QUANTITATIVE ESTIMATION
(DEFORMULATION)
OF Propylene Glycol and Polyethylene Glycol 400
Topiramate Oral solution 25 mg/ mL

Formulation Facility:	Study Performed by:
Nuwill Research and Innovations Pvt Ltd, No.640,3rd floor, Janardhana Towers, B block, Bilekahalli, Bannerghatta Road, Bangalore-560076. **Contact:** Dr.Phani Kumar **Contact No:** 9741899615	**SK PHARMATECH SOLUTIONS PVT LTD.** Flat No.6-48/4/1,Third Floor, Gourav Arcade, Lankelapalem Main Road, Visakhapatnam, AP, INDIA, Pin: 531019

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1.0 Objective:

To estimate quantitatively the contents of Propylene Glycol and Polyethylene Glycol 400 in the finished product of Topiramate Oral solution 25 mg/ mL. The study was initiated based on the purchase order (NRIPL/ADD/SO/065/25-26) received from M/s Nuwill Research and Innovations Pvt Ltd. LTD, No.640,3rd floor, Janardhana Towers, B block, Bilekahalli, Bannerghatta Road, Bangalore-560076.

2.0 List of API and excipients :

Following samples used for the study.

S.No.	Material Description	Batch No.	Make
1	Test solution with known composition	Trial 1	NA
2	Placebo for Polyethylene glycol 400	Trial 3	NA
3	Placebo for propylene glycol	Trial 4	NA
4	Common placebo (without Topiramate USP API)	Trial 6	NA
5	RLD sample	RLD	NA
6	Topiramate USP	KTRP250033	NA
7	Methyl paraben	MP/1/1311023	NA
8	Propyl paraben	PP/JHA/049/20-21	NA
9	Propylene glycol	404427123CW	NA
10	Polyethylene glycol 400	D210N2K000	NA
11	Glycerin	PG24010579	NA
12	Sucralose	KH-S60-240921-11	NA
13	Mixed berry flavour (FS-970-110-9)	BLA0064485	NA

3.0 Instruments and equipment's:

Different types of instruments are used for the study and listed in below table.

S.No.	Name of the Instrument
1	HPLC with RI/PDA/UV/CAD/FLASH
2	Analytical balance
3	pH meter
4	LCMS
5	GCMS
6	ICPMS

4.0 Samples and materials:

Below are the working or reference standards used for the study.

S.No.	Name of the Material	Make	Batch No.	Expiry date
1	Polyethylene Glycol 400	SK Pharmatech	SK-WS-25-347	Aug-2026
2	Propylene Glycol	SK Pharmatech	SK-WS-25-596	Aug-2026

5.0 HPLC columns used:

S.No.	Column Details	Dimensions	Make
1	InertChrom ODS-Select,	250 mm x 4.6 mm, 5 microns	SK Pharmatech
2	InertChrom C8-HD	250 mm x 4.6 mm, 5 microns	SK Pharmatech
3	InertChrom Phenyl	250 mm x 4.6 mm, 5 microns	SK Pharmatech
4	IC624 CAPPILARY COLUMN	30m*0.32mm*1.8µm	SK Pharmatech

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5	IC-5	50m*0.53mm*0.5µm	SK Pharmatech
6	Inertpro SCX	250 mm x 4.6 mm, 5 microns	SK Pharmatech

6.0 Development Procedure:

6.1 During review of all the available literature below details are the observations

6.1.1 Category

Topiramate belongs to the anticonvulsant (also known as antiepileptic) class of medications. It is also classified as an antimigraine agent

6.1.2 Purpose:

Polyethylene glycol 400:

It is a low-toxicity, water-soluble liquid used in a wide variety of applications, including pharmaceuticals, personal care products, and industrial processes. It acts as a solvent, humectant, and lubricant, and in medicine and it is a clear, colourless, and viscous liquid with properties including high solubility in water and many organic solvents, low toxicity, and a low freezing point. It is hydrophilic, meaning it attracts and retains moisture, has a high boiling point, and is non-volatile and non-irritating

Propylene glycol:

Propylene glycol is a synthetic liquid substance that absorbs water. Propylene glycol is also used to make polyester compounds, and as a base for dicing solutions. Propylene glycol is used by the chemical, food, and pharmaceutical industries as antifreeze when leakage might lead to contact with food. And it is a colourless, odourless, viscous liquid that is miscible with water and many other solvents. It has a molecular formula of $C_3H_8O_2$ a boiling point of around 188°C. Key properties include its hygroscopic nature, its use as a solvent and humectant, and its ability to depress the freezing point of water when mixed with it

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6.2 Development Procedure:

6.2.1 Manufacturing formula:

Table:1: Manufacturing Formula

S.No	Name of the ingredient	Quantity in %
1	Topiramate	2.5
2	Glycerin	38
3	Methylparaben	0.12
4	Propylparaben	0.02
5	Mixed berry flavor	0.05
6	Polyethylene glycol 400	**To be determined**
7	Sucralose	0.4
8	Propylene glycol	**To be determined**

6.3 Method-I: This method capable for estimation of content of Polyethylene Glycol 400. The method if found specific, precise and accurate for estimation of Polyethylene Glycol 400 in Topiramate oral solution

S.No.	Sample description	Description	Content	Content identified
1	Trail-1	Test solution	Polyethylene Glycol 400	359.2 mg/mL
2	Trail-3	Placebo with Polyethylene Glycol 400	Polyethylene Glycol 400	Nil
3	Trail-4	Placebo for Propylene Glycol	Polyethylene Glycol 400	342.5 mg/mL
4	Trail-6	Common placebo (Without Topiramate USP API)	Polyethylene Glycol 400	351.5 mg/mL
5	RLD Sample	NA	Polyethylene Glycol 400	516.5 mg/mL

6.4 Method-II: This method capable for estimation of content of Propylene Glycol. The method if found specific, precise and accurate for estimation of Propylene Glycol in Topiramate oral solution

S.No.	Sample description	Description	Content	Content identified
1	Trail-1	Test solution with known composition	Propylene Glycol	243.6 mg/mL
2	Trail-3	Placebo with Polyethylene Glycol 400	Propylene Glycol	255.8 mg/mL
3	Trail-4	Placebo for Propylene Glycol	Propylene Glycol	NA
4	Trail-6	Common placebo (Without Topiramate USP API)	Propylene Glycol	251.8 mg/mL
5	RLD Sample	NA	Propylene Glycol	50.2 mg/mL

7.0 Conclusion

Based on the above data, the results are confirmed with theoretical input values in the In-House formulation.

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The obtained results are comparable with respective theoretical values.

The values are determined quantitatively in reference product by using HPLC techniques.

Hence the observed results are true and the same quantity shall be used for the drug product development.

8.0 Data:

Attachment-I: Method-I Chromatograms

Attachment-II: Method-II Chromatograms

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