




Product Quality Review

Review Period


From 01/01/2023 to 31/12/2023

PRODUCT NAME	Kranton
PRODUCT CODE	0001
STRENGTH	150 IU
BATCH SIZE	Batch size varies as per potency of bulk.
TOTAL NO. OF BATCHES	3


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Product Name:Kranton		

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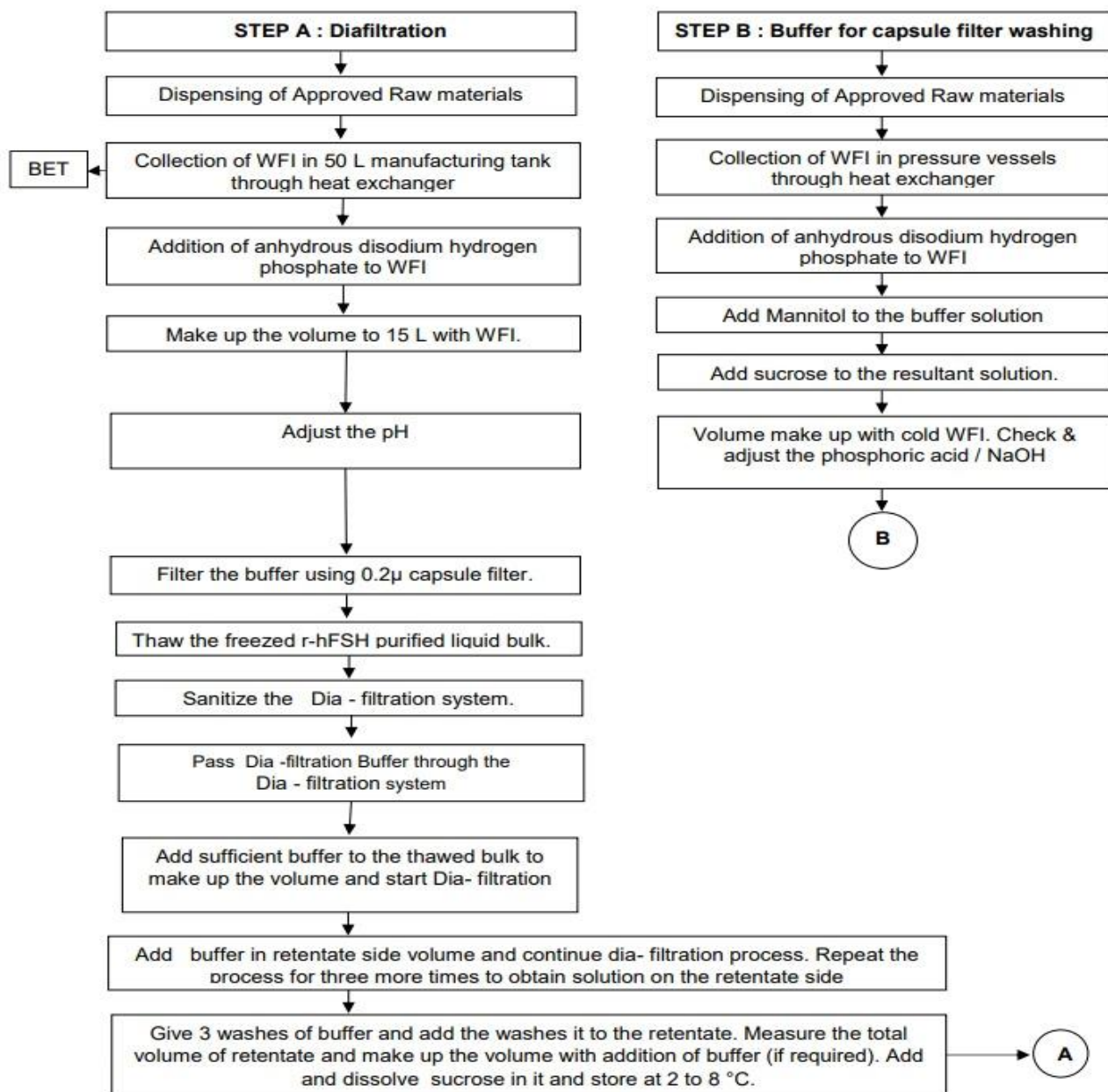
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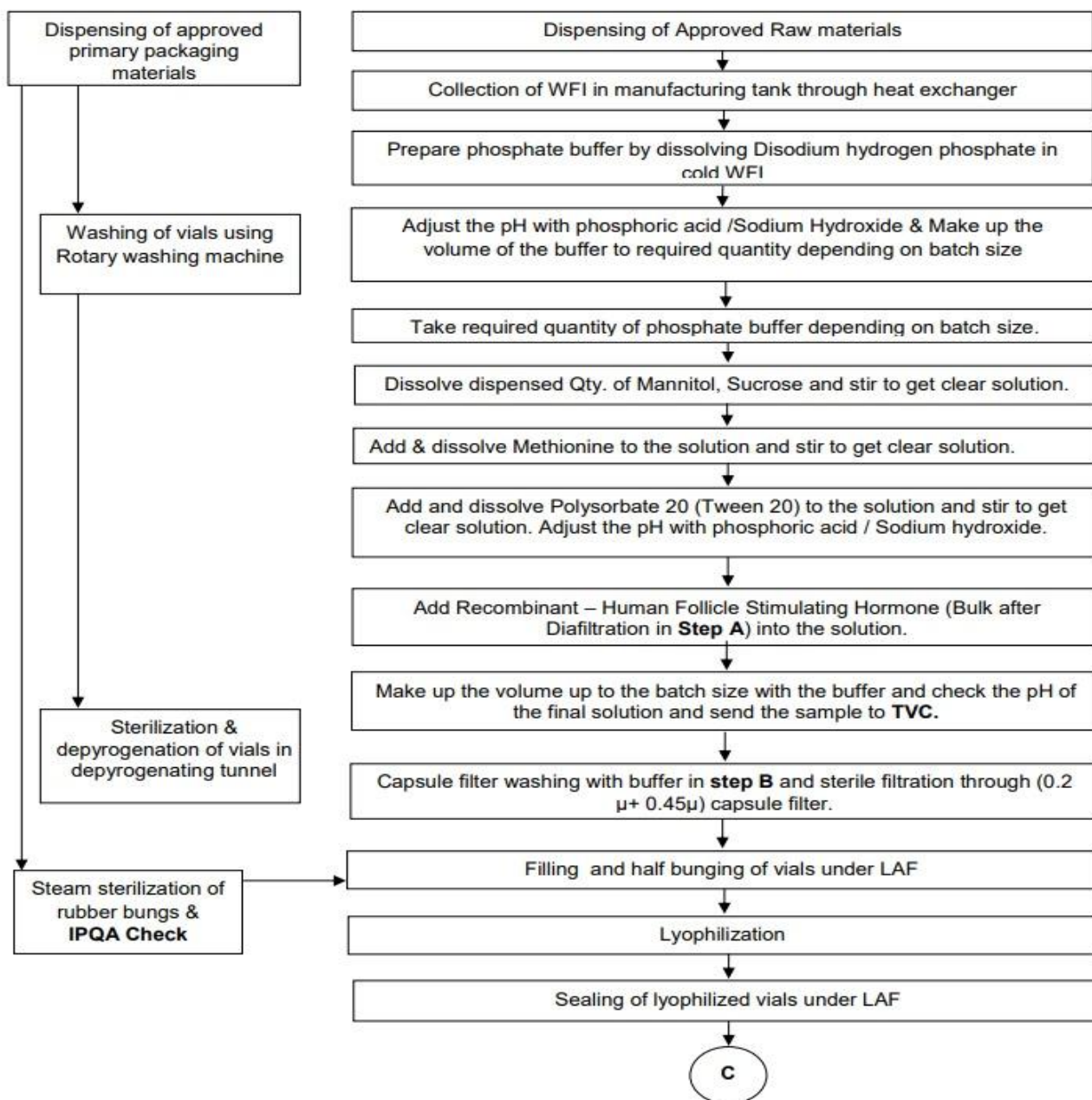
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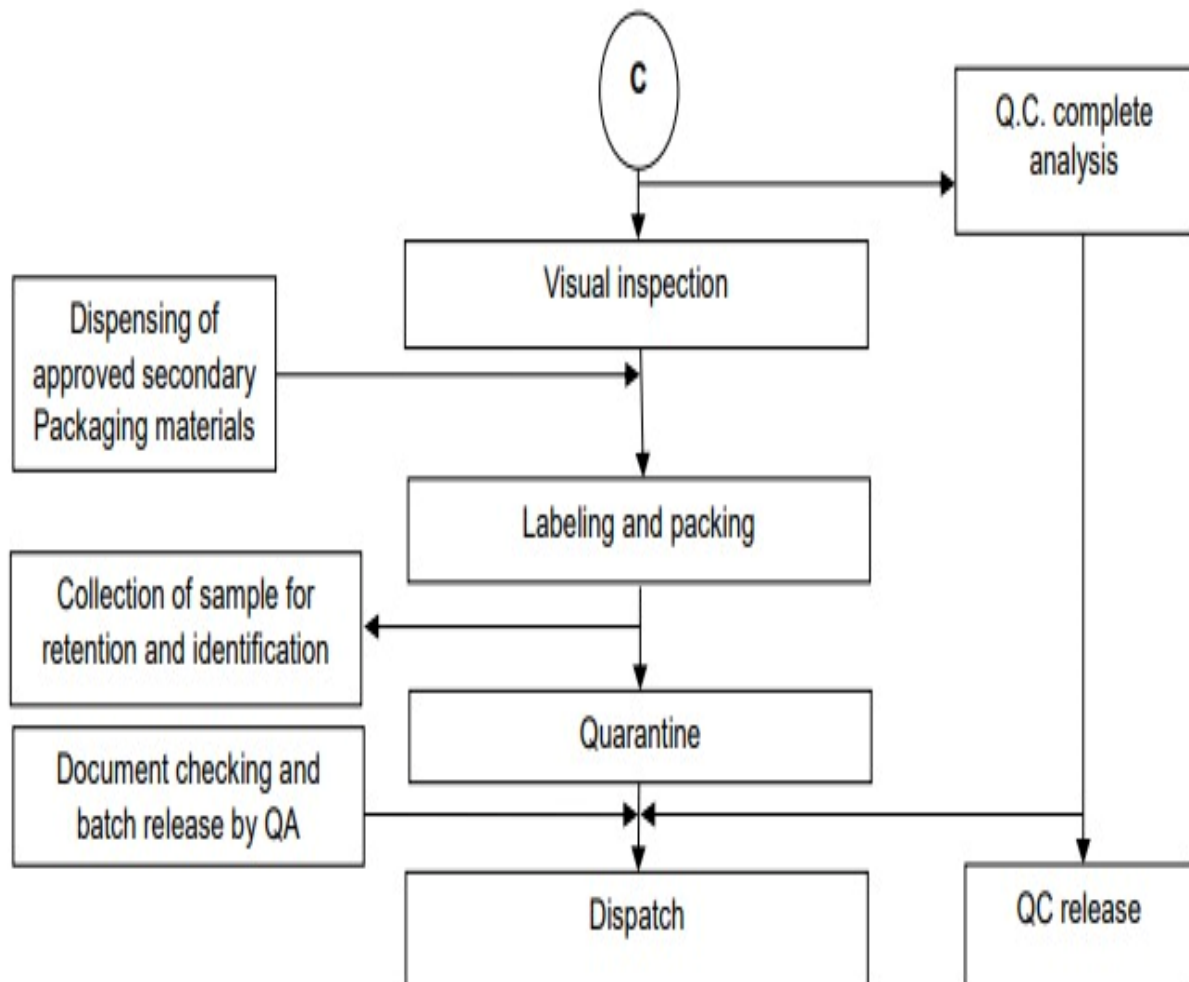
1.Product Information

ProductCode	0001
Product Name	Kranton
Generic Name	Kranton
Label Claim	Each vial contains: Human Follicle Stimulating Hormone..... 150 I.U.
Batch Size	Batch size varies as per potency of bulk.
Shelf life	24 Months
Fill Volume	0.515 gm to 0.5253 gm
Manufacturing License No.	KD-4
Storage Condition	Store between 2°C to 8°C. Do not freeze. Protect from light
Pack Size	2 ml Vial
Product Sap Code	300000023
Location	Unit II Production A
Specification Number	IKS/0001/IH & IPS /0001/IH
Test Procedure Number	ILM/0001/IH & PLM/0001/IH

2. Process Flow Chart









3. Review Of Master Formula Records, Batch Manufacturing Records & Batch Packaging Records

3.1 Data of the total number of batches manufactured, released and rejected during the review period

Batch No.	Mfg. Date	Exp. Date	Batch Size (Kg/lit)	Batch Size (No.s)	Master Formula Record Number	BMR No.(Part I)	BMR No.(Part II)	BPR No.	Release Quantity (No's)
B000123001	02/23	01/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:90156:IN:01/R7	8,010
B000123001	02/23	01/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	4,938
B000123001	02/23	01/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	2,025
B000123001	02/23	01/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	450
B000123001	02/23	01/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	6,000
B000123002	05/23	04/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	5,500
B000123002	05/23	04/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	8,178

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B000123002	05/23	04/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90421:NG	4,600
B000123002	05/23	04/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	1,080
B000123002	05/23	04/25	Batch size varies as per potency of bulk.	Batch size varies as per potency of bulk.	MMF:0001:A	BMR1:0001:A/R1	BMR2:0001:A/R1	BPR:B:90156:IN:01/R7	200
B000123003	11/23	10/25	11.824	23648	MMF:0001:A	BMR1:0001:A/R1/PV	BMR2:0001:A/R1	BPR:B:90156:01/R7	200
B000123003	11/23	10/25	11.824	23648	MMF:0001:A	BMR1:0001:A/R1/PV	BMR2:0001:A/R1	BPR:B:90156:01/R7	5,860
B000123003	11/23	10/25	11.824	23648	MMF:0001:A	BMR1:0001:A/R1/PV	BMR2:0001:A/R1	BPR:B:90156:01/R7	10,141
B000123003	11/23	10/25	11.824	23648	MMF:0001:A	BMR1:0001:A/R1/PV	BMR2:0001:A/R1	BPR:B:90156:01/R7	690
B000123003	11/23	10/25	11.824	23648	MMF:0001:A	BMR1:0001:A/R1/PV	BMR2:0001:A/R1	BPR:B:90156:01/R7	5,033


Remarks/Comments:

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3.2 Review of master batch manufacturing records(BMR),master packaging records(BPR) and master manufacturing formula(MMF).

Sr.No.	Document Name	Document No.	Document Revision No.	Reason For Change
1	BMR Part I	BMR1:0001:A/R1	NA	NA
2	BMR Part II	BMR2:0001:A/R1	NA	NA
3	Batch Packaging Record	BPR:B:9012D	NA	Product needs to be introduced in Kazakhstan Export Market hence common pack insert artwork to be implemented.
4	Batch Packaging Record	BPR:B:676:01/R7	NA	NA
5	Batch Packaging Record	BPR:90:A1	NA	All TMR Product needs to be Introduced in domestic market hence all artwork to be implemented.
6	MMF	MMF:0001:A	NA	NA


Remarks/Comments:

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3.3 Review of details for Batch Release/ Rejection/ Recall during the Year

Sr.No	Description	Observation
1	Number of batches manufactured during the review period	3
2	Total number of batches Released	3
3	Total number of batches Released for Sales	0
4	Total number of batches Rejected	0
5	Rejected Batch No.s	0
6	Total number of batches Recalled	0
7	Recalled Batch No.s	0

Remarks/Comments:

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4. Review Of Starting Materials And Packing Materials

4.1 Review of Active Pharmaceutical Ingredient

4.1.1 Receipt,Release and Rejection Details of API


Sr.No.	Description	Observation
1	No. Of Batches Of API received	8
2	No. Of Batches Of API released	4
3	No. Of Batches Of API rejected	2

4.1.2 Vendor/Suppliers Performance Review

Sr.No.	Name of API	Vendor Batch No./A.R.No.	Vendor Name	Reported Issues	Proposed CAPA	Implementation Status Review
1	NA	NA	NA	NA	NA	NA

4.1.3 Review of API Specification/MOA and Analytical Data


Sr.No.	SAP Code	API Material Name	Specification & Test Method No.	Specification & Test Method no. After Revision	Brief Description of Revision
1	300000123	Kranton	IPS/B40/IH/R3 & IPM /B40/IH/R3	NA	NA

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4.1.4 Change in approved Vendor (if Any)

Sr.No.	Name of New Vendor	Approved On	AR.No./Batch No. Received from Vendor
1	NA	NA	NA

Remarks/Comments:

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4.1.5 Review of analytical data of the consignment received during the year

300000123(Kranton) Version No: 01

Parameters	Appearance	PH	Assay	Proteins	Identification	Identification	Purity Test	Aggregate by HPLC	Proteins
Limits	Clear, colourless liquid	Min And Max Range - 7.0-8.0	NLT - Bioassay - 500 IU/ml	NLT - 30 µg/ml	By HPLC method - Retention Time between 17.0 minute and 19.0 minute	By Bioassay method - Causes enlargement of the ovaries of immature female rats when administered as directed in the bioassay	The Lane containing test solution should show a single broad band corresponding In position to the band of comparator drug	NMT - 3.0 %	NMT - Host cell proteins - Less than 5 ng/75 IU - 5
BB4023004	Complies	7.47	9767.64	13901.75	Complies	Complies	Complies	0.03	0.969
BB4023003	Complies	7.56	8813.71	13901.75	Complies	Complies	Complies	0.2	0.516
BB4023004	Complies	7.47	9767.64	13901.75	Complies	Complies	Complies	0.03	0.969
BB4023003	Complies	7.56	8813.71	13901.75	Complies	Complies	Complies	0.2	0.516
Min	Complies	7.47	8813.71	13901.75	Complies	Complies	Complies	0.03	0.516
Max	Complies	7.56	9767.64	13901.75	Complies	Complies	Complies	0.2	0.969


300000123(Kranton) Version No: 01

Bacterial Endotoxin	sterility
NMT - Less than 30 EU/75 IU - 30	Sterile
<30	sterile
<30	Sterile
<30	sterile
<30	Sterile
<30	sterile
<30	sterile

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4.1.6 Details of API supply chain traceability

Raw Material Name	Kranton
Name and Address of the Vendor(Manufacturer)	Amplelogic
Material SAP Code	300000123
Is the API Supply Chain Complex?	Direct Supply By Manufacturer
Is Vendor(Manufacturer)approved?	Yes
Name and Address of Supplier	Amplelogic
Is Supplier Approved?	Yes
On site Inspection Done for manufacturer/Supplier?	NA
Are required Technical / Quality agreements are made and current?	NA
Mode of Transport	NA
Route of Transport	NA
Does API Requires Specific Storage Conditions?	Yes -20° C ± 5 °C
Cold Chain Transportation is Provided by Vendor if Specific Storage Conditions are Required?	NA
Are data loggers provided and continuous storage condition monitoring possible during the transportation?	NA

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4.1.7 Details of the API used


Sr.No.	Batch No.	SAP Code	AR No./Bulk Batch No.	Name of Manufacturer	Name(s) of Supplier	Is Storage Condition Maintained During Transport? (Yes/No)	Mode of Transport	Route of Transport
1	B000123001	300000123	BSB22FPB0013	Amplelogic	Amplelogic	Yes	NA	NA
2	B000123002	300000123	BSB23FPB005	Amplelogic	Amplelogic	Yes	NA	NA

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4.2 Review of Excipients

4.2.1 Receipt, Release, Rejection and Specification details of Excipients used

Sr.No.	Name of Excipient	Excipient Material Code	Specification & Test Method No.	Specification & Test Method No. After Revision	Number Of Consignments Excipient Received	Number Of Consignments Excipient Released	Number Of Consignments Excipient Rejected
1	Phosphoric Acid	100000148	RMS/100000148/A C /R1 RMM/100000148/ AC/ R1	NA	2	2	0
2	Polysorbate 20 (Tween20)	100000116	RMS/100000116/A C /R2 & RMM/100000116/ AC/R3	NA	2	2	0
3	Sucrose	100000112	RMS/100000112/A C/R3 RMM/100000112/ AC/R4	NA	1	1	0
4	Sodium Hydroxide	100000103	RMS/100000103/A C/R4 RMM/100000103/ AC/R3	NA	8	8	0
5	Methionine	100000066	RMS/100000066/B P/R2 RMM/100000066/ BP/R1	NA	1	1	0
6	Anhydrous Disodium Hydrogen Phosphate	100000038	RMS/100000038/B P/R2 RMM/100000038/ BP/R1	NA	1	1	0

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4.2.2 Excipient Vendor/Suppliers Performance Review

Sr.No.	Excipient Raw Materials	Vendor Name	Vendor Batch No./A.R.No	Reported Issues	Proposed CAPA	Implementation Status Review
1	Sodium Hydroxide	Halogens	ARM2216896, ARM2216918	During sampling analyst observed large lumps in four container out of supplied 12 containers.	NA	Observed issues is related to moisture ingress due to improper sealing, Training was provided by vendor to concern person, hence CAPA was closed.

Remarks/Comments:

4.2.3 Review of analytical data of the consignment recieved during the Year

Specifications of :Phosphoric Acid

Specification Test	Appearance	Solubility	Relative density	Identification	Identification	Appearance	Chloride	Sulfate	Heavy Metals
Specification Limits	A clear, colourless, odorless, syrupy liquid, corrosive. It may solidify, producing a mass of colourless crystals which do not melt until the temperature reaches 28°C	Miscible with water, miscible with ethanol (96%)	NMT 1.7	Chemical Test-The solution is strongly acidic.	Chemical test-Neutral Solution forms yellow precipitate with silver nitrate solution.	Solution S/A is clear and colourless	NMT - 50 ppm	NMT - 100 ppm	NMT - 10 ppm
BRM2317969	Complies	Complies	0.70	Complies	Complies	clear	Complies	Complies	Complies
BRM2317516	Complies	Complies	2.71	Complies	Complies	Red	Complies	Complies	Complies
Min	Complies	Complies	1.63	Complies	Complies	Red	Complies	Complies	Complies
Max	Complies	Complies	1.47	Complies	Complies	clear	Complies	Complies	Complies

Product Name:Kranton
Specifications of :Phosphoric Acid

Arsenic	Iron	Iron	Assay	Assay	Specific gravity	Substances Precipitated with ammonia	Hypophosphorous Acid and Phosphorous Acid	Chloride and sulfate	Alkali Phosphates
NMT - 2 ppm	NMT - BP - 50 ppm	NMT - IP - 60 ppm	Min And Max Range - m/m of H ₃ PO ₄ (BP & IP) - 84.0-90.0 %	Min And Max Range - w/w H ₃ PO ₄ (USP) - 85.0-88.0 %	About 1.71	Any opalescence in the solution is not more intense than that in a mixture of 10 ml of solution S and 8ml of water	The solution shows no change in appearance	No precipitate is formed immediately	No turbidity is produced
Complies	Complies	Complies	91.47	86.76	1.70	Complies	Complies	Complies	Complies
Complies	Complies	Complies	86.50	86.53	1.71	Complies	Complies	Complies	Complies
Complies	Complies	Complies	84.948	86.53	1.7	Complies	Complies	Complies	Complies
Complies	Complies	Complies	70.47	86.76	1.71	Complies	Complies	Complies	Complies

Specifications of :Phosphoric Acid

Aluminium and Calcium	Limit of Nitrate
The Solution remains clear	The blue colour is not discharge within 1 minute
Complies	Complies
Complies	Complies
Complies	Complies
Complies	Complies

Specifications of :Polysorbate 20 (Tween20)

Specification Test	Appearance	Solubility	Identification by infrared absorption spectrum	Identification	Identification	Identification	Relative density	PH	Acid value
Specification Limits	Oily, colourless or lemon to amber-colored or yellowish or brownish-yellow, clear or almost clear or slightly opalescent liquid.	Soluble in water, in anhydrous ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin	Test spectrum is concordant with the reference spectrum of polysorbate 20	Hydroxyl Value-96 to 108	Saponification value-40 to 50	Composition of fatty acids-To comply	About 1.10	5.0-7.0	NMT - 2.0
BRM2317626	Complies	Complies	Complies	98.9	46.0	Complies	1.10	5.99	1.20
BRM2317277	Complies	Complies	Complies	101.2	44.0	Complies	1.10	5.96	0.60
Min	Complies	Complies	Complies	98.9	44	Complies	1.1	5.96	0.6
Max	Complies	Complies	Complies	101.2	46	Complies	1.1	5.99	1.2

Specifications of :Polysorbate 20 (Tween20)

Peroxide Value	Heavy Metals	Sulfated Ash	Water	Identification	Viscosity	Hydroxyl value	Iodine value	Composition of fatty acid	Composition of fatty acid
NMT - 10.0	NMT - 10 ppm	NMT - 0.2 %	NMT - 3.0 %	Chemical test-The solution becomes blue	About 400 m Pa.s at 25°C	96-108	NMT - 5.0	Caproic acid-Maximum 1.0%	Caprylic acid-Maximum 10.0%
3.93	Complies	0.10	0.73	Complies	Complies	98.9	2.20	0.09	0.02
8.10	Complies	0.06	1.23	Complies	Complies	101.2	1.90	0.04	0.05
3.93	Complies	0.06	0.73	Complies	Complies	98.9	1.9	0.04	0.02

Specifications of :Polysorbate 20 (Tween20)

Composition of fatty acid	Composition of fatty acid	Composition of fatty acid	Composition of fatty acid	Composition of fatty acid	Composition of fatty acid	Composition of fatty acid	Ethylene oxide and dioxan	Total ash	Reducing impurities
Capric acid- Maximum 10.0%	Lauric acid- 40% - 60%	Myristic acid- 14.0% - 25.0%	Palmitic acid- 7.0% - 15.0%	Stearic acid- Maximum 7.0%	Oleic acid- Maximum 11.0%	Linoleic acid- Maximum 3.0%	Maximum 1 ppm of Ethylene dioxide Maximum 10 ppm of dioxan	NMT - 0.25 %	NMT - of 0.01M ceric ammonium sulphate is required - 2.0 ml
0.03	51.33	21.34	11.46	1.56	8.90	1.94	0.0	0.120	1.40
0.23	44.40	23.80	13.50	5.60	10.80	0.25	<1.0	0.050	1.60
0.03	44.4	21.34	11.46	1.56	8.9	0.25	0	0.05	1.4
0.23	51.33	23.8	13.5	5.6	10.8	1.94	0	0.12	1.6

Product Name:Kranton
Specifications of :Sucrose

Specification Test	Appearance	Solubility	Identification by infrared absorption spectrum	Identification	Identification	Appearance of solution	Appearance of solution	Specific optical rotation	Specific optical rotation
Specification Limits	White or almost white, crystalline powder or lustrous, colourless or white or almost white crystals, taste sweet	Very soluble in water, Freely soluble in ethanol (70%), Slightly soluble in ethanol (96%) practically insoluble in anhydrous ethanol	Identification A - Test spectrum is concordant with the reference spectrum of Sucrose CRS	Identification B (By Thin layer chromatography) The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a)	(Identification C Chemical test) An orange precipitate is produced immediately.	The solution is clear (BP & EP)	Solution is clear or its opalescence is not more pronounced than that of reference suspension 1. (USP)	Min And Max Range - (BP, EP & USP) - 66.3-67.0	Min And Max Range - (IP) - 65.9-67.0
ARM2318006	Complies	Complies	Complies	Complies	Complies	Complies	Complies	66.60	66.40
Min	Complies	Complies	Complies	Complies	Complies	Complies	Complies	66.6	66.4
Max	Complies	Complies	Complies	Complies	Complies	Complies	Complies	66.6	66.4

Product Name:Kranton

Specifications of :Sucrose

Acidity or Alkalinity	Barium	Heavy Metals	Sulphated ash	LOD	Bacterial Endotoxins	Color Value	Conductivity
NMT - The solution is colourless and not more than 0.6 ml of 0.01 M sodium hydroxide is required to change the colour of the solution to pink - 0.6 ml	Any opalescence is not more intense than that of a mixture of 1 ml of distilled water and 10 ml of solution A	NMT - 10 ppm	NMT - 0.1 %	NMT - 0.1 %	NMT 0.25 IU/mg	NMT - 45	NMT - at 20°C - 35 μ S. cm ⁻¹
0.40	Complies	12.475	0.245	0.030	Complies	9.0	11.96
0.4	Complies	10.373	0.1846	0.03	Complies	9	11.96
0.4	Complies	4.484	0.03	0.03	Complies	9	11.96

Specifications of :Sodium Hydroxide

Specification Test	Appearance	Solubility	PH	Reaction of Sodium	Appearance of solution	Carbonates	Carbonates	Chlorides	Chlorides
Specification Limits	White or almost white, crystalline masses, supplied as pellets, sticks or slabs, deliquescent, is hard and brittle and shows a crystalline fracture. Readily absorbing carbon dioxide and moisture.	Very soluble in water and freely soluble in ethanol (96%)	NLT - (Identification) - 11	A dense, white precipitate is produced. (Identification)	A solution is complete, clear, and colorless to slightly colored	NMT - Maximum - 2.0 %	NMT - 3.0 %	NMT - Maximum - 50 ppm	NMT - 125 ppm
ARM2318022	Complies	Complies	11.10	Complies	Complies	1.59	1.58	Complies	Complies
ARM2317957	Complies	Complies	11.53	Complies	Complies	1.06	1.41	Complies	Complies
ARM2317861	Complies	Complies	11.33	Complies	Complies	1.59	1.41	Complies	Complies
ARM2317770	Complies	Complies	11.28	Complies	Complies	1.10	1.30	Complies	Complies
ARM2317693	Complies	Complies	11.30	Complies	Complies	1.10	1.40	Complies	Complies
ARM2317660	Complies	Complies	11.28	Complies	Complies	0.50	0.70	Complies	Complies
ARM2317527	Complies	Complies	11.03	Complies	Complies	1.40	1.05	Complies	Complies
ARM2317404	Complies	Complies	12.86	Complies	Complies	1.10	1.41	Complies	Complies
Min	Complies	Complies	11.03	Complies	Complies	0.5	0.7	Complies	Complies
Max	Complies	Complies	12.86	Complies	Complies	1.59	1.58	Complies	Complies

Specifications of :Sodium Hydroxide

Product Name:Kranton

Sulphates NMT - Maximum - 50 ppm	Sulphates NMT - 75 ppm	Iron NMT - Maximum - 10 ppm	Iron NMT - 20 ppm	Heavy Metals NMT - 20 ppm	Potassium By chemical method-No precipitate is formed	Potassium NMT - By Atomic Absorption Spectrophoto metry (AAS) Method - 0.5 %	Arsenic NMT - 4 ppm	Assay Min And Max Range - of total alkali, calculated as NaOH. - 97.0- 100.5 %	Assay Min And Max Range - of total alkali, calculated as sodium hydroxide (NaOH) - 95.0- 100.5 %
Complies	Complies	Complies	Complies	Complies	Complies	0.420	Complies	99.17	99.10
Complies	Complies	Complies	Complies	Complies	Complies	0.120	Complies	99.20	99.38
Complies	Complies	Complies	Complies	Complies	Complies	0.396	Complies	99.44	99.76
Complies	Complies	Complies	Complies	Complies	Complies	0.203	Complies	97.40	97.60
Complies	Complies	Complies	Complies	Complies	Complies	0.156	Complies	97.50	97.70
Complies	Complies	Complies	Complies	Complies	Complies	0.261	Complies	99.90	99.40
Complies	Complies	Complies	Complies	Complies	Complies	0.033	Complies	98.01	98.59
Complies	Complies	Complies	Complies	Complies	Complies	0.350	Complies	98.80	99.00
Complies	Complies	Complies	Complies	Complies	Complies	0.033	Complies	97.4	97.6
Complies	Complies	Complies	Complies	Complies	Complies	0.42	Complies	99.9	99.76

Specifications of :Sodium Hydroxide


Content of Sodium
Between - (By AAS method) - 54.0-59.8 %
54.23
55.28
56.99
55.18
56.41
56.27
55.60
55.58
54.23
56.99

Product Name:Kranton

Specifications of :Methionine

Specification Test	Appearance	Solubility	Identification	Identification by infrared absorption spectrum	Identification	Chemical test	Appearance of solution	PH	Specific optical rotation
Specification Limits	A white or almost white crystalline powder or colourless crystals.	Soluble in water, very slightly soluble in ethanol (96%)	Test for Specific Optical Rotation- + 22.5 to +24.0 (dried substance)	ISpectrum concordant with the spectrum obtained with Methionine CRS/WS.	By Thin-layer Chromatography method- The principal spot in the chromatogram obtained with the test solutions similar in position, colour and size to the principal spot in the chromatogram	A dark-red colour develops.	The solution S is clear and colourless.	Between - 5.5-6.5 -- Select / --	+22.5 to 24.0 (dried substance)
BRM2317392	Complies	Complies	Complies	Complies	Complies	Complies	Complies	5.98	22.80
Min	Complies	Complies	Complies	Complies	Complies	Complies	Complies	5.98	22.8
Max	Complies	Complies	Complies	Complies	Complies	Complies	Complies	5.98	22.8

Specifications of :Methionine

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Chlorides	Sulfate	Related Substances	Related Substances	Iron	LOD	Sulphated ash	Assay	Ammonium
NMT - 200 ppm	NMT - 300 ppm	Unspecified impurities-For each impurity maximum 0.10%	Total-Maximum 0.3%	NMT - 10 ppm	NMT - 0.5 %	NMT - 0.1 %	Min And Max Range - (dried substances) - 99.0-101.0 %	NMT - 200 ppm
<200	<300	0.030	0.03	<10	0.10	0.030	100.70	<200
<200	<300	0.03	0.03	<10	0.1	0.03	100.7	<200
<200	<300	0.03	0.03	<10	0.1	0.03	100.7	<200

Specifications of :Anhydrous Disodium Hydrogen Phosphate

Specification Test	Appearance	Solubility	Identification	Loss on Drying	Reaction of Phosphates	Reaction of Sodium	Appearance of solution	Reducing Substance	Monosodium phosphate
Specification Limits	White or almost white powder hygroscopic.	Soluble in water, practically insoluble in ethanol (96%)	Chemical Test-Solution S is slightly alkaline i.e. color of solution S is colourless or pink	NMT - 1 %	A Yellow colour develops	A dense white precipitate is formed	Solution S is clear & colourless	The colour of the permanganate is not completely discharged.	NMT - The ratio $(n_2 - 25)/(25 - n_1)$ is not greater than 0.025 - 2.5 %
BRM2317316	Complies	Complies	Complies	0.30	Complies	Complies	Complies	Complies	0.0
Min	Complies	Complies	Complies	0.3	Complies	Complies	Complies	Complies	0
Max	Complies	Complies	Complies	0.3	Complies	Complies	Complies	Complies	0


Product Name:Kranton

Specifications of :Anhydrous Disodium Hydrogen Phosphate

Chlorides	Sulfate	Arsenic	Iron	Assay
NMT - 200 ppm	NMT - 500 ppm	NMT - 2 ppm	NMT - 20 ppm	Between - (Dried substance) - 98.0-101.0 %
<200	<500	<2	<20	101
<200	<500	<2	<20	101
<200	<500	<2	<20	101

Specifications of :Mannitol


Specification Test	Description	Solubility	Identification by infrared absorption spectrum	Melting Point	Appearance of solution	Chloride	Arsenic	Sulphates	Assay
Specification Limits	A white, or almost white crystals, white crystalline powder or free flowing granules.	Freely soluble in water, slightly soluble in pyridine, very slightly soluble in alcohol, practically insoluble in ether, ethanol (96%), and in chloroform. Soluble in alkaline solutions.	The spectrum obtained with mannitol corresponds with the spectrum obtained with mannitol CRS/WS or with the reference spectrum of Mannitol	Min And Max Range - 165-170 °C	Solution is clear and colorless	NMT - 50 ppm	NMT - 2 ppm	NMT - 100 ppm	Min And Max Range - of C ₆ H ₁₄ O ₆ (dried substances) - 97.0-102.0 %
ARM2318004	Complies	Complies	Complies	166	Complies	Complies	Complies	Complies	100.97
ARM2317918	Complies	Complies	Complies	167.5	Complies	Complies	Complies	Complies	99.50
ARM2317834	Complies	Complies	Complies	168.1	Complies	Complies	Complies	Complies	99.40
ARM2317639	Complies	Complies	Complies	167.5	Complies	Complies	Complies	Complies	99.30
ARM2317572	Complies	Complies	Complies	167.9	Complies	Complies	Complies	Complies	101

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ARM2317483	Complies	Complies	Complies	168.5	Complies	Complies	Complies	Complies	99.80
ARM2317385	Complies	Complies	Complies	169.7	Complies	Complies	Complies	Complies	99.20
ARM2317294	Complies	Complies	Complies	166.0	Complies	Complies	Complies	Complies	99.90
Min	Complies	Complies	Complies	166	Complies	Complies	Complies	Complies	99.2
Max	Complies	Complies	Complies	169.7	Complies	Complies	Complies	Complies	101

Specifications of :Mannitol

Loss on Drying	Bacterial Endotoxins	Specific optical rotation	Sulphated ash	Related Substances	Related Substances	Related Substances	Related Substances
NMT - 0.5 %	NMT - 4 EU/gm	Between +23.0° and +25.0°	NMT - 0.1 %	NMT - 2.0 %	NMT - 2.0 %	NMT - 0.1 %	NMT - 2.0 %
0.20	Complies	24.10	0.04	0.44	0.0	0.0	0.44
0.20	Complies	24.10	0.04	0.40	0.40	0.0	0.40
0.10	Complies	23.83	0.05	0.11	0.0	0.0	0.11
0.160	Complies	23.90	0.03	0.10	0.0	0.0	0.10
0.30	Complies	24.20	0.01	0.10	0.0	0.0	0.10
0.040	Complies	24.0	0.01	0.40	0.02	0.02	0.40
0.03	Complies	23.40	0.01	0.03	0.10	0.02	0.90
0.090	Complies	24.0	0.05	0.70	0.09	0.0	0.80
0.03	Complies	23.4	0.01	0.03	0	0	0.1
0.3	Complies	24.2	0.05	0.7	0.4	0.02	0.9

Remarks/Comments:

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Product Name:Kranton		

4.2.4 Details of excipients used

Name of Excipient:Mannitol

Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123001	100000033	ARM2216696	Parkway Solon OH 44139, France	No. 7 Regency Park, Near Chakki Naka, Kalyan (East) Dist. Thane 421306	Qualified	100000033
B000123003	100000038	BRM2317316	Ambernath east, Thane 421501.	1st Pokhran Road, Khopat , Thane	Qualified	100000033

Name of Excipient:Anhydrous Disodium Hydrogen Phosphate

Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123001	100000038	BRM2216901	additional MIDC, Anand nagar, Ambernath east, Thane 421501.	Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000038
B000123002	100000112	A22RTM0028	Corsham, Wiltshire, SN13 9XN, United Kingdom	#140D, Pocket-4, Mayur Vihar, New Delhi	Qualified	100000038

Name of Excipient:Methionine

Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123002	100000103	ARM2317404	Corsham, Wiltshire, SN13 9XN, United Kingdom	Hasti Industrial Premises Co. Op. Soc. Ltd. Navi Mumbai	Qualified	100000066


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B000123003	100000033	ARM2317639	Fountain Parkway Solon OH 44139, France	No. 7 Regency Park, Near Chakki Naka, Kalyan (East) Dist. Thane 421306	Qualified	100000066

Name of Excipient:Sodium Hydroxide

Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123001	100000103	BRM2216824	Corsham, Wiltshire, SN13 9XN, United Kingdom	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000103
B000123001	100000116	BRM2317277	Corsham, Wiltshire, SN13 9XN, United Kingdom	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000103
B000123002	100000033	ARM2317483	Corsham, Wiltshire, SN13 9XN, United Kingdom	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000103
B000123003	100000148	BRM2317516	Corsham, Wiltshire, SN13 9XN, United Kingdom	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000103

Name of Excipient:Sucrose

Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123001	100000112	ARM2216467	Tundav, Tal: Savli, Dist: Vadodara	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000112
B000123001	100000066	BRM2216801	Tundav, Tal: Savli, Dist: Vadodara	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000112


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Product Name:Kranton						
B000123002	100000116	BRM2317277	Tundav, Tal: Savli, Dist: Vadodara	Thane-Belapur Road, Shirwane – 400706, Navi Mumbai, India.	Qualified	100000112
B000123003	100000103	ARM2317770	Tundav, Tal: Savli, Dist: Vadodara	No.65, Hasti Industrial Premises Co. Op. Soc. Ltd. Navi Mumbai	Qualified	100000112

Name of Excipient:Polysorbate 20 (Tween20)


Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123002	100000148	BRM2217144	MIDC, Anand nagar, Ambernath east, Thane 421501.	Chemicals	Qualified	100000116
B000123003	100000066	BRM2317392	MIDC, Anand nagar, Ambernath east, Thane 421501.	#140D, Pocket-4, Mayur Vihar, New Delhi	Qualified	100000116
B000123003	100000116	BRM2317626	MIDC, Anand nagar, Ambernath east, Thane 421501.	Chemicals	Qualified	100000116

Name of Excipient:Phosphoric Acid

Batch No.	Material SAP Code	AR.No.	Vendors Name & address	Suppliers Name & address	Vendor/Supplier (Qualified/Notqualified)	Material ID
B000123001	100000148	BRM2217144	MIDC, Anand nagar, Ambernath east, Thane 421501.	Ganatra Indl Estate,1st Pokhran Road, Khopat , Thane	Qualified	100000148
B000123002	100000038	BRM2317316	Plot K-43, additional MIDC, Anand nagar, Ambernath east, Thane 421501.	Chemicals	Qualified	100000148

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B000123002	100000066	BRM2317277	Plot K-43, additional MIDC, Anand nagar, Ambernath east, Thane 421501.	#140D, Pocket-4, Mayur Vihar	Qualified	100000148
B000123003	100000112	A23RTM0037	Plot K-43, additional MIDC, Anand nagar, Ambernath east, Thane 421501.	Chemicals	Qualified	100000148

Remarks/Comments:


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4.3 Primary Packing Materials

4.3.1 Primary Packing Material Details

Sr.No.	Name of Primary Packing Material	Specification & Test Method No.	Specification & Test Method No. After Revision	Reason for Change	Number Of Consignments Received	Number Of Consignments Released	Number Of Consignments Rejected
1	2 ml tubular flint glass vials	PMS/200000120/R 2 & PMM/GV/02	NA	NA	4	4	0
2	13 mm Aluminium flip off seals olive green	PMS/200000046/R 1 & PMM/FS/04	NA	NA	3	3	0
3	13 mm slotted Rubber Bung (RB013AC0)	PMS/200000019/R 1 & PMM/RB/03	NA	NA	8	8	0

Remarks/Comments:

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Product Name:Kranton		

4.3.2 Vendor/suppliers performance review

Packing Material	Vendor Batch No./AR.No.	Vendor Name	Reported Issues	Proposed CAPA	Implementation Status Review
NA	NA	NA	NA	NA	NA

Remarks/Comments:

4.3.3 Review of analytical data of the critical parameter of the primary packing material

Name of Packing:2 ml tubular flint glass vials

Parameters	Description	Total Height	Body Diameter	Inner Diameter of the rim	Outer Diameter of the rim	Height of The Rim	Body wall thickness	Filled volume up to the rim	Arsenic test
Limits	2 ml clear, colorless, glass U.S.P. TYPE I (Neutral Borosilicate) tubular vial with concave bottom.	Min And Max Range - 34.50-35.50 mm	Min And Max Range - 15.75-16.25 mm	Min And Max Range - 6.80-7.20 mm	Min And Max Range - 12.70-13.20 mm	Min And Max Range - 3.40-3.80 mm	Min And Max Range - 0.95-1.05 mm	NLT - 2.90 ml	NMT - 0.1 ppm
APP2325130	Complies	35.05	15.98	6.88	12.96	3.70	1.00	3.80	Complies
APP2324994	Complies	35.04	15.92	6.90	12.90	3.72	1.01	3.19	Complies
BPP2324885	Complies	34.92	15.95	6.89	12.90	3.71	1.00	3.83	Complies
APP2324792	Complies	34.97	16.02	6.92	12.92	3.68	1.00	3.13	Complies
Min	Complies	34.92	15.92	6.88	12.9	3.68	1	3.13	Complies
Max	Complies	35.05	16.02	6.92	12.96	3.72	1.01	3.83	Complies

Name of Packing:2 ml tubular flint glass vials

Glass Grain test	Surface glass test
NMT - NMT 0.1 ml of 0.02 N Hydrochloric acid.(Hydrolytic resistance) - 0.1 ml	NMT - NMT 1.3 ml of 0.01 M Hydrochloric acid per 100.0 ml of test solution.(Hydrolytic resistance) - 1.3 ml
0.05	0.30
0.05	0.30
0.03	0.30
0.04	0.30
0.03	0.3
0.05	0.3


Name of Packing:13 mm Aluminium flip off seals olive green

Product Name:Kranton

Parameters	Description	Colour of the flip Off Seal	Inner Diameter of seal	outer diameter of the flip off Disc	outer diameter of the flip off Disc	Height of the flip disc	Total Height off the Flip off seal	Inside height of flip off seal	Thickness of the Flip off seal
Limits	Clear lacquered (outside only) 13 mm aluminum Flip off seal.	Olive green as per approved Specimen	Min And Max Range - 13.30-13.60 mm	Min And Max Range - 13.50-13.90 mm	Min And Max Range - 14.50-14.90 mm	Min And Max Range - 2.70-4.00 mm	Min And Max Range - 7.40-7.80 mm	Min And Max Range - 5.90-6.30 mm	Min And Max Range - 0.17-0.21 mm
BPP2325024	Complies	Complies	13.41	13.73	14.70	3.37	7.66	6.10	0.19
APP2324826	Complies	Complies	13.47	13.74	14.76	3.18	7.59	6.20	0.19
APP2324797	Complies	Complies	14.76	13.74	14.75	3.21	7.64	6.13	0.20
Min	Complies	Complies	13.35	13.73	14.7	3.18	7.59	6.1	0.19
Max	Complies	Complies	13.47	13.74	14.76	3.37	7.66	6.2	0.2

Name of Packing:13 mm slotted Rubber Bung (RB013AC0)


Parameters	Description	Disc diameter of the Rubber Bung	Disc thickness of the Rubber bung	Height of the rubber bungs	Fragmentation Test	Appearance of the solution	Acidity and Alkalinity	Absorbance	Reducing substance
Limits	Rubber Bung 13 mm Slotted	Min And Max Range - 12.00-12.40 mm	Min And Max Range - 1.75-1.95 mm	Min And Max Range - 9.90-10.40 mm	The total number of fragments does not exceed 5	Solution S is not more opalescent than reference suspension II	Maximum 0.3 ml of 0.01M Sodium hydroxide or maximum 0.8 ml of 0.01M Hydrochloric acid is required to obtain either a blue or a yellow colour respectively	Maximum absorbance of 0.2 at wavelengths from 220 nm to 360 nm	The difference between the titration volumes is not greater than 3.0 ml of 0.01M Sodium Thiosulphate
BPP2325283	Complies	12.29	1.92	10.24	Complies	Complies	Complies	Complies	Complies

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BPP2325284	Complies	12.31	1.87	10.11	Complies	Complies	Complies	Complies	Complies
BPP2325285	Complies	12.23	1.90	10.16	Complies	Complies	Complies	Complies	Complies
BPP2325223	Complies	12.27	1.83	10.06	Complies	Complies	Complies	Complies	Complies
BPP2325220	Complies	12.35	1.91	10.33	Complies	Complies	Complies	Complies	Complies
BPP2325219	Complies	12.31	1.91	10.30	Complies	Complies	Complies	Complies	Complies
BPP2325027	Complies	12.21	1.81	10.31	Complies	Complies	Complies	Complies	Complies
BPP2325028	Complies	12.21	1.83	10.22	Complies	Complies	Complies	Complies	Complies
Min	Complies	12.21	1.81	10.06	Complies	Complies	Complies	Complies	Complies
Max	Complies	12.35	1.92	10.33	Complies	Complies	Complies	Complies	Complies

Name of Packing:13 mm slotted Rubber Bung (RB013AC0)

Ammonium	Extractable Zinc	Extractable Heavy Metals	Residue on evaporation	Volatile Sulfides	Sterilization test
NMT - 2 ppm	NMT - 5 ppm	NMT - 2 ppm	Maximum 2.0 mg per 50.0 ml of solution S	Any black colour stain on the paper is not more intense than that of standard	The closure does not soften or become tacky and there is no visual change in the closure
Complies	Complies	Complies	0.33	Complies	Complies
Complies	Complies	Complies	0.30	Complies	Complies
Complies	Complies	Complies	0.19	Complies	Complies
Complies	Complies	Complies	0.29	Complies	Complies
Complies	Complies	Complies	0.14	Complies	Complies
Complies	Complies	Complies	0.38	Complies	Complies
Complies	Complies	Complies	0.30	Complies	Complies
Complies	Complies	Complies	0.36	Complies	Complies
Complies	Complies	Complies	0.14	Complies	Complies
Complies	Complies	Complies	0.38	Complies	Complies

Remarks/Comments:

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Product Name:Kranton		


4.3.4 Primary packaging material Vendor review

Name of Packing:13 mm slotted Rubber Bung (RB013AC0)

Batch No.	Material SAP Code	AR.No.	Manufacturer Name & Address	Supplier Name & Address	Vendor Qualified/Notqualified
B000123001	200000019	BPP2224556	Joo, Koon circle, Singapore 629046	Joo, Koon circle, Singapore 629046	Qualified
B000123002	200000019	BPP2224737	West pharmaceuticals Koon circle, Singapore 629046	Joo, Koon circle, Singapore 629046	Qualified
B000123003	200000019	BPP2325223	15, Joo, Koon circle, Singapore 629046	Joo, Koon circle, Singapore 629046	Qualified

Name of Packing:13 mm Aluminium flip off seals olive green

Batch No.	Material SAP Code	AR.No.	Manufacturer Name & Address	Supplier Name & Address	Vendor Qualified/Notqualified
B000123001	200000046	AP22RT0015 APP2224622	(16,17,18,19) Bharat Industrial estate, Village – Bhimpore, Nani daman, Daman- 396210	(16,17,18,19) Bharat Industrial estate, Village – Bhimpore, Nani daman, Daman- 396210	Qualified
B000123002	200000046	APP2324797	(16,17,18,19) Bharat Industrial estate, Village – Bhimpore, Nani daman, Daman- 396210	(16,17,18,19) Bharat Industrial estate, Village – Bhimpore, Nani daman, Daman- 396210	Qualified

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Name of Packing:2 ml tubular flint glass vials

Batch No.	Material SAP Code	AR.No.	Manufacturer Name & Address	Supplier Name & Address	Vendor Qualifed/Notqualified
B000123001	200000120	BPP2224693	survey No. 50/4, Kadaiya village, post Bhimpore, nani Daman 396210 India.	survey No. 50/4, Kadaiya village, post Bhimpore, nani Daman 396210 India.	Qualified
B000123002	200000120	BPP2324884	survey No. 50/4, Kadaiya village, post Bhimpore, nani Daman 396210 India.	survey No. 50/4, Kadaiya village, post Bhimpore, nani Daman 396210 India.	Qualified
B000123003	200000120	BPP2325082	survey No. 50/4, Kadaiya village, post Bhimpore, nani Daman 396210 India.	survey No. 50/4, Kadaiya village, post Bhimpore, nani Daman 396210 India.	Qualified

Remarks/Comments:


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Product Name:Kranton		

4.4 Review of Secondary packing materials

4.4.1 vendor/suppliers performance review

Sr.No.	Vendor Batch no/ AR.No	VendorName	Reported Issues	Proposed CAPA	Implementation Status Review
1	NA	NA	NA	NA	NA

Remarks/Comments:

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	PRODUCT QUALITY REVIEW	Document No:PQR/23/103
Product Name:Kranton		


5. Review of diluents supplied with product(if Applicable)

5.1 Details of Diluent

Name Of Diluent	Approved Vendor	Fill Volume	Packed In (Vial/Ampoule)	Remarks (If Any)
NA	NA	NA	NA	NA


5.2 Diluent Packaging Details

Product Batch No.	Description	Diluent Batch No.	Diluent Mfg. Date	Diluent Exp. Date	Quantity Used (nos)
B000123001	Sterile water for injection 0.5 ml	A09423002	06/23	05/28	4988
B000123001	Sterile water for injection 0.5 ml	A09423001	06/23	05/28	205
B000123001	Sterile water for injection 0.5 ml	A09423001	06/23	05/28	2942
B000123003	Sterile water for injection 0.5 ml	A09423006	12/23	11/28	202
B000123002	Sterile water for injection 0.5 ml	A09423002	06/23	05/28	1092
B000123002	Sterile water for injection 0.5 ml	A09423003	09/23	08/28	6190
B000123003	Sterile water for injection 0.5 ml	A09623006	12/23	11/25	5125
B000123003	Sterile water for injection 0.5 ml	A09423005	10/23	09/28	5912
B000123003	Sterile water for injection 0.5 ml	A09623005	10/23	09/28	702
B000123002	Sterile water for injection 0.5 ml	A09423004	10/23	09/28	2077
B000123003	Sterile water for injection 0.5 ml	A09623004	10/23	09/28	10892

		AMPLELOGIC			
		PRODUCT QUALITY REVIEW		Document No:PQR/23/103	
Product Name:Kranton					
B000123002	Sterile water for injection 0.5 ml	A09423002	06/23	05/28	4645
B000123002	Sterile water for injection 0.5 ml	A09423003	09/23	08/28	5555
B000123001	Sterile water for injection 0.5 ml	A09423001	06/23	05/28	8078

5.3 Review of Diluent COA


Parameters	Description	Appearance of solution	Acidity or alkalinity	Conductivity	Oxidisable substances	Oxidisable substances	Chlorides	Chlorides	Nitrates
Specification Limits	A clear colourless liquid; odourless	Clear and colourless and practically free from suspended particles	To comply	NMT - 25 μ S. cm-1	The solution remain faintly pink	The pink color of solution does not disappear completely	The appearance of the solution does not change for at least 15 minutes	NMT - 0.5 ppm	NMT - 0.2 ppm
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423001	complies	complies	complies	15.91	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2

				AMPLELOGIC					
				PRODUCT QUALITY REVIEW			Document No:PQR/23/103		
Product Name:Kranton									
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423001	complies	complies	complies	15.91	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09623005	complies	complies	complies	21.85	complies	complies	complies	<0.5	<0.2
A09423006	complies	complies	complies	15.53	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09423004	complies	complies	complies	18.44	complies	complies	complies	<0.5	<0.2
A09423003	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
A09423001	complies	complies	complies	15.91	complies	complies	complies	<0.5	<0.2
A09423002	complies	complies	complies	15.10	complies	complies	complies	<0.5	<0.2
A09423001	complies	complies	complies	15.91	complies	complies	complies	<0.5	<0.2
A09423001	complies	complies	complies	15.91	complies	complies	complies	<0.5	<0.2
Min	complies	complies	complies	12.12	complies	complies	complies	<0.5	<0.2
Max	complies	complies	complies	21.85	complies	complies	complies	<0.5	<0.2

Remarks/Comments:

Product Name:Kranton

Sulphates	Ammonium	calcium and magnesium	Residue on Evaporation	Particular Contamination Sub-visible Particles	Particular Contamination Sub-visible Particles	Sterility	Bacterial Endotoxins	Extractable volume
The solution shows no change in appearance for at least 1 hour	NMT - 0.6 ppm	A pure blue color is produced	NMT - 4 mg	NMT - Particle greater than or equal to 10µm NMT 6000 particle per container - 6000 Particles/container	NMT - Particle greater than or equal to 25µm NMT 600 particle per container - 600 Particles/container	Sterile	NMT - 0.25 IU/ml	The content of containers is not less than the sum of the nominal volumes of the containers taken collectively(i.e. 2.5mL)
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.16	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	1.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	violate	2.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	1.37	37	01	sterile	<0.25	2.8
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	Violate	3.45	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.16	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6

			AMPLELOGIC					
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complies	<0.6	complies	0.16	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.16	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.16	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.37	37	01	sterile	<0.25	2.8
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.17	62	01	Sterile	<0.25	2.8
complies	<0.6	complies	0.15	59	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.16	57	01	sterile	<0.25	2.7
complies	<0.6	complies	0.25	43	01	Sterile	<0.25	2.7
complies	<0.6	complies	0.37	37	01	sterile	<0.25	2.8
complies	<0.6	complies	0.21	73	01	sterile	<0.25	2.6
complies	<0.6	complies	0.37	37	01	sterile	<0.25	2.8
complies	<0.6	complies	0.37	37	01	sterile	<0.25	2.8
complies	<0.6	complies	0.15	37	1	Sterile	<0.25	2.6
complies	<0.6	complies	0.37	73	1	Sterile	<0.25	2.8

Remarks/Comments:

6. Review Of In-process Parameters


6.1 Washing & Depyrogenation details

Version No :01

Parameters	Compressed air Pressure (Max)	Compressed air Pressure (Min)	WFI Pressure (Max)	WFI Pressure (Min)	Purified water (Max)	Purified water (Min)	Recycle water pressure (Max)	Recycle water pressure (Min)	Min Tunnel Temp of Sterilization zone (Max)
Specification Limits	NLT - 3 Kg/cm²	NLT - 3 Kg/cm²	NLT - 1 Kg/cm²	NLT - 1 Kg/cm²	NLT - 2 Kg/cm²	NLT - 2 Kg/cm²	NLT - 1 Kg/cm²	NLT - 1 Kg/cm²	NLT - 300 °C
B000123002	4	4	2	2	5	4	2	2	342
B000123001	3	3	2	2	5	4	1	1	331
B000123003	4	3	2	2	5	4	2	1	334
Min	3	3	2	2	5	4	1	1	331
Max	4	4	2	2	5	4	2	2	342

Version No :01

Min Tunnel Temp of Sterilization zone (Min)	Max Conveyor Speed
NLT - 300 °C	NMT - 85 mm/min
302	85
303	85
302	85
302	85
303	85

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6.2 Component Sterilization details

Version No :01

Load Pattern Name	Diafiltration Load (Max)	Diafiltration Load (Min)	Diafiltration Load (Hold time)	Garment Load (Max)	Garment Load (Min)	Garment Load (Hold time)	13 mm Rubber Stopper Load (Max)	13 mm Rubber Stopper Load (Min)	13 mm Rubber Stopper Load (Hold time)
Load Pattern No	Load Pattern No.04	Load Pattern No.04	Load Pattern No.04	Load Pattern No.01	Load Pattern No.01	Load Pattern No.01	Load Pattern No.02	Load Pattern No.02	Load Pattern No.02
Specification Limits	Min And Max Range - 121-124 °C	Min And Max Range - 121-124 °C	30 min	Min And Max Range - 121-124 °C	Min And Max Range - 121-124 °C	30 min	Min And Max Range - 121-124 °C	Min And Max Range - 121-124 °C	30 min
B000123002	123.4	122.5	30	123.4	122.8	30	123.4	122.5	30
B000123001	123.1	122.5	30	123.1	122.5	30	123.1	122.4	30
B000123003	123.6	122.4	30	123.5	122.4	30	123.8	122.4	30
Min	123.1	122.4	30	123.1	122.4	30	123.1	122.4	30
Max	123.6	122.5	30	123.5	122.8	30	123.8	122.5	30

Version No :01

50.00 Ltrs filling and filtration Assembly load (Max)	50.00 Ltrs filling and filtration Assembly load (Min)	50.00 Ltrs filling and filtration Assembly load (Hold time)
Load Pattern No.03	Load Pattern No.03	Load Pattern No.03
Min And Max Range - 121-124 °C	Min And Max Range - 121-124 °C	30 min
123.5	122.5	30
123.1	122.4	30
123.9	122.4	30
123.1	122.4	30
123.9	122.5	30


7. Review of Manufacturing Parameter

Version No:01

Select Parameter	BET of heat exchanger	BET	buffer pH of filter wash	Final Buffer pH	final pH	TVC
Specification Limits	NMT - 0.25 EU/ml	NMT - Manufacturing Tank - 0.25 EU/ml	Min And Max Range - 7.1-7.3	Min And Max Range - 7.1-7.3	Min And Max Range - Bulk - 7.1-7.3	NMT - 10 cfu/ml
B000123002	Complies	Complies	7.14	7.26	7.12	Complies
B000123001	Complies	Complies	7.16	7.21	7.19	Complies
B000123003	Complies	Complies	7.26	7.29	7.24	Complies
Min	Complies	Complies	7.14	7.21	7.12	Complies
Max	Complies	Complies	7.26	7.29	7.24	Complies

Version No:02

Select Parameter	initial pH	final pH	flow rate	pH	time	Retentate flow rate (ml / min)	Flux (LMH)	Permeate flow rate (ml/min)	Flux (LMH)
Specification Limits	Initial pH (Diafiltration Buffer)	Min And Max Range - (Diafiltration Buffer) - 7.1-7.3	Min And Max Range - (Pre-sanitization) - 47-53 ml / min	To be recorded (Pre-sanitization)	(In mins) (Pre-sanitization)	Min And Max Range - (Pre-sanitization) - 332-368 ml/min	Min And Max Range - (Pre-sanitization) - 95-115 L/m2/Hr	Min And Max Range - (Pre-sanitization) - 47-53 ml / min	Min And Max Range - (Pre-sanitization) - 13-17 L/m2/Hr
B000123002	9.12	7.28	50	6.92	70	350	105	50	15
B000123001	8.9	7.23	50	6.92	70	350	105	50	15
B000123003	9.23	7.26	50	6.93	70	350	105	50	15
Min	8.9	7.23	50	6.92	70	350	105	50	15
Max	9.23	7.28	50	6.93	70	350	105	50	15


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Version No:02

No. of pass
(Thawed Bulk)
3
3
3
3
3

Version No:03

Select Parameter	flow rate	time	Retentate flow rate (ml / min)	Flux (LMH)	Permeate flow rate (ml/min)	Flux (LMH)
Specification Limits	Min And Max Range - (Post sanitization) - 47-53 ml / min	(In mins) (Post sanitization)	Min And Max Range - (Post sanitization) - 332-368 ml/min	Min And Max Range - (Post sanitization) - 95-115 L/m2/Hr	Min And Max Range - (Post sanitization) - 47-53 ml / min	Min And Max Range - (Post sanitization) - 13-17 L/m2/Hr
B000123002	50	80	350	105	50	15
B000123001	50	80	350	105	50	15
B000123003	50	80	350	105	50	15
Min	50	80	350	105	50	15
Max	50	80	350	105	50	15


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8. Review of process loss

Version No :01

Type of Parameter	Empty Vial Processing Loss	Rubber bungs	Seals Processing Loss	Visual Inspection Loss	Lyophilization Loss
Limits	NMT - 5 %	NMT - 5 %	NMT - 5 %	NMT - 5 %	NMT - 3 %
B000123002	2.13	9.95	2.13	0.79	1.11
B000123001	1.91	26.28	1.91	0.66	0.88
B000123003	3.79	22.65	3.79	0.033	1.83
Min	1.91	9.95	1.91	0.033	0.88
Max	3.79	26.28	3.79	0.79	1.83

Remarks/Comments:


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9. Review of Filtration,Filling,Lyophilization and Sealing process

Version No :01

Filtration Parameters	Filter Integrity	Filtration Time	Nitrogen Pressure	Fill Volume	Filling Time	Lyophilization Time	Sealing Time	Sealing Quality	Leak Test Results
Specification Limits	Pass/Fail	NMT - 15 min	Min And Max Range - 0.4-1.0 Kg/cm ²	Min And Max Range - 0.515-0.5253 gm	NMT - To be recorded - 8 Hrs	To be recorded	To be Recorded	Ok/Not Ok	Pass/ Fail
B000123002	Pass	11	0.8	Complies	02:04	3503	02:23	OK	Pass
B000123001	Pass	17	0.98	Complies	02:15	3547	02:32	OK	Fail
B000123003	Pass	8	0.8	Complies	02:22	3493	02:45	OK	Pass
Min	Pass	8	0.8	Complies	02:04	3493	02:23	OK	Pass
Max	Pass	11	0.8	Complies	02:22	3547	02:45	OK	Pass

Remarks/Comments:


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10. Review of Final Yield

Version No:01

Process Parameters	Manufacturing Yield	Visual Inspection Yield	Packaging Yield
Specification Limits	NLT - 93 %	NLT - 95 %	NLT - 98 %
B000123002	98.89	99.21	100
B000123001	99.12	99.34	100
B000123003	98.17	99.96	100
Min	98.17	99.21	100
Max	99.12	99.96	100


Remarks/Comments:

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11 Review Of Microbiological Monitoring Of Area And Purified Water Results

11.1 Temperature Relative Humidity Results monitored

Areas	Parameter	Specifications	Frequency Of Monitoring	Review Outcome Based on BMR review
Packaging Area	Temperature	Below 25 °C	During Activity	Satisfactory
Manufacturing Area	Humidity	NMT 65 %	During Activity	Satisfactory
Filtration Area	Temperature	20 °C ± 2 °C	During Activity	Satisfactory
Dispensing Area	Humidity	NMT 65 %	During Activity	Satisfactory
Manufacturing Area	Temperature	22 °C ± 2 °C	During Activity	Satisfactory
Filtration Area	Humidity	NMT 65 %	During Activity	Satisfactory
Dispensing Area	Temperature	22 °C ± 2 °C	During Activity	Satisfactory
Filling & Sealing Area	Temperature	20 °C ± 2 °C	During Activity	Satisfactory
	Humidity	NMT 65 %	During Activity	Satisfactory


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11.2 Review of trends

11.2.1 Review of Environmental Monitoring Results

11.2.1.1 Review of Viable Monitoring


Review of Viable Monitoring Area	Grades	Frequency of Monitoring	Settle Plate(cfu/Plate) Alert Limit	Settle Plate.(cfu/Plate) Action Limit	Settle Plate,(cfu/Plate) Specifications	Air Sampling(cfu/M3) Alert Limit	Air Sampling.(cfu/M3) Action Limit	Air Sampling,(cfu/M3) Specifications	Contact Plate(cfu/plate) Alert Limit
Dispensing Area	Grade C	Weekly Once	30	40	50	60	80	100	15
Filling & Sealing Area	Grade A	Twice in Week/ During Activity	NA	NA	No Growth	NA	NA	No Growth	NA
	Grade B	Twice in Week/ During Activity	03	04	05	06	08	10	03
Filtration Area	Grade A	Twice In Week/During Activity	NA	NA	No Growth	NA	NA	No Growth	NA
	Grade B	Twice In Week/ During Activity	03	04	05	06	08	10	03
Manufacturing Area	Grade C	Weekly Once	30	40	50	60	80	100	15

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Contact Plate.(cfu/plate) Action Limit	Contact Plate,(cfu/plate) Specifications	Swab Dab(cfu/Glove) Alert Limit	Swab Dab.(cfu/Glove) Action Limit	Swab Dab,(cfu/Glove) Specifications	Review Outcome based on last 12-month trend review
20	25	NA	NA	NA	Review and found satisfactory
NA	No Growth	NA	NA	No Growth	Review and found satisfactory
04	05	03	04	05	Review and found satisfactory
NA	No Growth	NA	NA	No Growth	Review and found satisfactory
04	05	03	04	05	Review and found satisfactory
20	25	NA	NA	NA	Review and found satisfactory


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11.2.1.2 Review of Non-Viable Monitoring

Area	Grade	Frequency of Monitoring	In-Operation(0.5 u)	In-Operation(5.0 u)	Review outcome Based On last 12 - month trend Review
Change Room And Corridor	Grade D	Yearly/Quarterly	Not Defined	Not Defined	Non-viable Particle count IN-Operation record of Change room and corridor area has been reviewed and found satisfactory.
Dispensing Area	Grade A	Half Yearly	3520	20	Non-viable Particle count IN-Operation record of Dispensing area has been reviewed and found satisfactory.
	Grade C	Yearly Once/During Operation Once in Week	3520000	29000	Non-viable Particle count IN-Operation record of Dispensing area has been reviewed and found satisfactory.
Filling And Sealing Area	Grade A	During activity/Half Yearly	3520	20	Non-viable Particle count IN-Operation record of Filling and sealing area has been reviewed and found satisfactory.
	Grade B	During Activity/Half Yearly	352000	2900	Non-viable Particle count IN-Operation record of Filling and sealing area has been reviewed and found satisfactory.
Filtration Area	Grade A	During Activity/Half Yearly	3520	20	Non-viable Particle count IN-Operation record of Filtration area has been reviewed and found satisfactory.

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	Grade B	During Activity/Half Yearly	352000	2900	Non-viable Particle count IN-Operation record of Filtration area has been reviewed and found satisfactory.
Manufacturing Area	Grade C	Yearly once/ During operation once in week	3520000	29000	Non-viable Particle count IN-Operation record of Manufacturing area has been reviewed and found satisfactory.

Area	Grade	Frequency of Monitoring	At-Rest (0.5 u)	At-Rest (5.0 u)	Review outcome Based On last 12 - month trend Review
Change Room And Corridor	Grade D	Quarterly	3520000	29000	Non- Viable particle AT- Rest Count record of Change room area has been reviewed and found satisfactory.
Dispensing Area	Grade A	Twice in Week	3520	20	Non-viable Particle count AT-REST record of Dispensing area has been reviewed and found satisfactory.
	Grade C	Once in Week	352000	2900	Non-viable Particle count , AT-REST record of Dispensing area has been reviewed and found satisfactory.
Filling And Sealing Area	Grade A	Twice in Week	3520	20	Non-viable Particle count AT-REST record of Filling and sealing area has been reviewed and found satisfactory.
	Grade B	Twice in Week	3520	29	Non-viable Particle count AT-REST record of Filling

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					and sealing area has been reviewed and found satisfactory.
Filtration Area	Grade A	Twice In Week	3520	20	Non-viable Particle count AT-REST record of Filtration area has been reviewed and found satisfactory.
	Grade B	Twice in Week	3520	29	Non-viable Particle count AT-REST record of Filtration area has been reviewed and found satisfactory.
Manufacturing Area	Grade C	Once in Week	352000	2900	Non-viable Particle count AT-REST record of Manufacturing area has been reviewed and found satisfactory.

11.2.1.3 Review of Personnel Monitoring

Month and Year	Area	Review Outcome Based On Last 12-Month Log / Trends check
January 2023 to December 2023	Unit II Production A	Personnel Monitoring data has been reviewed and found satisfactory.

Remarks/Comments:

11.2.1.4 Review of WFI,Purified Water,Pure Steam,Soft Water Monitoring
CHEMICAL

Parameters	Alert Limit of TOC	Action Limit of TOC	Spec Limit of TOC	Frequency of TOC	AlertLimit Conductivity at(25°C)	ActionLimit Conductivity at(25°C)	SpecLimit Conductivity at(25°C)	Frequency Conductivity at(25°C)	Review Outcome Based on Last 12-month Trend Review
Pure Steam	NMT 300ppb	NMT 400 ppb	NMT 500 ppb	Monthly	NMT 1.1 µS/cm	NMT 1.2 µS/cm	NMT 1.3µS/cm	Monthly	Review and found satisfactory
Purified Water	NMT 300 ppb	NMT 400 ppb	NMT 500 ppb	Daily (Return and Generation Point) and Monthly (Supply and User Point)	NMT 1.1 µS/cm	NMT 1.2 µS/cm	NMT 1.3 µS/cm	Daily (Return and Generation Point) Monthly (Supply and User Point)	Review and found satisfactory
WFI	NMT 300 ppb	NMT 400 ppb	NMT 500 ppb	Daily (Return and Generation point) Monthly (Supply & User Point)	NMT 1.1 µS/cm	NMT 1.2 µS/cm	NMT 1.3 µS/cm	Daily (Return and Generation Point) Monthly (Supply and User Point)	Review and found satisfactory

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MICROBIOLOGICAL

Parameters	Alert Limit of BET	Action Limit of BET	Spec Limit of BET	Frequency of BET	Alert Limit of TVC	Action limit of TVC	Spec Limit of TVC	Frequency of TVC	Review Outcome Based on Last 12-month Trend Review
Pure Steam	NA	NA	NMT 0.25 EU/ml	Daily (Return and Generation Point) and Monthly (Supply and User Point)	NMT 06cfu/100ml	NMT 08 cfu/100ml	NMT 10cfu/100ml	Monthly	Review and found satisfactory
Purified Water	NA	NA	NA	NA	NMT 60 cfu/ml	NMT 80cfu/ml	NMT 100 cfu/ml	Daily (Return and Generation Point) Monthly 9Supply and User Point)	Review and found satisfactory
Soft Water	NA	NA	NA	NA	NMT 300 cfu/ml	NMT 400 cfu/ml	NMT 500 cfu/ml	Quarterly	Review and found satisfactory
WFI	NA	NA	NMT 0.25 EU/ml	Daily (Return and Generation Point) Monthly (Supply and User Point)	NMT 06 cfu/100 ml	NMT 08 sfu/100 ml	NMT 10 cfu/100 ml	Daily (Return and Generation Point) and Monthly (Supply and User Point)	Review and found satisfactory



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11.3 Review of Nitrogen Gas and Compressed Air Monitoring by Using Pinocchlo Super II**11.3.1 Nitrogen Gas Monitoring**

Area	Frequency	Limit	Review outcome Based on Last 12 Month Sampling Data
Filtration Area & Filing,Filing &Sealing Area	Monthly	No Growth	Review based on last periodic data and found satisfactory.

11.3.2 Compressed Air Monitoring

Area	Frequency	Limit	Review outcome Based on Last 12 Month Sampling Data
Filtration Area & Filing,Filing &Sealing Area,Manufacturing & Dispensing	Quarterly	No Growth	Review based on last periodic data and found satisfactory.

Remarks/Comments:

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12. Review of Qualification Status of Critical Equipment and Utilities

12.1 Major Changes In Area Or Equipment


Sr.No.	Name of area	Details Of Modifications Throughout The Review Period	Justification If Any
1	NA	NA	NA

12.2 Critical Equipment Qualification/Periodic Validation Details

Equipment Name	Equipment Id No.	Qualification/Requalification Frequency	Qualification/Requalification Done date	Qualification/Requalification Due date	Remarks
Depyrogenation & Sterilization Tunnel	B/DT/G001	Half Yearly	01/03/23	01/09/23	Satisfactory
Lyophilizer	B/LY/G001	Yearly	08/06/23	08/06/24	Satisfactory
Sealing Machine	B/SM/G001	Yearly	16/03/23	16/03/24	Satisfactory
Steam Sterilizer	B/SS/G001	Half Yearly	23/09/23	23/03/24	Satisfactory
Vial Filling & Bunging machine	B/FM/G001	Yearly	16/03/23	16/03/24	Satisfactory
Vial washing machine	B/WM/G001	Yearly	16/03/23	16/03/24	Satisfactory

12.3 Critical Utility Qualification

Utility	Qualification/Requalification Frequency	Qualification/Requalification Done date	Qualification/Requalification Due date	Remarks
Compressed Air	Yearly	01/02/23	01/02/24	Satisfactory
Nitrogen Gas	Yearly	28/01/23	28/01/24	Satisfactory

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HVAC Name	Qualification/Requalification Frequency	Qualification/Requalification Done date	Qualification/Requalification Due date	Remarks
Filling and sealing (B/AHU/04)	Half Yearly	14/03/23	14/09/23	Satisfactory
Manufacturing I (B/AHU/12)	Yearly	07/04/23	07/04/24	Satisfactory
Manufacturing II (B/AHU/06)	Yearly	07/04/23	07/04/24	Satisfactory
Production(B/AHU/02)	Yearly	08/04/23	08/04/24	Satisfactory
Unit preparation and sealing (B/AHU/03)	Yearly	14/04/23	14/04/24	Satisfactory
Washing (B/AHU/05)	Yearly	08/04/23	08/04/24	Satisfactory

12.4 Media Fill Activity Review


Sr No.	Date	Report No.	Reason	Status	Remarks
1	NA	NA	NA	NA	NA

12.5 Process Validation

Sr. No.	Batch No.	Reason For Validation	Validation Report No.	Status of Validation
1	NA	NA	NA	NA

12.6 Analytical Method Validation Details of FP/API/Excipients

Test Name	MOA NO.	Method Validation Report No	Reason	Status	Remark
Sterility	FPM/0001/IH	VP:MV:FLG:ST:A:2	To verify suitability of analytical procedure under actual condition of use	Completed	Satisfactory
Moisture content	FPM/0001/IH	VR:MV:FSH:MC:A	To verify suitability of analytical procedure under actual condition of use	Completed	Satisfactory

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Mannitol content (Assay)	FPM/0001/IH	VR:MV:FG:MAN:ASS:A:2	To verify suitability of analytical procedure under actual condition of use	Completed	Satisfactory
Bacterial Endotoxin test	FPM/0001/IH	VR:MV:FLG:BT:A:1	To verify suitability of analytical procedure under actual condition of use	Completed	Satisfactory
Reconstitution time	FPM/0001/IH	VR:MV:SR:RE:FGR:A	To verify suitability of analytical procedure under actual condition of use	Completed	Satisfactory
Sterility	FPM/0001/IH	VR:MV:FG:ST:A:1	To verify suitability of analytical procedure under actual condition of use	Completed	Satisfactory

12.7 Cleaning Validation


Sr. No.	Validation Report no.	Reason for Validation	Status of Validation(if any)	Remarks
1	NA	NA	NA	NA

12.8 Hold Time Study

Sr. No.	Stage	Report No.	Reason	Status of Validation(if any)
1	NA	NA	NA	NA

12.9 Transport Validation


Sr. No.	Location	Reason for Validation	Report no.	Status of Validation(if any)
1	NA	NA	NA	NA

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12.10 Visual Inspectors Validation

Sr No.	Name of Person	Frequency	Done on	Remark
1	NA	NA	NA	NA


Remarks/Comments:

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13 . Review Of Batch Analytical Data

Version No:01


Select Parameters	Appearance	Identification	PH	Clarity & color of solution	Assay	Sterility	Uniformity of Dosage unit (Mass Variation)	Uniformity of Dosage unit (Mass Variation)	Particulate matter by light obscuration particle count method)
Limits	White to off white cake	Should causes enlargement of the ovaries of immature female rats when administered as directed in the assay.	Min And Max Range - 6.0-8.0	Clear colorless liquid	Min And Max Range - 80-120 %	Sterile	NMT - For 10 Vials: Acceptance value - 15	NMT - For 30 Vials: Acceptance value - 25	NMT - Particles greater than or equal to 10µm. - 6000 Particles/cont ainer
B000123002	white cake	complies	7.16	complies	117.32	sterile	NA	17.74	19
B000123001	White cake	complies	7.21	complies	90.73	sterile	9.26	NA	11
B000123003	white cake	complies	7.16	complies	117.32	sterile	NA	17.74	19
Min	white cake	complies	7.16	complies	90.73	sterile	9.26	17.74	11
Max	white cake	complies	7.21	complies	117.32	sterile	9.26	17.74	19

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Version No:01

Particulate matter by light obscuration particle count method)	Abnormal toxicity	Solubility	Bacterial Endotoxin test	Moisture content
NMT - Particles greater than or equal to 25µm - 600 Particles/container	75 IU/ml intravenously. No death of animals.	Soluble	NMT - NMT 30 EU / 75 IU of r-hFSH - 30	NMT - 5.0 %
01	complies	soluble	<30	2.86
01	No death of animals	soluble	<30	4.74
01	complies	soluble	<30	2.86
1	complies	soluble	<30	2.86
1	No death of animals	soluble	<30	4.74

Remarks/Comments:

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Product Name:Kranton		

14 . Review of Stability Data

14.1 Review of Stability Protocol:


Sr. No.	Stability Protocol no.	Stability Protocol no. After Revision	Reason for Change
1	SPP/0001/AC-01	NA	NA

Remarks/Comments:

14.2 Review of Stability Studies:

Sr. No.	Batch No.	Condition	Period	Status of Completion	Review of results	Any adverse Trends? (yes/no)	Type of Study
1	NA	NA	NA	NA	NA	NA	NA


Remarks/Comments:

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15. Review of Control Samples

Sr. No.	Batch No.	Description (as per Specification)	Integrity of Container	Color / Clarity (as per Specification)	Legibility of coding detail on Carton /label	Label Pasting On Vials/ ampoules	Physical appearance of Cartons / box
1	B000122002	NA	NA	NA	NA	NA	NA

Remarks/Comments:

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16. Review Of Any OOS/OOT During Stability Studies

Sr. No.	OOS/OOT No.	Details	Corrective and Preventive action taken
1	NA	NA	NA


Remarks/Comments:

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17. Review of Out of Specification Report:

Sr. No	OOS NO.	Details (Initiation Date)	Details (Name of the material /Product)	Details (Batch Number)	Details (Description of OOS)	Root Cause	Corrective and Preventive action taken	Closed on	Remark
1	NA	NA	NA	NA	NA	NA	NA	NA	NA


Remarks/Comments:

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18. Review of Deviation Reports

Date	Deviation Report Number	Details of deviation	Root cause	CAPA no.	Status of Deviation
NA	NA	NA	NA	NA	NA


Remarks/Comments:

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19. Review of Laboratory Incidents

Date of Incident	Name of the Material/Product	Bach Number/A.R.NO.	Laboratory incident number	Reason	Initiaed on	Status of Incident
NA	NA	NA	NA	NA	NA	NA


Remarks/Comments:

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20. Review of Out of Trend Report

Date	Out Of Trend Parameter	Description	Remarks, if any
12/07/23	uniformity of dosage units	Batch no. B000123002,Test result for uniformity of dosage units observed as 19.20 for L1 against Specification limit - 15.	OOT i.e OOT/23/009 report has been reviewed and found invalid.


Remarks/Comments:

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21. Review of Change Control Reports

Sr. No.	Date	Change Control No.	Description	Closed out date	Status Of Change Control
1	NA	NA	NA	NA	NA


Remarks/Comments:

	AMPLELOGIC	
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Product Name:Kranton		

22. Review of Batch failures

Sr.No.	Batch no.	Description
1	NA	NA

Remarks/Comments:

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Product Name:Kranton		

23. Review of Batch rejections

Sr.No.	Batch no.	Description
1	NA	NA

Remarks/Comments:

	AMPLELOGIC	
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Product Name:Kranton		

24. Review of Returned Goods

Sr. No.	Batch No.	Date	Returned product No.	Quantity Returned	Reason for return	Date of Disposition
1	NA	NA	NA	NA	NA	NA


Remarks/Comments:

	AMPLELOGIC	
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Product Name:Kranton		

25. Review of Product recalls

Sr. No.	Batch no.	Recall Product No.	Quantity Recalls	Reason for Recall	Date of Disposition
1	NA	NA	NA	NA	NA


Remarks/Comments:

	AMPLELOGIC	
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Product Name:Kranton		

26. Review of Market Complaints

Sr. No.	Batch no.	Complaint No.	Product Name	Description of Complaint	Complaint category	Closure Date	Status of MarketComplaint
1	NA	NA	NA	NA	NA	NA	NA


Remarks/Comments:

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27. Review of corrective and Preventive action


Sr. no.	Date Of Initiation	Refence Document No.	Title of CAPA	CAPA No.	CAPA Description	Completion Date	Status of CAPA	Remark
1	NA	NA	NA	NA	NA	NA	NA	NA

Remarks/Comments:

	AMPLELOGIC	
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28. Review of Technical agreements

Sr. no.	Agreement tracking no.	Details of the Agreement	Agreement made with the party	Approval Date	Next Renewal Date	Remarks
1	AMP/TA/22/007	Secondary Packaging Material vendor	Taluka indl. Estate, Gaurai pada, Vasai (E), Thane 401208	15/02/2022	14/02/2025	Approved
2	AMP/TA/22/011	Secondary Packaging Material vendor	TTC Industrial Estate, Pawane MIDC, Navi Mumbai – 400 705	15/02/2022	14/02/2025	Approved
3	AMP/TA/22/006	Secondary Packaging Material vendor	Bellasis Road, Opp Alexander Cinema, Next to College	15/02/2022	14/02/2025	Approved
4	AMP/TA/22/013	Raw Material Vendor	Ingoldmells Court, Edinburgh Way, Corsham Wiltshire	15/02/2022	14/02/2025	Approved
5	AMP/TA/19/005	Raw Material Vendor	Frankfurter strabe 250, 64291 Darmstadt, Germany	01/02/2019	31/01/2024	Approved
6	AMP/TA/22/020	Secondary Packaging Material vendor	10-A, Industrial Area, behind S.K.Biscuits, Near Octoroi Naka, Ulhasnagar (E)	18/04/2022	17/04/2025	Approved
7	AMP/TA/22/009	Secondary Packaging Material vendor	Plot no.7 Valiv Village, Sativali Road,Vasai (East), Thane.- 401 208	15/02/2022	14/02/2025	Approved
8	AMP/TA/21/013	Secondary Packaging Material vendor	Mumbai	28/10/2021	27/10/2024	Approved
9	AMP/TA/21/015	Contract Testing Laboratory	510/B, At Post – Palsana, Dist. Surat	29/11/2021	28/11/2024	Approved
10	AMP/TA/22/030	Primary Packaging Material vendor	609/5/6/2, 609/1,609/5/610/1 and 610/9, Village	23/09/2022	22/09/2025	Approved

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			Umarsadi,Taluka Pardi, Valsad-396125, India			
11	AMP/TA/22/008	Secondary Packaging Material vendor	Shed – D, 4/A, Wadi Bunder Road, Mazgaon, Mumbai, 400010	15/02/2022	14/02/2025	Approved
12	AMP/QA/0026	Primary packaging material vendor	Bhimpore, Nani Daman, Daman – 396210 UT (India)	20/02/2023	19/02/2026	Approved
13	AMP/TA/22/054	Raw Material Vendor	savli road, tundav, tal. savli, dist vadodra.	23/09/2022	22/09/2025	Approved
14	AMP/TA/22/003	Secondary Packaging Material vendor	Thane – Belapur Road, Mahape, Navi Mumbai, 400701	10/02/2022	09/02/2025	Approved
15	AMP/TA/22/002	Secondary Packaging Material vendor	Vardhaman Market, Sector - 17, Vashi, Navi Mumbai – 400 705	10/02/2022	09/02/2025	Approved
16	AMP/TA/22/055	Primary packaging material vendor	15, Joo, Koon circle, Singapore 629046	29/09/2022	28/09/2025	Approved


Remarks/Comments:

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29. Review of Previous Year PQR

Document No	Date	Remarks
NA	NA	NA

Remarks/Comments:

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30. Review of Recommendations / CAPA from previous PQR,if any

Date	Details of Recommendations / CAPA From previous PQR	Current Status	Remarks
NA	NA	NA	NA


Remarks/Comments:

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31. Review of Repacking Activities

Date	Repacking No.	Product Name	Batch No.	Quantity (No.)	Remarks
NA	NA	NA	NA	NA	NA

Remarks/Comments:

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32. Review of Risk Assessment Studies

Sr. No.	Subject	Document No.	Certified on	Remarks
1	NA	NA	NA	NA

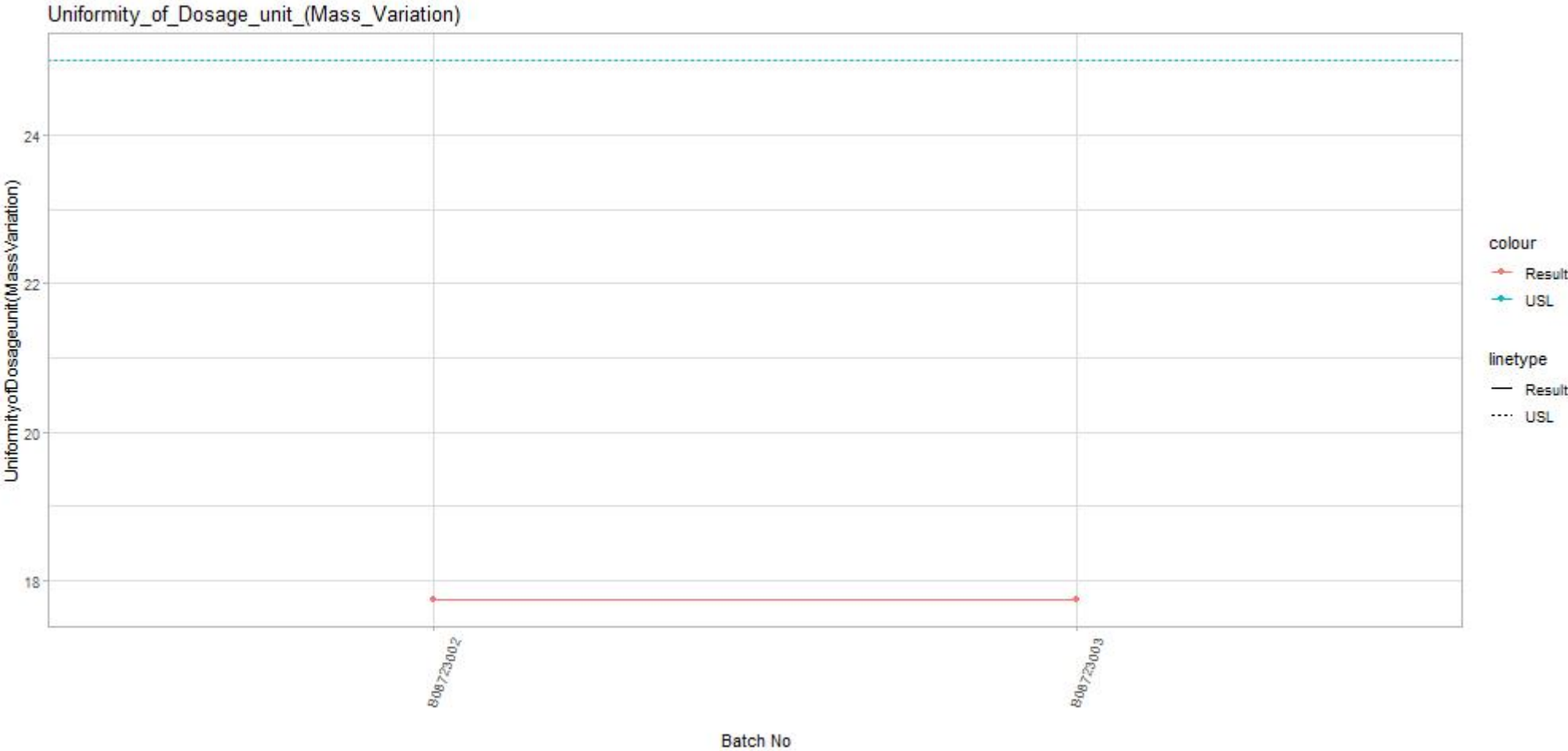
Remarks/Comments:

33. Review of Dossier Registration And Approvals and verifications / Changes made in the registered Dossiers

Sr. No.	Dossier Submitted Country	Status	Remarks
1	Myanmar	Submitted to MOH	Dossier submitted to MOH
2	Uzbekistan	Registered	01599/04/16 Dated 15.04.2016
3	Mali	Submitted to MOH	Dossier submitted to MOH
4	Ghana	Registered	FDA/BS/183-05005 Dated 17.05.2018
5	Senegal	Submitted to MOH	Dossier submitted to MOH
6	Ethiopia	Registered	N553/09 Dated 18.04.2017
7	Sri Lanka	Registered	M-002751-FR Dated 09.05.2018
8	Burkina Faso	Registered	N2019-0696/MS/SG/ANRP Dated 21.05.2019
9	Mauritius	Registered	PB12816/05/2016 Dated 03.11.2018
10	Cuba	Registered	B-16-144-G03 Dated 21.07.2016
11	Madagascar	Registered	33.1.1.068 Dated 12.06.2019
12	Guyana	Submitted to MOH	Dossier submitted to MOH
13	Congo	Registered	18.1073/MSP/DGMPL/DPM-24 Dated 26.04.2018
14	Niger	Submitted to MOH	Dossier submitted to MOH
15	Tanzania	Registered	TZ15H0364 Dated 10.11.2015
16	Philippines	Submitted to MOH	Dossier submitted to MOH
17	Ukraine	Registered	UA/13073/01/02 Dated 12.09.2014
18	Benin	Registered	AMM 2017 1979 Dated 21.06.2017
19	Ivory Coast	Registered	E-2013-355 Dated 22.08.2018

Remarks/Comments:

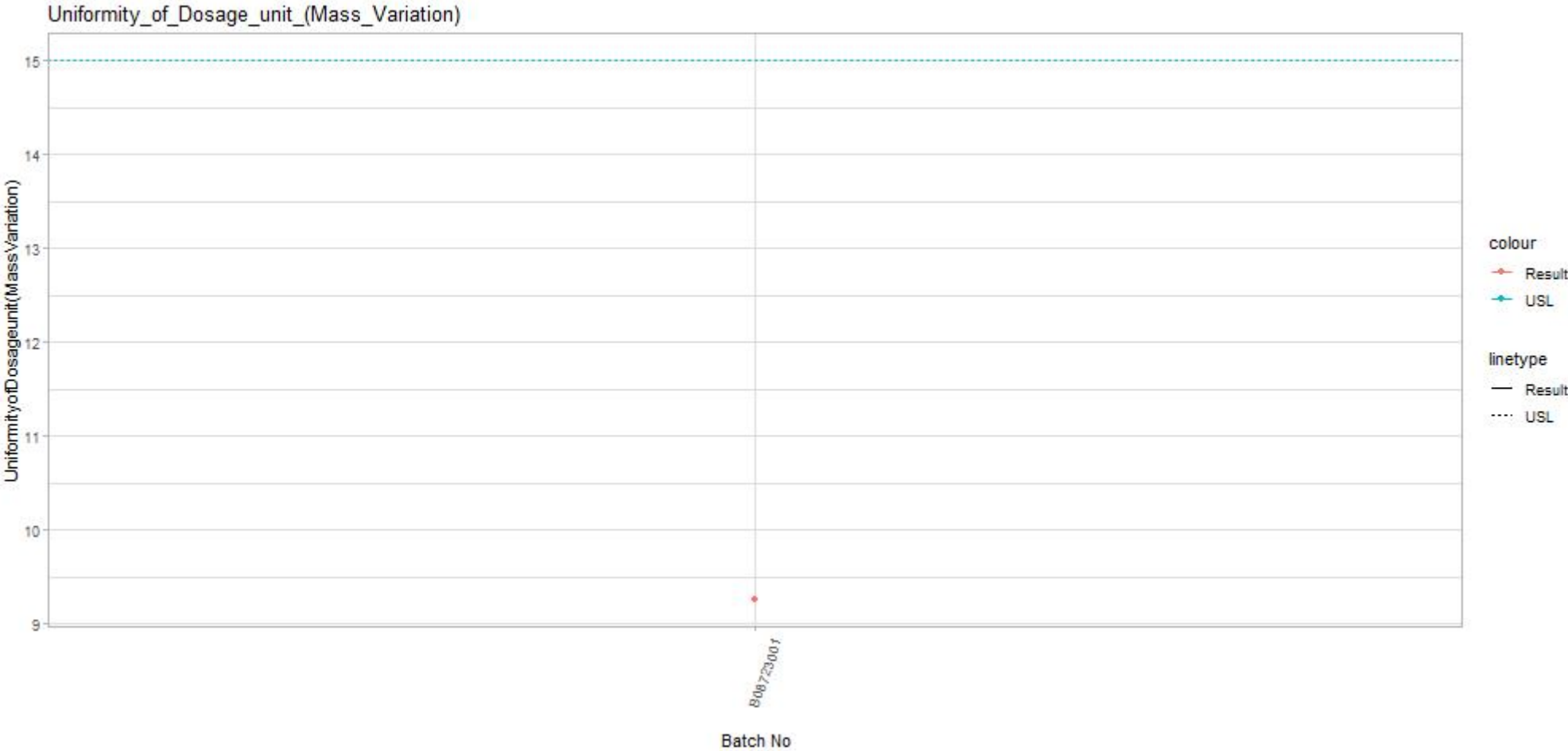
Product Name:Kranton



Annexure1 - Review of Analytical Results LSL=NA USL=25

Remarks/Comments:

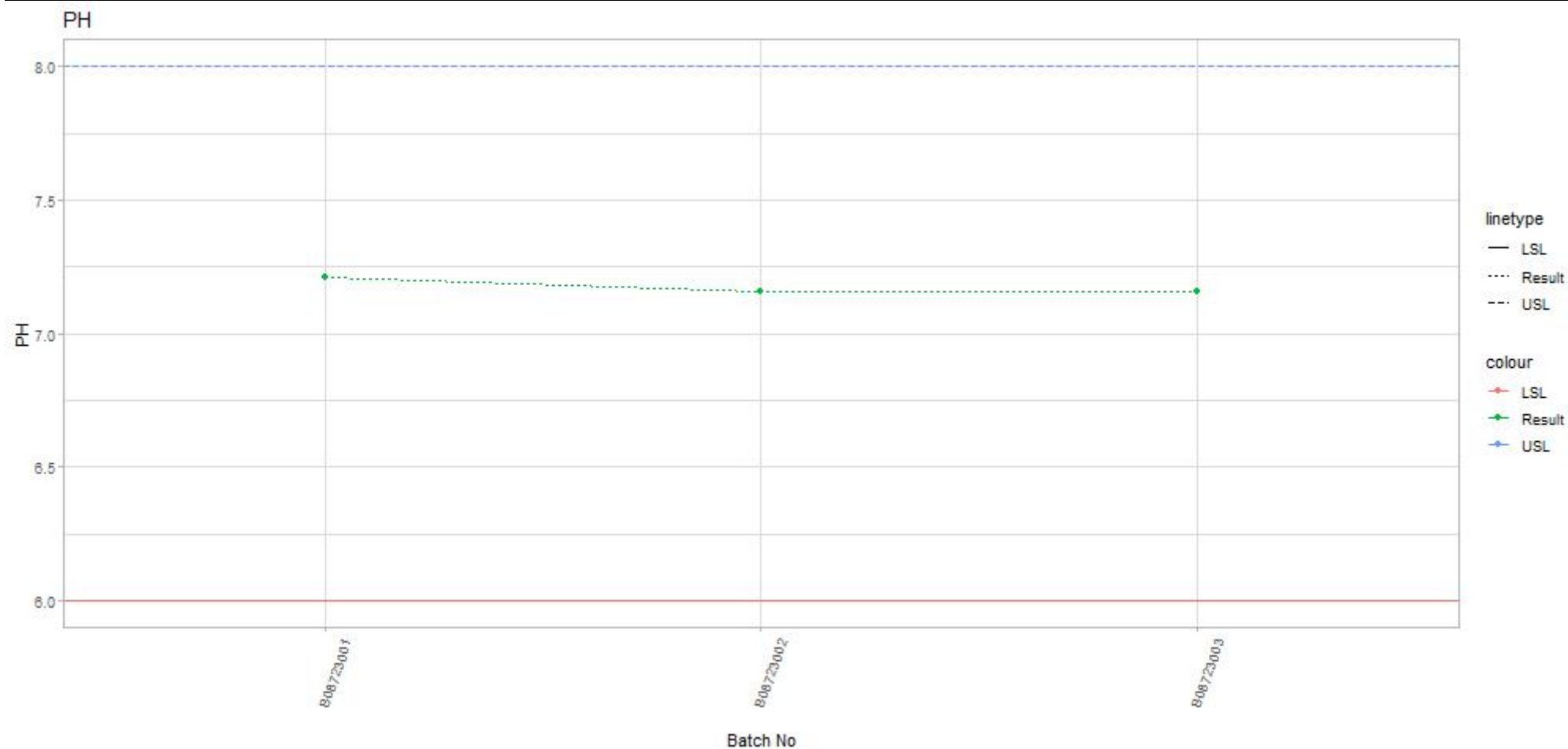
Product Name:Kranton



Annexure2 - Review of Analytical Results LSL=NA USL=15

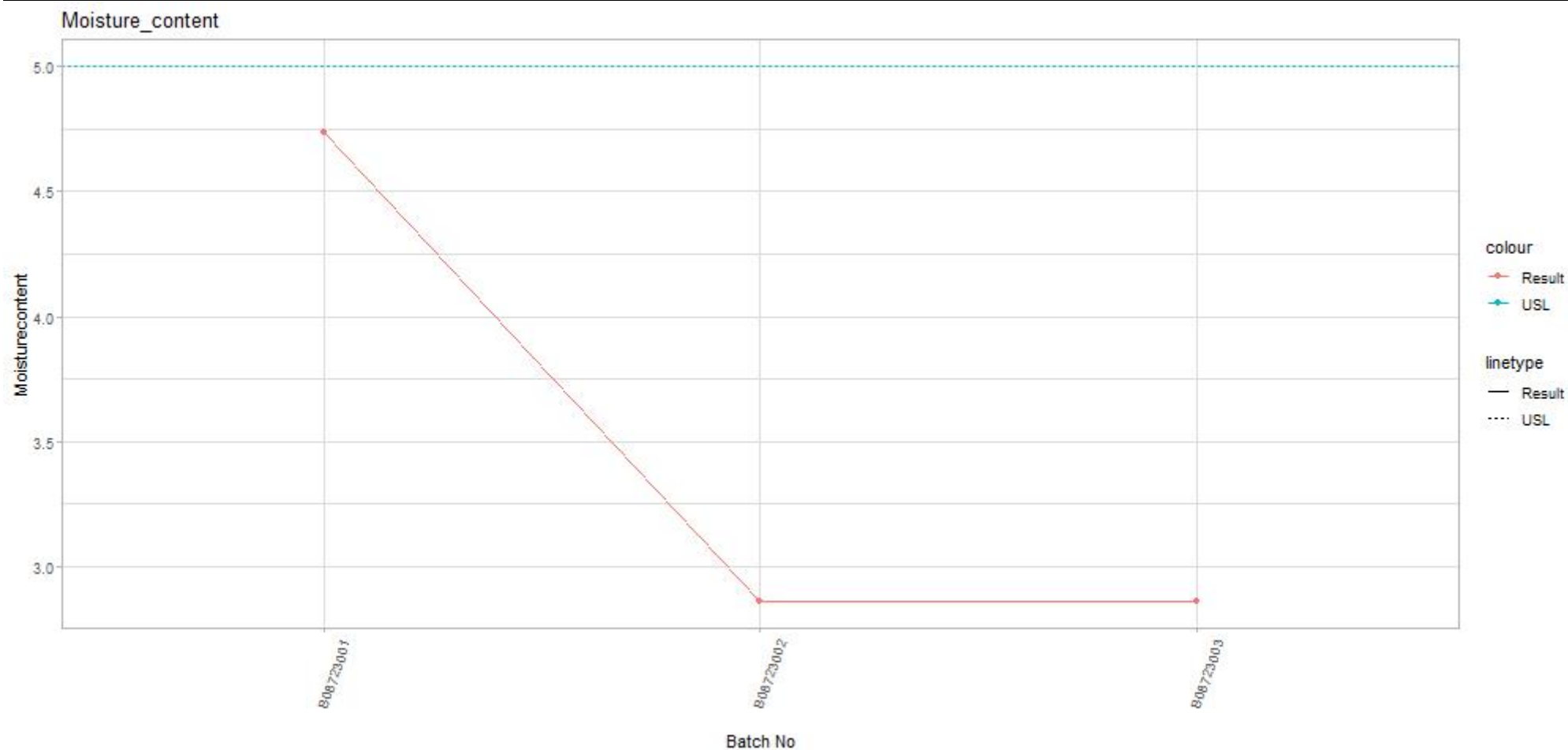
Remarks/Comments:

Product Name:Kranton



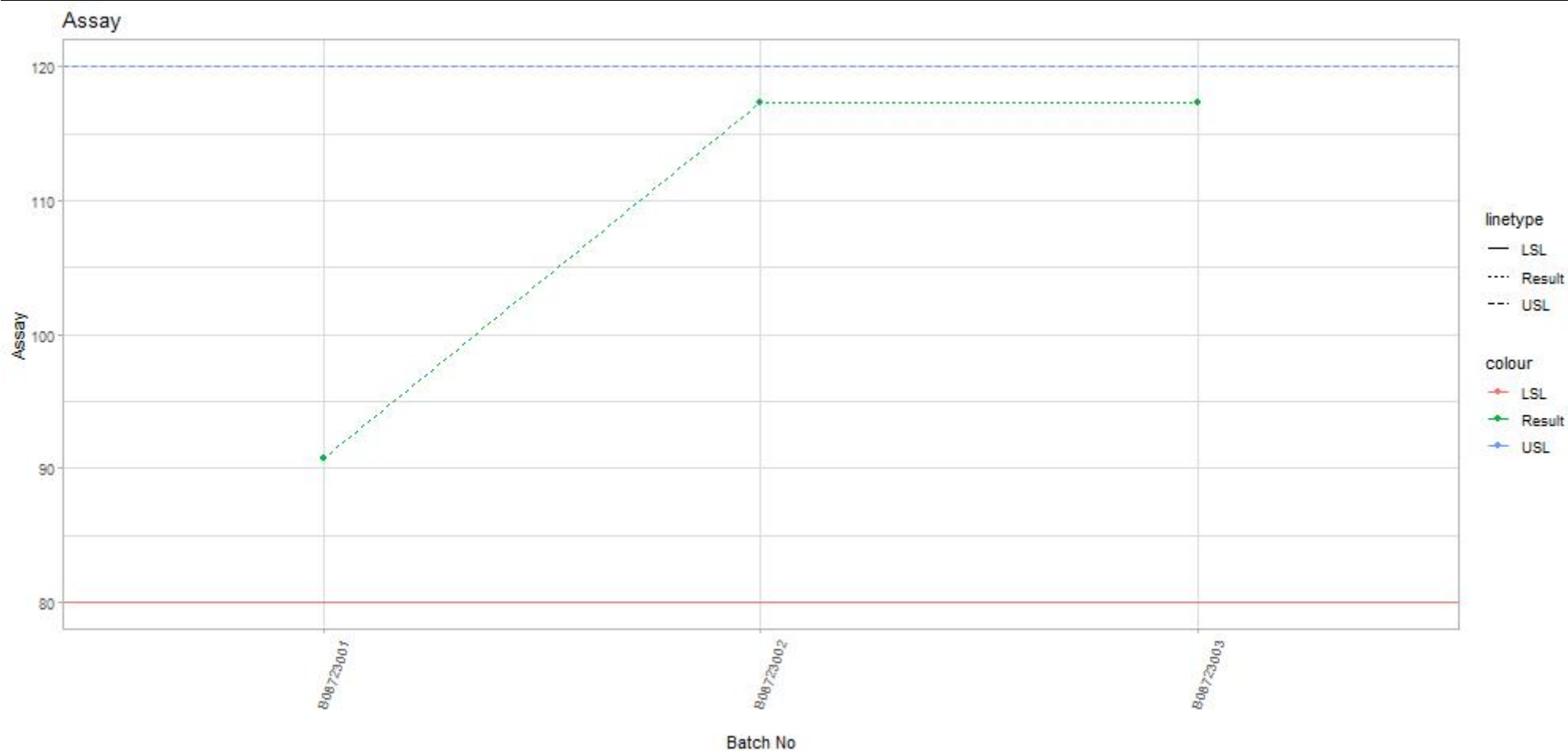
Annexure3 - Review of Analytical Results LSL=6.0 USL=8.0

Remarks/Comments:



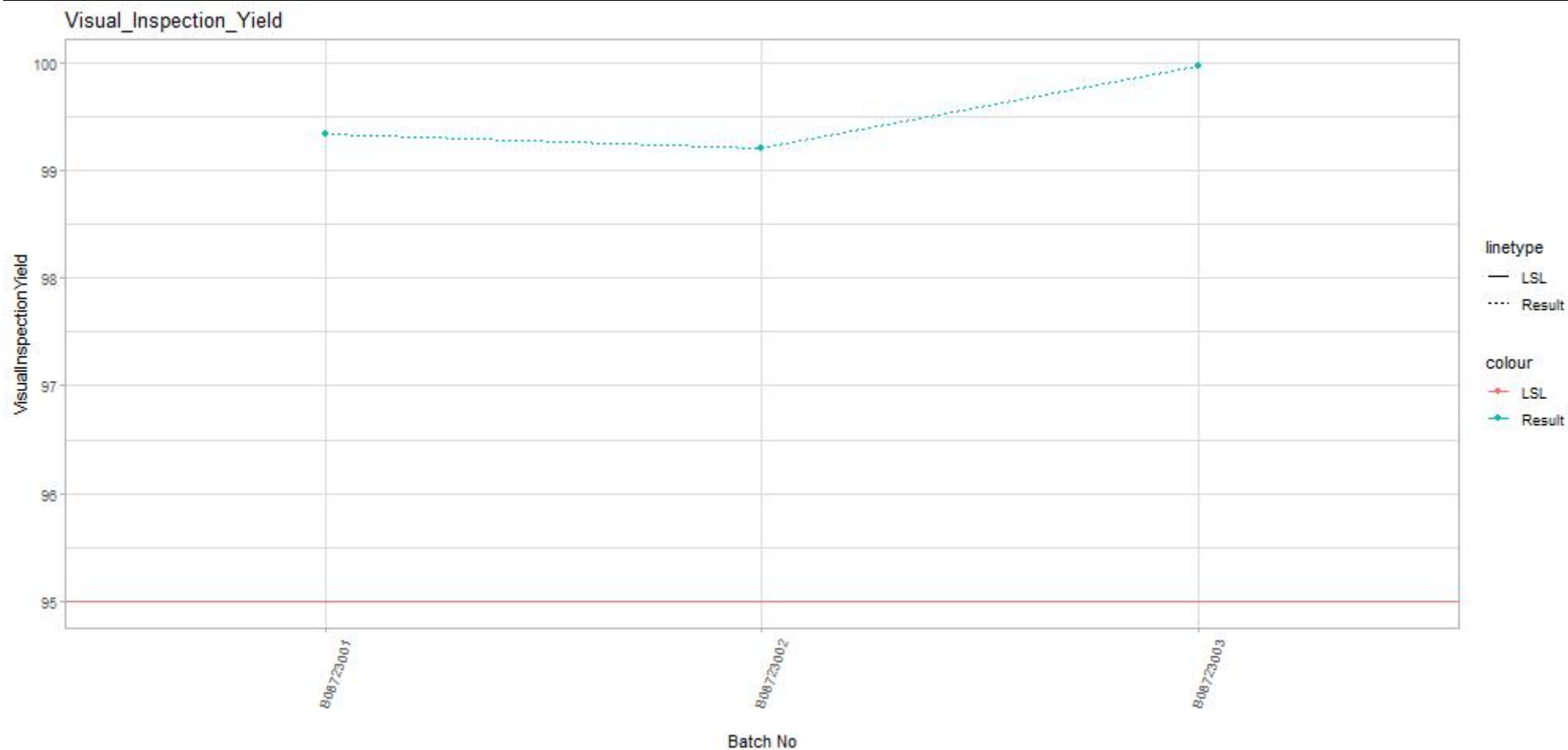
Annexure4 - Review of Analytical Results LSL=NA USL=5.0

Remarks/Comments:



Annexure5 - Review of Analytical Results LSL=80 USL=120

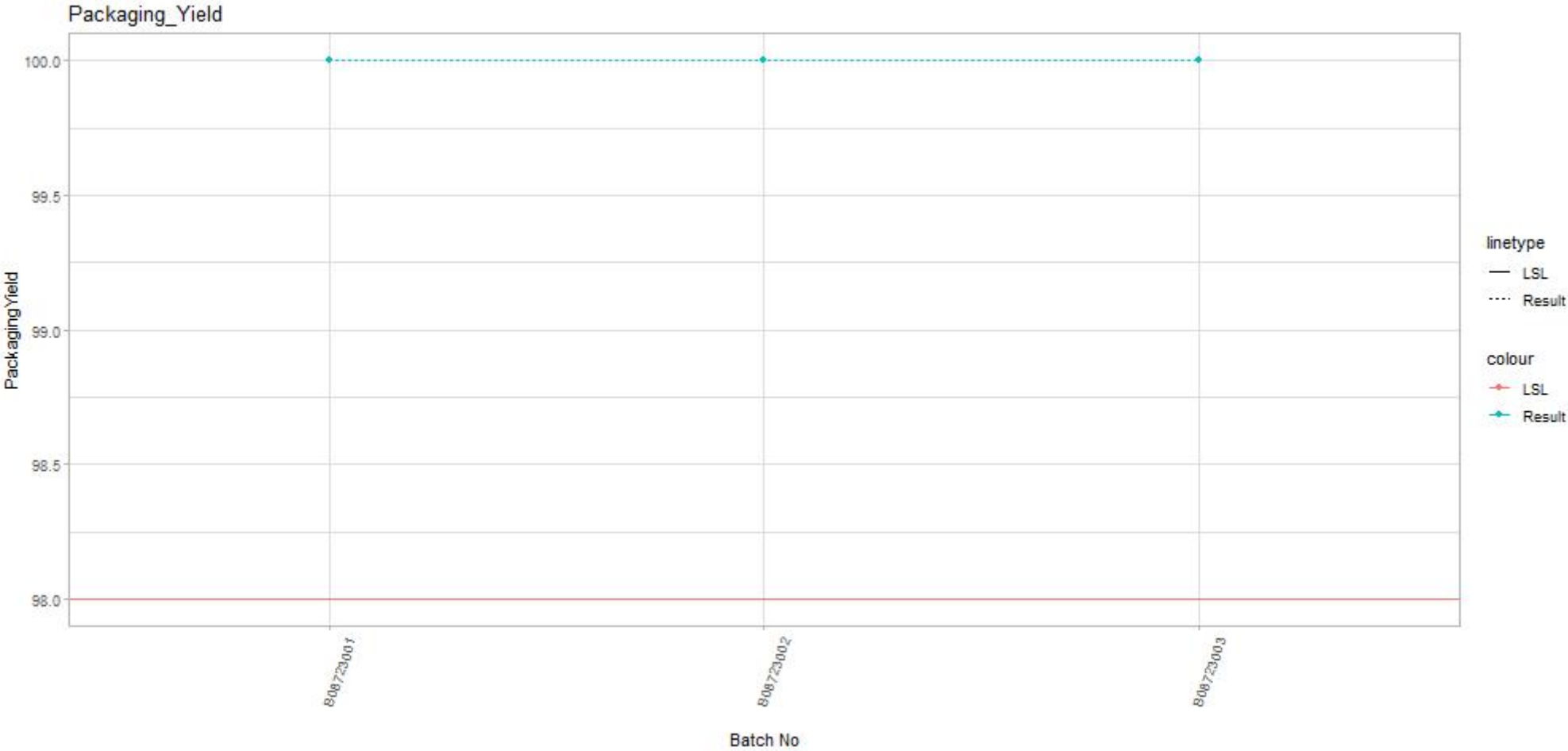
Remarks/Comments:



Annexure6 - Review of final yield LSL=95 USL=NA

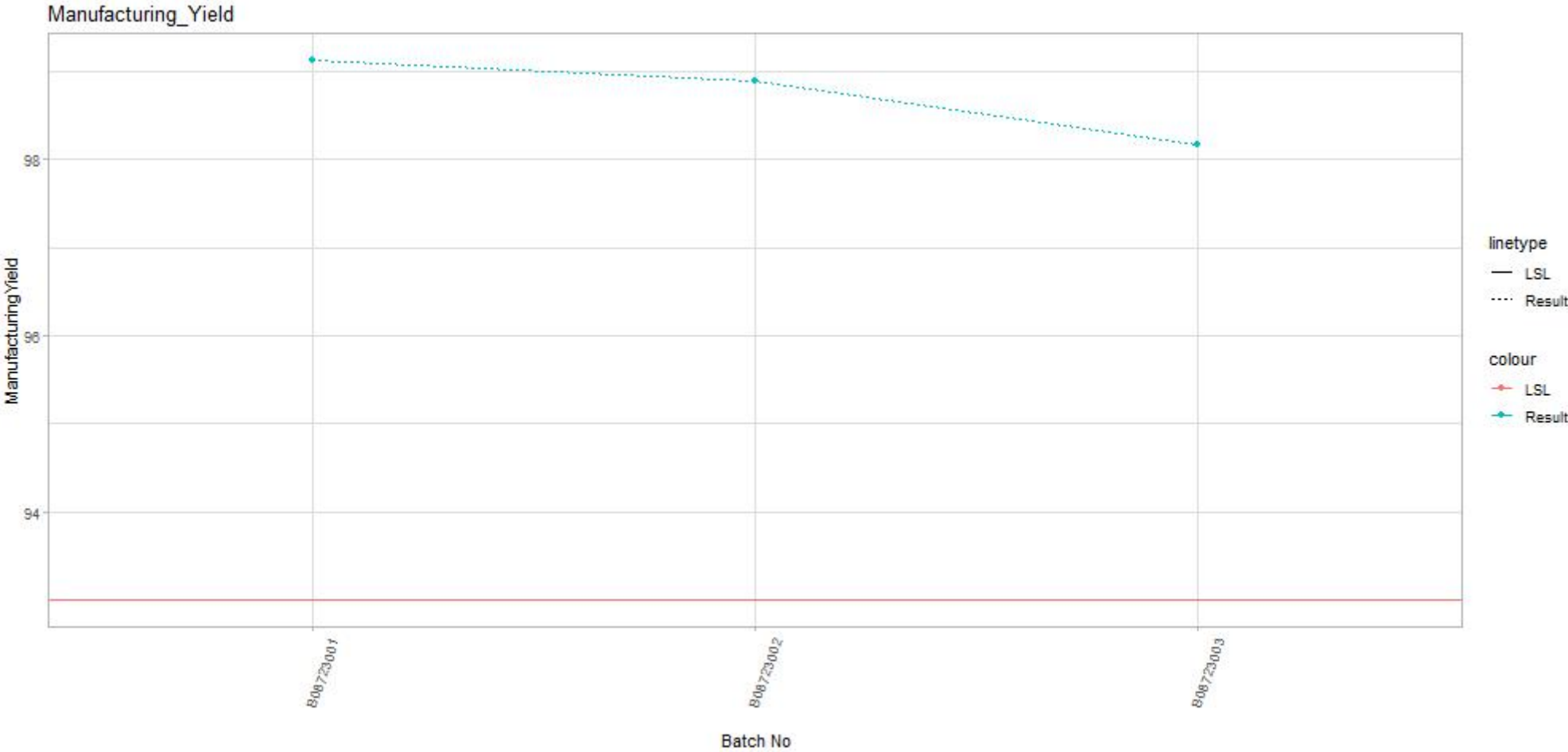
Remarks/Comments:

Product Name:Kranton



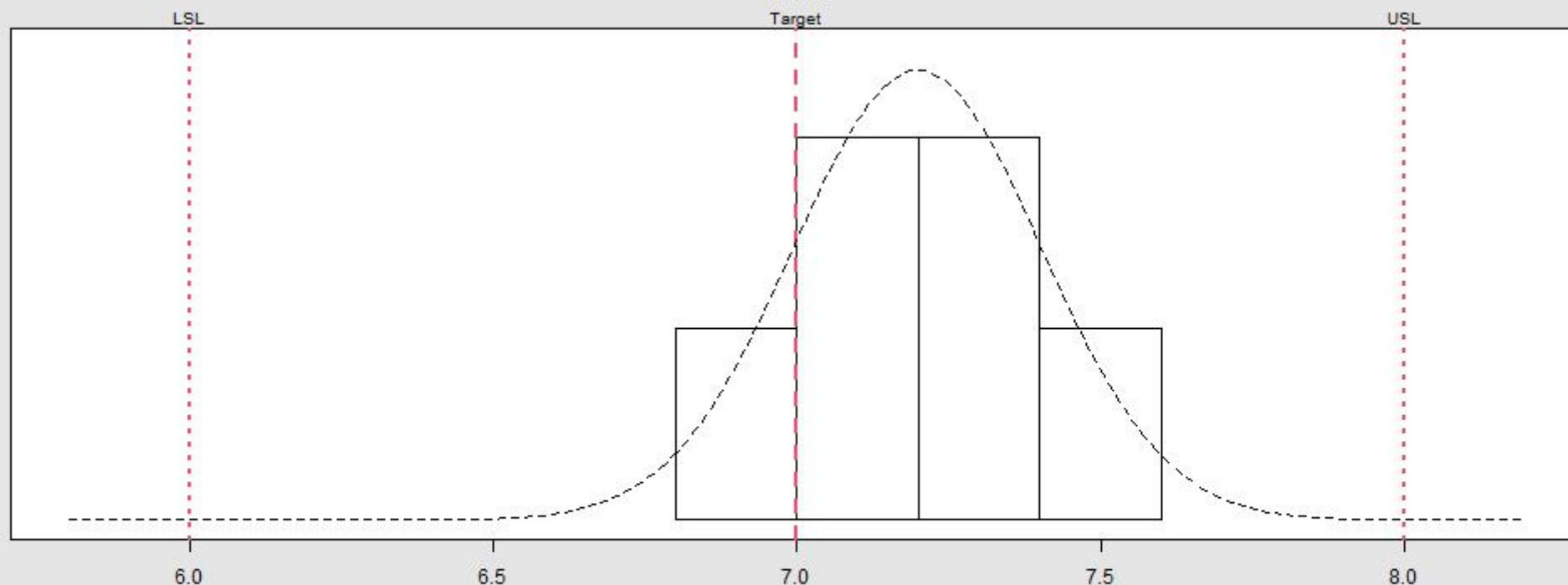
Annexure7 - Review of final yield LSL=98 USL=NA

Remarks/Comments:



Remarks/Comments:

Annexure8 - Review of final yield LSL=93 USL=NA

Product Name:Kranton
**Process Capability Analysis
for PH**


Number of obs = 6
Center = 7.198333
StdDev = 0.2039007

Target = 7
LSL = 6
USL = 8

Cp = 1.63
Cp_l = 1.96
Cp_u = 1.31
Cp_k = 1.31
Cpm = 1.17

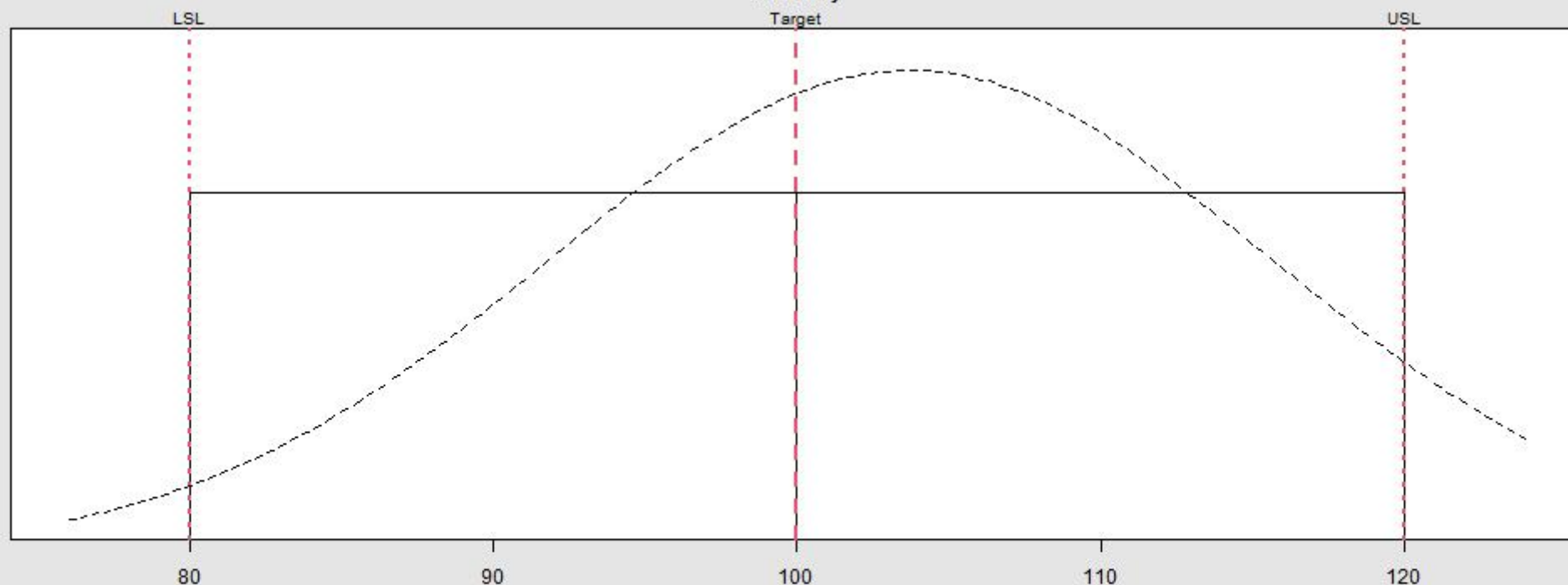
Exp<LSL 0%
Exp>USL 0%
Obs<LSL 0%
Obs>USL 0%

Annexure cpkppk Result 1

Remarks/Comments:

Product Name:Kranton

**Process Capability Analysis
for Assay**



Number of obs = 6
Center = 103.7333
StdDev = 11.92021


Target = 100
LSL = 80
USL = 120

Cp = 0.559
Cp_l = 0.664
Cp_u = 0.455
Cp_k = 0.455
Cpm = 0.534

Exp<LSL 2.3%
Exp>USL 8.6%
Obs<LSL 0%
Obs>USL 0%

Annexure cpkppk Result 2

Remarks/Comments:

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Product Name:Kranton		

34 Review Of Trends and statistical evaluation of analytical and yield results:

34.1 Review Of Trends

parameters	Annexure Number
Uniformity of Dosage unit (Mass Variation)	Annexure 1
Uniformity of Dosage unit (Mass Variation)	Annexure 2
PH	Annexure 3
Moisture content	Annexure 4
Assay	Annexure 5
Visual Inspection Yield	Annexure 6
Packaging Yield	Annexure 7
Manufacturing Yield	Annexure 8

34.2 Review Of Statistical Analysis

parameters	Annexure Number
PH	Annexure cpkppk Result 1
Assay	Annexure cpkppk Result 2