0.83%	1.01%	1.69%
12.0	Any significant change observed	Yes/ No	NA	No	No	No	No	No	No
13.0	Remarks	(Passes / Fails)	Passes	Passes	Passes	Passes	Passes	Passes	Passes

NA: Not Applicable.

Current Specification No. : FP/QC/035f

Verified By CQA Officer/Executive Sign & Date	09/11/21
Approved By CQA Executive/Manager Sign & Date	09/11/21

Otsuka Pharmaceutical India Private Limited

Product Stability Summary Sheet

Ref SOP No.: CO/CQA/017

Product Name:	**Paracetamol Infusion (1% w/v)**
Fill Volume and Container:	**100 ml Fill Volume in Non PVC Bag**

Sr. No.	Storage period and condition	Batch No.
		2194011
00	**Initial**	Complies
01	**3 months 30°C**	Complies
02	**6 months 30°C**	Complies
03	**9 months 30°C**	Complies
04	**12 months 30°C**	Complies
05	**18 months 30°C**	Complies
06	**24 months 30°C**	Complies

Conclusion:

The stability study are conducted for **Paracetamol Infusion (1% w/v) - 100 ml Fill Volume in Non PVC Bag** on one Batch No. – 2194011 for 24 months at 30°C ± 2°C and 75% ± 5% RH. The results of above stability study at 30°C till now are complying with the pre-defined acceptance criteria and hence it is concluded that at this stage the **product is stable** when manufactured according to the master formula.

Signature : _____

Name : Arkaprava Banerjee

Designation : Senior Process Incharge - Stability

Date : 09/11/21

Otsuka Pharmaceutical India Private Limited

Product Stability Summary Sheet

Ref SOP No.: CO/CQA/017

Product Name:	**Paracetamol Infusion (1% w/v)**
Fill Volume and Container:	**100 ml Fill Volume in Non PVC Bag**

Special Note:

01 Stability study tests are conducted on one Batch No. – 2194011 for 24 months at the interval of 3 months for the first year (0 (initial), 3, 6, 9 and 12 months) and 18 and 24 month at 30°C ± 2°C and 75% ± 5% RH.

02 Test for Description, pH, light absorption, Related substances of 4-Amino phenol, 4-Chloroacetanilide and Any other impurity, Assay of Paracetamol, Sodium Chloride and Content of Sodium Metabisulphite and Osmolality are performed at initial time and each stage of stability study and Water Vapor Permeability test is performed at each stage of stability study at above-mentioned condition.

03 Test for Particulate Matter, Bacterial Endotoxins and Sterility test are performed at initial time 12 months and 24 months

Signature : _____

Name : Arkaprava Banerjee

Designation : Senior Process Incharge - Stability

Date : 09/11/21