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APPLICANT NAME	1 . Mrs. Asmita Vikas Gaikwad 2 . Dr. Preeti Khulbe 3 . Dr. Ganesh Yogiraj Dama 4 . Dr. Manojkumar Mukundrao Nitalikar
TITLE OF INVENTION	HPLC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF CANAGLIFLOZIN IN BULK AND MARKETED DOSAGE FORM
FIELD OF INVENTION	CHEMICAL
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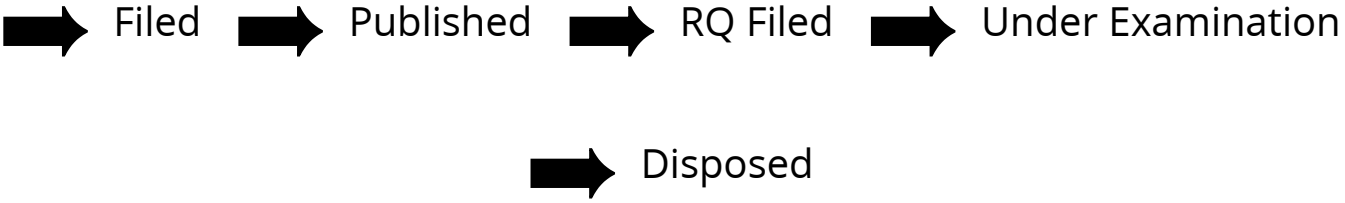

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(57) Abstract :
The present invention relates to an efficient and simple HPLC method developed and validated for the determination of anti-diabetic drug canagliflozin in marketed formulations containing canagliflozin.

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FORM 2

THE PATENTS ACT 1970 (39 of 1970)

AND

The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule13)

TITLE OF THE INVENTION

HPLC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF CANAGLIFLOZIN IN BULK AND MARKETED DOSAGE FORM

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The following specification particularly describes the invention and the manner in which it is to be performed.

FIELD OF INVENTION

The present invention relates to a efficient and simple HPLC method for the determination of canagliflozin in marketed formulations containing canagliflozin.

BACKGROUND OF THE INVENTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia. It may be due to impaired insulin secretion, resistance to peripheral actions of insulin, or both. According to the International Diabetes Federation (IDF), approximately 415 million adults between the ages of 20 to 79 years had diabetes mellitus in 2015. DM is proving to be a global public health burden as this number is expected to rise to another 200 million by 2040. The prevalence of type 2 diabetes mellitus has doubled over the past 3 decades and is likely to affect a half a billion people in the next 3 decades. The sodium-glucose co-transporter 2 (SGLT2) inhibitors have recently emerged as important new treatments for diabetes mellitus. These are a new class of antihyperglycemic agents that lower blood glucose levels in patients with type 2 diabetes. SGLT2 inhibitors have an insulin-independent mechanism of action, acting to inhibit the reabsorption of glucose in the kidney, which leads to increases in urinary glucose excretion (UGE) in individuals with elevated blood glucose levels. Canagliflozin is a C-glycosyl compound, a member of thiophenes, and an organofluorine compound.Its IUPAC name is (2*S*,3*R*,4*R*,5*S*,6*R*)-2-[3-[[5-(4-fluorophenyl)thiophen-2-yl]methyl]-4-methylphenyl]-6-(hydroxymethyl)oxane-3,4,5-triol ($C_{24}H_{25}FO_5S$). Analytical method validation ensures that various HPLC analytical techniques shall give reliable and repeatable results; it is a crucial step in developing new dosage forms as it provides information about accuracy, linearity, precision, detection, and quantitation limits. According to the ICH guideline, “the objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose.” It is now obligatory in the process of drug development to supply the validation data for the responsible authorities. Guidelines for analysis method validation include ICH and USP guidelines.

OBJECTS OF THE INVENTION

Some of the objects of the present disclosure, which at least one embodiment herein satisfies, are as follows.

It is an object of the present disclosure to ameliorate one or more problems of the prior art or to at least provide a useful alternative.

An object of the present disclosure is to develop and validate a simple, sensitive, rapid, economic and isocratic HPLC method for the determination of canagliflozin in marketed formulations containing canagliflozin alone and in combination.

Other objects and advantages of the present disclosure will be more apparent from the following description, which is not intended to limit the scope of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Figure 1. Canagliflozin λmax at 290 nm in methanol

Figure 2: HCl mediated degradation

Figure 3: NaOH mediated degradation

Figure 4: Hydrogen peroxide mediated degradation

Figure 5: Thermal degradation

Figure 6: Photolytic degradation

Figure 7: Calibration curve of Canagliflozin

Figure 8: HPLC Chromatogram of standard Canagliflozin

Figure 9: HPLC Chromatogram of Brand 1

Figure 10: HPLC Chromatogram of Brand 2

DETAILED DESCRIPTION OF THE INVENTION

The following description is of exemplary embodiments only and is not intended to limit the scope, applicability or configuration of the invention in any way. Rather, the following description provides a convenient illustration for

implementing exemplary embodiments of the invention. Various changes to the described embodiments may be made in the function and arrangement of the elements described without departing from the scope of the invention.

The HPLC system used for the method development and validation consisted of the Agilent LC1260 series, with VWD detector. Analysis and separation have been done on Symmetry, Waters C 18 (100 mm × 4.6 mm x 3.5µm) at 290 nm in an air-conditioned lab. The mobile phase used for the chromatographic runs consisted of 5 mM ammonium formate in water: methanol at ratio (25:75, v/v), the flow rate was set at 1 ml/min in an isocratic mode and the injection volume was set at 1 µl for all samples.

Preparation of the buffer solution

A 20 mM buffer solution was prepared by dissolving 1.26 g ammonium formate in 1000 mL Milli-Q water and the final pH adjusted to 3.5 using formic acid. The buffer solution was then filtered through (0.45 Nylon NY membrane filter) and degassed in a sonicator for 10 min.

Preparation of standard stock solution

100 mg of standard canagliflozin was accurately weighed and transferred into a 100 ml volumetric flask and 20 mL of the mobile phase mixture was added to it and sonicated for 10 min, the final volume was made up to 100 mL using the mobile phase mixture. This gave a standard stock solution of 1000 µg/ml. The standard stock solution was further diluted to get the desired concentrations.

Preparation of working solution

It was prepared by taking 1 ml of the stock solution into a 10 ml volumetric flask and the final volume was made up with diluent (100 µg/ml). The solution was filtered and then diluted immediately before use to appropriate concentration levels by using the mobile phase.

Preparation of Pharmaceutical sample

Brand 1

20 tablets of Canagliflozin® Invokana were weighed and crushed. 100 mg powder equivalent to one Canagliflozin® tablet (100 mg canagliflozin) was placed in a 100 ml volumetric flask and sonicated for 10 min and the final volume was made up to the mark with mobile phasemixture followed by 5 min shaking. The solution was filtered and 10 ml of the filtrate was transferred into 20 ml volumetric flasks and the final volume was made to the mark with the mobile phase mixture. An aliquot of 2 ml from the above solution was transferred into a 20 ml volumetric flask and the mobile phase was added to the mark to produce a final concentration of 50 µg/ml canagliflozin.

Brand 2

20 tablets of Canagliflozin® Prominad were weighed and crushed. 50 mg powder equivalent to one Canagliflozin® tablet (50 mg canagliflozin) was placed in a 50 ml volumetric flask and sonicated for 10 min and the final volume was made up to the mark with mobile phase mixture followed by 5 min shaking. The solution was filtered and 5 ml of the filtrate was transferred into 10 ml volumetric flasks and the final volume was made to the mark with the mobile phase mixture. An aliquot of 1 ml from the above solution was transferred into a 10 ml volumetric flask and the mobile phase was added to the mark to produce a final concentration of 50 µg/ml canagliflozin.

Method development and optimization

The suitability of the column and the mobile phase used in the optimized method has been decided based upon the basis of the selectivity, sensitivity as well as acceptable chromatographic parameters of the produced peaks. We used the mobile phase as a solvent for all samples to ensure minimum noise and to eliminate any unwanted solvent peaks.

Selection of UV wavelength

Canagliflozin has a λ_{max} at 290 nm in methanol.[9] An acceptable response was obtained upon the detection of both the brands of the drug at 290 nm. (Figure 1.2)

The optimized HPLC condition is depicted in table 1.

Table 1: HPLC conditions

System	Agilent 1260 Series
Mobile Phase	5 mM Ammonium formate : MeOH (25:75 v/v)
Flow rate	1 ml/min
Column	C-18, 100 x 4.6 mm, 3.5 µm (Symmetry, Waters)
Oven Temperature	40 degree Celsius
Wavelength of detection	290 nm
Back Pressure generated	134-136 bars
Total Run time	6 min
Average Retention time	2.64 In

Method validation

The method has been validated as per the International Conference of Harmonisation (ICH) guidelines Q2 (R1) [7] for evaluating system suitability, precision, accuracy, linearity, the limit of detection (LOD),the limit of quantitation (LOQ and forced degradation studies.

1. System suitability

System suitability parameters concerning tailing factor, number of theoretical plates, and retention time of canagliflozin peak were assessed by injecting a blank mobile phase followed by six replicates of canagliflozin (50 µg/ml)**.**

2. Linearity

Linear regression data over the range of 1 to 10 µg/mL for Canagliflozin with a correlation coefficient of 0.999 unfolds a good linear relationship between area and concentration in the calibration curve.

3.Precision, repeatability (intra-day precision) and intermediate (inter-day precision)

System and method precision were assessed by injecting 5 independent samples of canagliflozin (50 µg/ml each) on the same day under the same operating conditions.

Intermediate or inter-day precision was assessed by comparing the results of 5 independent determinations on 3 different days.

4. Accuracy study and recovery

Accuracy of the method was resolved by standard addition method in which standard addition of pure API at three different concentration levels of 70%, 100%, and 130% was performed in triplicate. The accuracy of the method is calculated in the terms of % recovery of the API.

5. LOD and LOQ

LOD and LOQ for canagliflozin were calculated from the linear regression equation based on the standard deviation of the intercept and the slope using the formula.

LOD = 3.3 Q/S and LOQ = 10 Q/S

where Q: the standard deviation of the intercept, S: the slope of the calibration curve.

6. Forced degradation studies

To assess the stability-indicating a property of the developed HPLC method stress studies were carried out under ICH recommended conditions. Forced degradation of Canagliflozin was carried out by exposing the bulk sample to acidic, alkaline, oxidative, photolytic, dry heat, and neutral conditions. The aim was to study the ability of the proposed method to measure the analyte response in the presence of its degradation products.

Acid and alkali hydrolysis Aliquot of 1 ml of Canagliflozin solution (1 mg/ml) was transferred to a small round bottom flask. The solution was mixed with 9 ml of 0.1N hydrochloric acid or 0.1 N sodium hydroxide. The prepared solutions were subjected to reflux for 2 h in a boiling water bath. The samples were cooled to room temperature (25ºC), neutralized with an amount of acid or base equivalent to that of the previously added. From the resulting neutral solution, 20 µl of each was injected into the HPLC system.

Oxidation One milliliter of Canagliflozin solution (1 mg/ml) was transferred to a round bottom flask. The contents were then mixed with 9 ml of 30% hydrogen peroxide solution, and the reaction mixture was allowed to proceed at room temperature (25ºC) for 2 h with intermittent shaking. A volume of 20 µl was injected into the HPLC system. **Irradiation with ultraviolet light** A sample powder of Canagliflozin (10 mg) was exposed to UV light (254 nm) for 48 h. The material was dissolved in 5 ml water. The solution was filtered with a syringe filtration disk claimed a concentration of 1 mg/ml. It was suitably diluted and a volume of 20 µl was injected into the HPLC system. As well, an aqueous solution

of Canagliflozin (1 mg/ml) was exposed to UV light (254 nm) for 48 h, and after diluting 20 µl was injected into the HPLC system.

Thermal degradation Canagliflozin (10 mg) was exposed to a temperature of 70ºC for 48 h in a hot air oven. The material was dissolved in 5 ml water. The solution was filtered with a syringe filtration disk claimed a concentration of 1 mg/ml. It was suitably diluted and a volume of 20 µl was injected into the HPLC system. As well, an aqueous solution of Canagliflozin (1 mg/ml) was exposed to a temperature of 70ºC for 48 h, and after diluting 20 µl was injected into the HPLC system

Linearity studies

The analytical calibration curve constructed for canagliflozin was linear in the specified ranges, indicated by the closeness of the correlation coefficient R^2 to 1 ($R^2 = 0.9999$). The linear regression equation for the drug is ($Y = 2.08081 \times 10^{-5}x + 0.570271$, $R^2 = 0.9999$).

Table 2: Linearity of Canagliflozin

Parameter	Result
Linearity range	1-10 mcg/ml
Slope	2.08081×10^{-5}
Intercept	0.570271
Coefficient of correlation	0.9999

Table 3: System suitability parameters

Parameter	Results

Retention time	2.647
Tailing factor	1.22
Theoretical plates	4640
% RSD	2.02918

Precision studies

Table 4: Intra-day precision studies of canagliflozin

Day 1 (Morning)	**Area (mAU)**
15 ng/ml	720236.2
50 ng/ml	2371504
95 ng/ml	4654963
Day 1 (Afternoon)	
15 ng/ml	713629.6
50 ng/ml	2377222
95 ng/ml	4693435.8
Day 1 (Evening)	
15 ng/ml	710425
50 ng/ml	2389567.4

95 ng/ml	4742636.2

Table 5: Inter-day precision studies of canagliflozin

Day 1	Area (mAU)
15 ng/ml	714763.6
50 ng/ml	2379431.0
95 ng/ml	4697011.6
Day 2	
15 ng/ml	720260.7
50 ng/ml	2439207.0
95 ng/ml	4919060.6
Day 3	
15 ng/ml	720098.0
50 ng/ml	2522346.3
95 ng/ml	5201346.6

Accuracy and recovery studies

Table 6 Accuracy Studies of Canagliflozin

Amount of sample taken (µg/ml)	2	2	2
Amount of standard added (µg/ml)	1.5	2.4	2

Percentage of Standard added	70	100	130
% Recovery	99.5	99.8	99.6
Relative Standard Deviation	0.15	0.14	0.08

*Average of three determinations (n=3)

LOD and LOQ

The calculated LOD and LOQ were 0.002669 ng and 0.008007 ng for canagliflozin.

Forced degradation studies

Table 7: Forced degradation studies of canagliflozin

Sample	Concentration used (ng/ml)	Concentration left after degradation (ng/ml)	% Recovery
Acid hydrolysis	25	0.009	0.036
Alkaline hydrolysis	25	0	0
Photolytic	25	25	100
Oxidation	25	0	0
Thermal	25	0	0

Various mobile phases of different compositions were tested to develop an optimum mobile phase to achieve a satisfactory separation and good peak symmetry for Canagliflozin. A mobile phase consisting of 5 mM Ammonium formate: MeOH (25:75 v/v)was developed. The analysis was carried out based on peak area with UV detection at 290 nm (Figure1.2). The retention time obtained for Canagliflozin was at 2.64 min. The detector response was linear in the concentration range of 1-10 µg/ml.

Validation of the proposed method

A. System suitability

The obtained results of 6 replicate injections showed that the parameters tested were within the acceptable range. Canagliflozin was repeatedly retained at 2.64 min with RSD% of the recorded retention 2.02918 to indicate good repeatability of replicate injections on the integral HPLC system used, the tailing factor never exceeded 1.24 in all peaks indicating good peak symmetry (acceptance limit is < 2) and the number of theoretical plates was always >2000 in all chromatographic runs to ensure good column efficacy throughout the developed separation process. The results of system suitability are given in table 3.

B. Linearity

A linear correlation was attained between peak area used absorbance vs concentration of Canagliflozin in the range of 1-10 mcg/ml. The linearity of the calibration curve was validated by the high value of the correlation coefficient of regression as shown in Figure (7) and the results are shown in Table 2.

C. Accuracy

The accuracy experiments were carried out by the standard addition method. The high value of recoveries obtained for Canagliflozin indicates that method is accurate as shown in Table 6.

D. Precision

The %RSD values of intra-day and inter-day for Canagliflozin are less than 2% which reveal that the proposed method is precise and is shown in Table 4 and 5.

E. Limit of Detection (LOD) and Limit of Quantification (LOQ)

The LOD and LOQ of Canagliflozin were found 0.002669 ng and 0.008007 ng, respectively.

STABILITY INDICATING STUDY

From the forced degradation, it was clear that there was no effect of photolytic degradation on the drug as it was completely recovered (Figure 6). Moreover, the acid stability of Canagliflozin was also appreciable as it was degraded to a negligible amount (Figure 2). However, in the case of alkaline hydrolysis, thermal and oxidation degradation, complete degradation of the drug was seen. In the case of acid hydrolysis, alkaline hydrolysis and oxidation degradation were observed and are shown in the respective chromatograms (Figure 3-5). Nonetheless, the method was able to isolate completely the degradation products from the intact Canagliflozin.

This confirmed stability-indicating the property of the proposed method. The concentration of the produced degradation products analogous to the intact Canagliflozin was calculated and is shown in table 7.

The HPLC chromatogram of standard Canagliflozin and that of Brand 1 and 2 are shown in figure 8-10.

The current invention epitomizes the report that deals with the development of a stability-indicating HPLC method for determination of Canagliflozin in two different brands. The values of accuracy, precision, LOD, and LOQ were within the limits. Canagliflozin is very sensitive so it is unstable in alkaline, oxidative and thermal conditions but stable in UV light or acid conditions. Statistical analysis for the results demonstrates that the method is suitable for the determination of Canagliflozin in different marketed drugs without any

interference from the degradation products, and it is endorsed for routine use in quality control industry laboratories.

While considerable emphasis has been placed herein on the specific features of the preferred embodiment, it will be appreciated that many additional features can be added and that many changes can be made in the preferred embodiment without departing from the principles of the disclosure. These and other changes in the preferred embodiment of the disclosure will be apparent to those skilled in the art from the disclosure herein, whereby it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the disclosure and not as a limitation.

WE CLAIM,

1. A method for measuring caragliflozin by HPLC comprising the following:
using an octadecyl silane bonded silica gel as a chromatographic column filler;
a 5mM mM Ammonium formate: MeOH (25:75 v/v) is used as a mobile phase for isocratic elution,
a flow rate is 1 mL/min, the column temperature is 40 degree C;
an ultraviolet detector is to detect caragliflozin, and
a detection wavelength of the ultraviolet detector is 290 nm.
2. The method for measuring caragliflozin as claimed in claim 1, is characterized in that the chromatographic column dimensions are 100 mm × 4.6 mm.
3. The method for measuring caragliflozin as claimed in claim 1, is characterized in that the chromatographic column length is 100 mm.
4. The method for measuring caragliflozin as claimed in claim 1, is characterized in that the particle size of the chromatographic column filler is 3.5 μm.
5. The method for measuring caragliflozin as claimed in claim 1, is characterized in that the flow rate is 1.0 mL/min, and the column temperature is 40 degree C column temperature.
6. The method for measuring caragliflozin as claimed in claim 1, for measuring caragliflozin is characterized in that the detection wavelength of the ultraviolet detector is 290 nm.
7. The method for measuring caragliflozin as claimed in claim 1, for measuring caragliflozin is characterized in that the retention time is 2.6 minutes.
8. The method for measuring caragliflozin as claimed in claim 1, for measuring caragliflozin is characterized in that the run time is 6 minutes.

Dated this 24 February 2021

Dr. Amrish Chandra
Agent of the applicant
IN/PA No: 2959

TITLE: HPLC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF CANAGLIFLOZIN IN BULK AND MARKETED DOSAGE FORM

ABSTRACT

The present invention relates to an efficient and simple HPLC method developed and validated for the determination of anti-diabetic drug canagliflozin in marketed formulations containing canagliflozin.

FORM 5
THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003
DECLARATION AS TO INVENTORSHIP
[*See* section 10 (6) and rule 13 (6)]

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hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of my/our application numbered dated is/are

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Dated this 24 February 2021

Signature
Name: Amrish Chandra
(IN/PA 2959)

3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY THE APPLICANT(S) IN THE CONVENTION COUNTRY:—

We the applicant(s) in the convention country hereby declare that our right to apply for a patent in India is by way of assignment from the true and first inventor(s).

Dated this **NOT APLICABLE**

Signature

Name:

4. STATEMENT (to be signed by the additional inventor(s) not mentioned in the application form)
I /We assent to the invention referred to in the above declaration, being included in the complete specification filed in pursuance of the stated application.

NOT APLICABLE
Dated
Signature of the additional inventor(s):
Name:

To,
The Controller of Patents
The Patent Office, at New Delhi

Mrs. Asmita Vikas Gaikwad
Dr. Preeti Khulbe
Dr. Ganesh Yogiraj Dama
Dr. Manojkumar Mukundrao Nitalikar

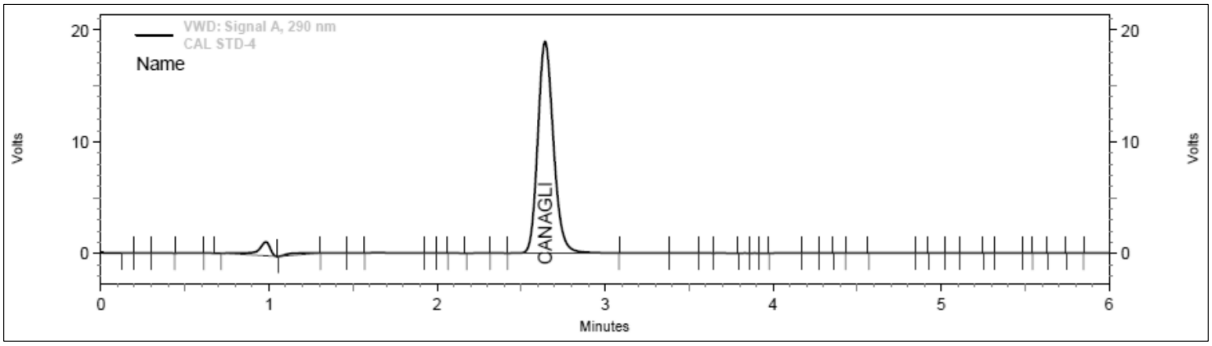

Figure 1

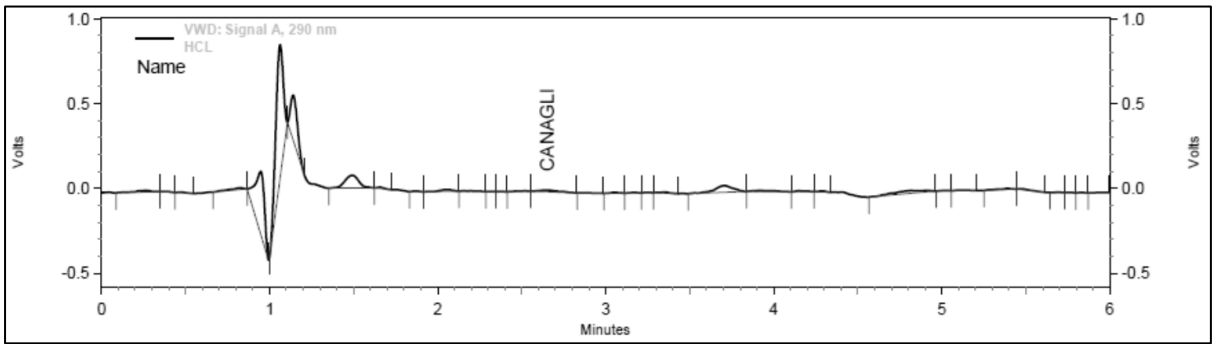

Figure 2

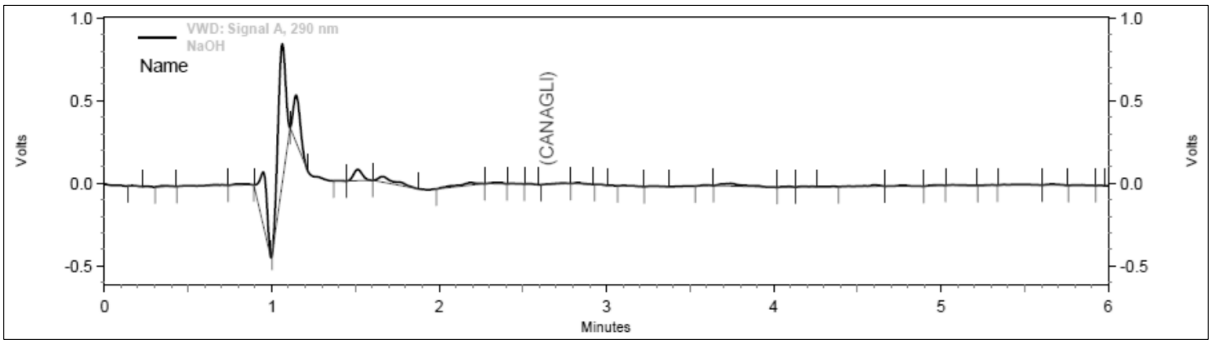

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Figure 3

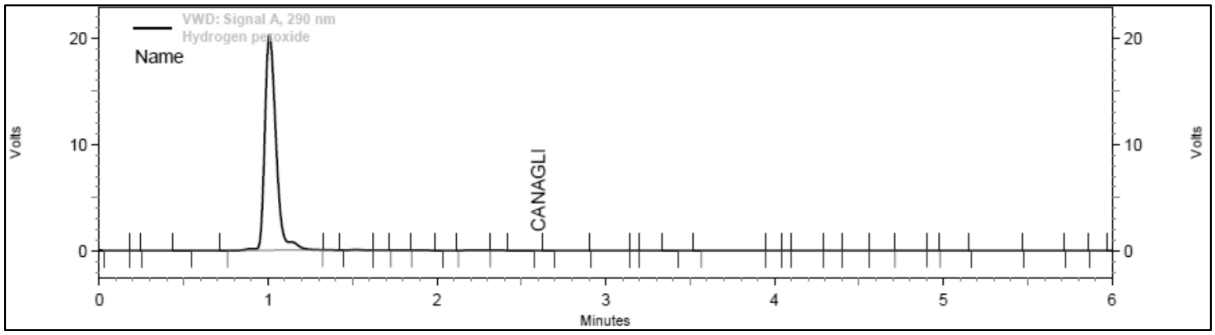

Figure 4

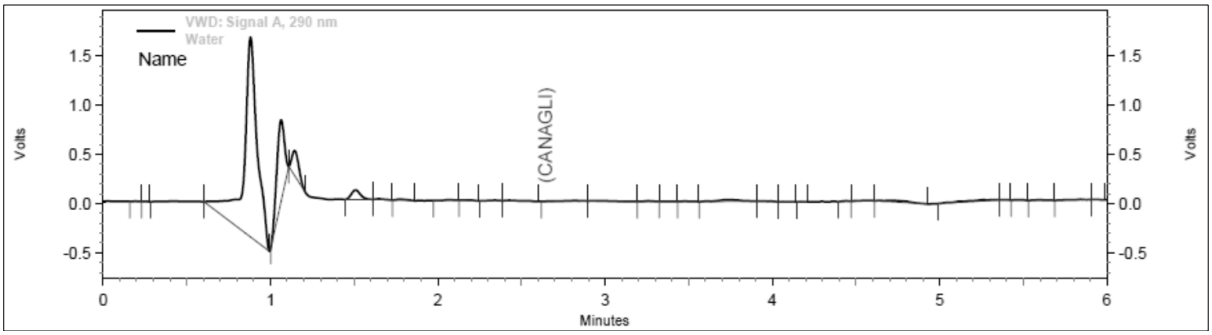

Figure 5

Amrish Chandra
Agent of the Applicant
IN/PA-2959

Mrs. Asmita Vikas Gaikwad
Dr. Preeti Khulbe
Dr. Ganesh Yogiraj Dama
Dr. Manojkumar Mukundrao Nitalikar

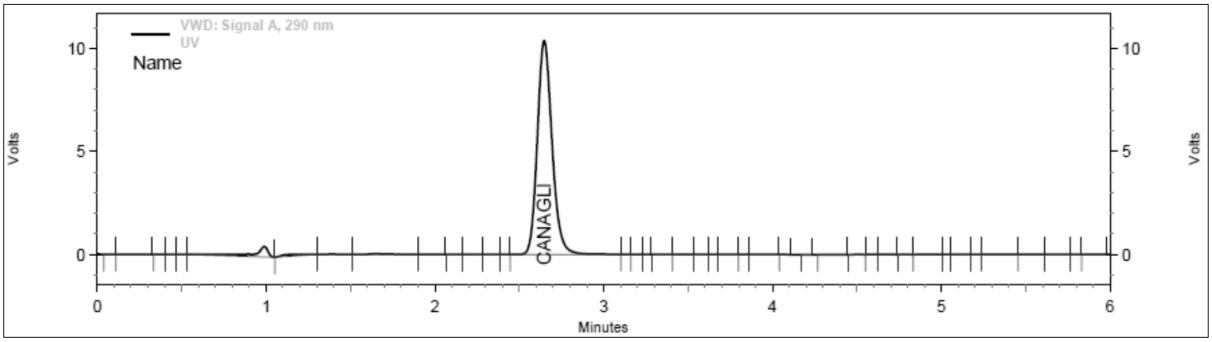

Figure 6

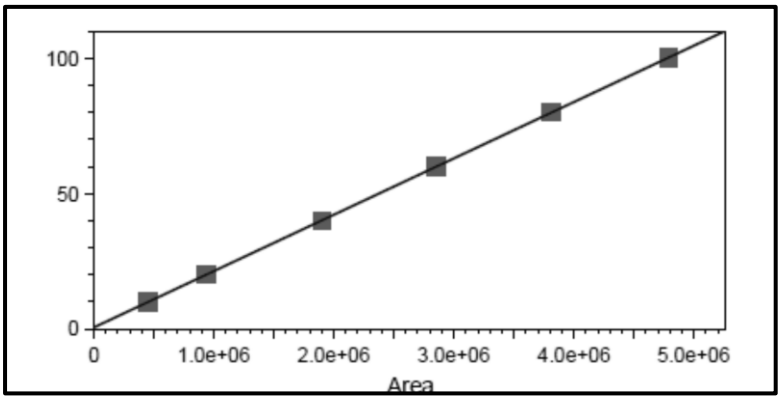

Figure 7

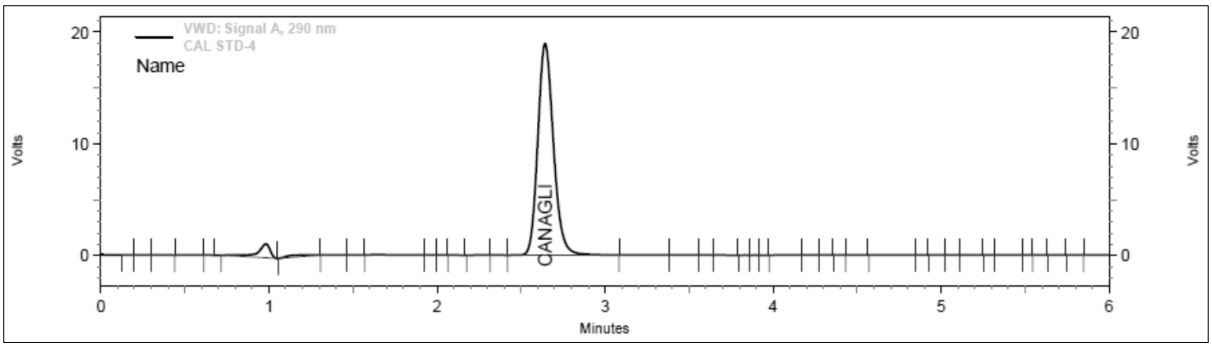

Figure 8

Amrish Chandra
Agent of the Applicant
IN/PA-2959

Mrs. Asmita Vikas Gaikwad
Dr. Preeti Khulbe
Dr. Ganesh Yogiraj Dama
Dr. Manojkumar Mukundrao Nitalikar

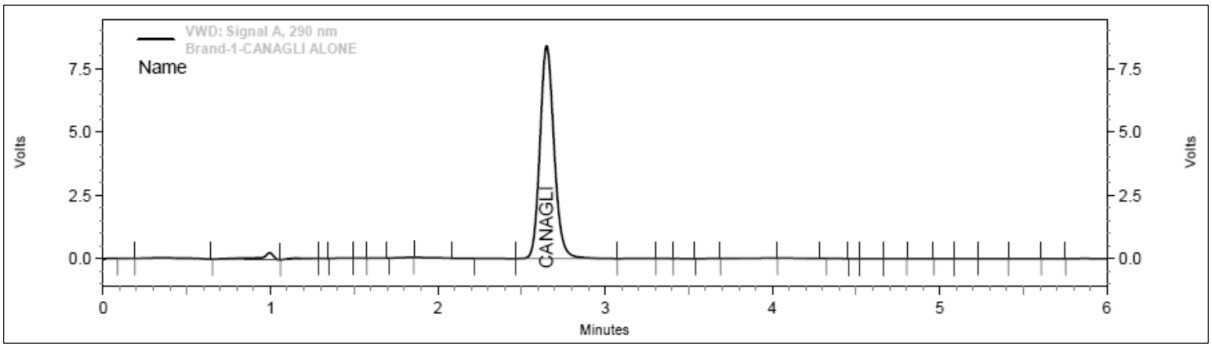

Figure 9

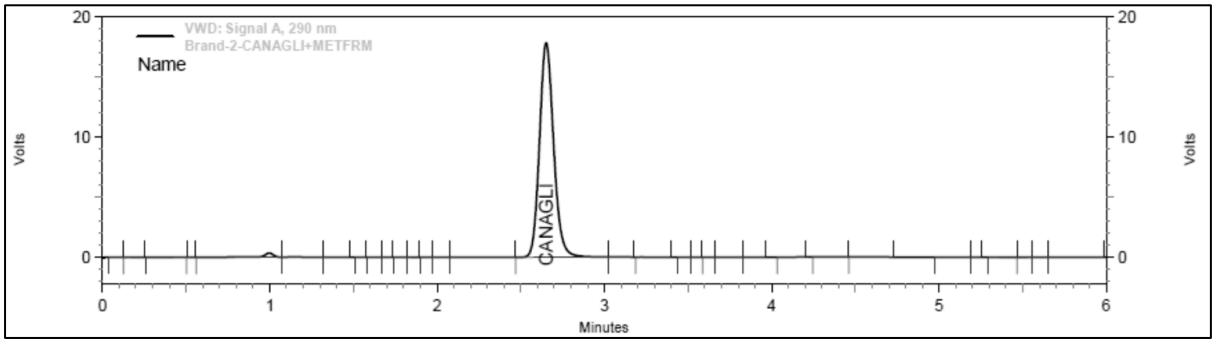

Figure 10

Amrish Chandra
Agent of the Applicant
IN/PA-2959

"**FORM 1** THE PATENTS ACT 1970 (39 of 1970) and THE PATENTS RULES, 2003 **APPLICATION FOR GRANT OF PATENT** (See section 7, 54 and 135 and sub-rule (1) of rule 20)		(FOR OFFICE USE ONLY)
	Application No.	
	Filing date:	
	Amount of Fee paid:	
	CBR No:	
	Signature:	
1. APPLICANT'S REFERENCE / IDENTIFICATION NO. (AS ALLOTTED BY OFFICE)		

2. TYPE OF APPLICATION [Please tick (√) at the appropriate category]

Ordinary (√)		Convention ( )		PCT-NP ( )	
Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )

3A. APPLICANT(S)			
Name in Full	**Nationality**	**Country of Residence**	**Address of the Applicant**
Mrs. Asmita Vikas Gaikwad	Indian	India	Research Scholar Suresh Gyan Vihar University & (Assistant Professor, SGMSPMs, Sharadchandra Pawar College of Pharmacy, Dumbarwadi, Pune), Mahal Jagatpura Jaipur 302017 Rajasthan India
Dr. Preeti Khulbe	Indian	India	Suresh Gyan Vihar University, Mahal Jagatpura Jaipur 302017 Rajasthan India
Dr. Ganesh Yogiraj Dama	Indian	India	SGMSPMs, Sharadchandra Pawar College of Pharmacy, At Dumbarwadi, Post Khamundi, Taluka- Junnar, 412409 Pune, Maharashtra, India

Dr. Manojkumar Mukundrao Nitalikar	Indian	India	Rajarambapu College of Pharmacy, Kasegaon Dist Sangli 415404 Maharashtra India

3B. CATEGORY OF APPLICANT [Please tick (√) at the appropriate category]

Natural Person (√) Small Entity ( ) Start up ( ) Others ( )

4. INVENTOR(S) [Please tick (√) at the appropriate category]

Are all the inventor(s) same as the applicant(s) named above? YES

Name in Full	Nationality	Country of Residence	Address of the Inventor
Mrs. Asmita Vikas Gaikwad	Indian	India	Research Scholar Suresh Gyan Vihar University & (Assistant Professor, SGMSPMs, Sharadchandra Pawar College of Pharmacy, Dumbarwadi, Pune), Mahal Jagatpura Jaipur 302017 Rajasthan India
Dr. Preeti Khulbe	Indian	India	Suresh Gyan Vihar University, Mahal Jagatpura Jaipur 302017 Rajasthan India
Dr. Ganesh Yogiraj Dama	Indian	India	SGMSPMs, Sharadchandra Pawar College of Pharmacy, At Dumbarwadi, Post Khamundi, Taluka- Junnar, 412409 Pune, Maharashtra, India
Dr. Manojkumar Mukundrao Nitalikar	Indian	India	Rajarambapu College of Pharmacy, Kasegaon Dist Sangli 415404 Maharashtra India

5. TITLE OF THE INVENTION

HPLC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF CANAGLIFLOZIN IN BULK AND MARKETED DOSAGE FORM

6. AUTHORISED REGISTERED PATENT

AGENT(S)
IN/PA No. IN/PA 2959
Name AMRISH CHANDRA
Mobile No. 9971117009

IN/PA No. IN/PA 2700
Name RAMANPREET WALIA

7. ADDRESS FOR SERVICE OF APPLICANT IN INDIA

Name AMRISH CHANDRA
Postal Address T21/1602, PARAS TIEREA, SECTOR 137, NOIDA 201301
Mobile No. 9971117009
E-mail ID info@lexgin.com

8. IN CASE OF APPLICATION CLAIMING PRIORITY OF APPLICATION FILED IN CONVENTION COUNTRY, PARTICULARS OF CONVENTION APPLICATION

Country	Application Number	Filing date	Name of the applicant	Title of the invention	IPC (as classified in the convention

9. IN CASE OF PCT NATIONAL PHASE APPLICATION, PARTICULARS OF INTERNATIONAL APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT)

International application number	International filing date

10. IN CASE OF DIVISIONAL APPLICATION FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION

Original (first) application No.	Date of filing of original (first) application

11. IN CASE OF PATENT OF ADDITION FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT

Main application/patent No.	**Date of filing of main application**

12. DECLARATIONS

(i) Declaration by the inventor(s)

(**In case the applicant is an assignee**: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated

within the prescribed period).

I/We, the above named inventor(s) is/are the true & first inventor(s) for this Invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

Name	Signature
Gaikwad Mrs. Asmita Vikas	
Khulbe Dr. Preeti	
Dama Dr. Ganesh Yogiraj	
Nitalikar Dr. Manojkumar Mukundrao	

Date 24 February 2021

(ii) Declaration by the applicant(s) in the convention country

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period)

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date
(b) Signature(s) **NOT APPLICABLE**
(c) Name(s) of the signatory

(iii) Declaration by the applicant(s)

I/We the applicant(s) hereby declare(s) that: -

√ I am/ We are in possession of the above-mentioned invention.

√ The ~~provisional~~/complete specification relating to the invention is filed with this application.

x The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.

√ There is no lawful ground of objection(s) to the grant of the Patent to me/us.

√ I am/we are the true & first inventor(s).

√ I am/we are the assignee or legal representative of true & first inventor(s).

x The application or each of the applications, particulars of which are given in Paragraph-8, was the first application in convention country/countries in respect of my/our invention(s).

x I/We claim the priority from the above mentioned application(s) filed in convention country/countries and state that no application for protection in respect of the invention had been made in a convention country before that date by me/us or by any person from which I/We derive the title.

x My/our application in India is based on international application under Patent Cooperation Treaty (PCT) as mentioned in Paragraph-9.

x The application is divided out of my /our application particulars of which is given in Paragraph-10 and pray that this application may be treated as deemed to have been filed on DD/MM/YYYY under section 16 of the Act.

x The said invention is an improvement in or modification of the invention particulars of which are given in Paragraph-11.

13. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION

(a) Form 2

Item	Details	Fee	Remarks
Complete/ ~~provisional~~ specification)#	No. of pages: 14	1600 INR	
No. of Claim(s)	No. of claims: 8 No. of pages: 2		
Abstract	No. of pages: 1		
No. of Drawing(s)	No. of drawings: 10 No. of pages: 4		

In case of a complete specification, if the applicant desires to adopt the drawings filed with

his provisional specification as the drawings or part of the drawings for the complete specification under rule 13(4), the number of such pages filed with the provisional specification are required to be mentioned here.

(b) Complete specification (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).

(c) Sequence listing in electronic form

(d) Drawings (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).

(e) Priority document(s) or a request to retrieve the priority document(s) from DAS (Digital Access Service) if the applicant had already requested the office of first filing to make the priority document(s) available to DAS.

(f) Translation of priority document/Specification/International Search Report/International Preliminary Report on Patentability.

(g) Statement and Undertaking on Form 3

(h) Declaration of Inventorship on Form 5

(i) Power of Authority

I/We hereby declare that to the best of my/our knowledge, information and belief the fact and matters slated herein are correct and I/We request that a patent may be granted to me/us for the said invention.

Dated this 24 February 2021

Signature: 

Name: Amrish Chandra
IN/PA2959

To,
The Controller of Patents
The Patent Office, at
New Delhi

FORM 9

THE PATENTS ACT, 1970 (39 of 1970)

&

THE PATENTS RULES, 2003

REQUEST FOR PUBLICATION

[*See* section 11A (2); rule 24A]

I /We

Name in Full	Mrs. Asmita Vikas Gaikwad
Nationality	Indian
Country of Residence	India
Address of the Applicant	Research Scholar Suresh Gyan Vihar University & (Assistant Professor, SGMSPMs, Sharadchandra Pawar College of Pharmacy, Dumbarwadi, Pune), Mahal Jagatpura Jaipur 302017 Rajasthan India
Name in Full	Dr. Preeti Khulbe
Nationality	Indian
Country of Residence	India
Address of the Applicant	Suresh Gyan Vihar University, Mahal Jagatpura Jaipur 302017 Rajasthan India
Name in Full	Dr. Ganesh Yogiraj Dama
Nationality	Indian
Country of Residence	India
Address of the Applicant	SGMSPMs, Sharadchandra Pawar College of Pharmacy, At Dumbarwadi, Post Khamundi, Taluka- Junnar, 412409 Pune, Maharashtra, India
Name in Full	Dr. Manojkumar Mukundrao Nitalikar
Nationality	Indian
Country of Residence	India
Address of the Applicant	Rajarambapu College of Pharmacy, Kasegaon Dist Sangli 415404 Maharashtra India

hereby request for early Publication of my/our Patent application No. dated under section 11A(2) of the Act.

Dated this 24 February 2021

Signature……

Dr. Amrish Chandra

IN/PA 2959

To

The Controller of Patents,
The Patent Office,
New Delhi

FORM 3

THE PATENTS ACT, 1970

(39 of 1970) AND
The Patents Rules, 2003

STATEMENT AND UNDERTAKING UNDER SECTION 8

[See section 8; rule 12]

I/We,

Name in Full	Mrs. Asmita Vikas Gaikwad
Nationality	Indian
Country of Residence	India
Address of the Applicant	Research Scholar Suresh Gyan Vihar University & (Assistant Professor, SGMSPMs, Sharadchandra Pawar College of Pharmacy, Dumbarwadi, Pune), Mahal Jagatpura Jaipur 302017 Rajasthan India
Name in Full	Dr. Preeti Khulbe
Nationality	Indian
Country of Residence	India
Address of the Applicant	Suresh Gyan Vihar University, Mahal Jagatpura Jaipur 302017 Rajasthan India
Name in Full	Dr. Ganesh Yogiraj Dama
Nationality	Indian
Country of Residence	India
Address of the Applicant	SGMSPMs, Sharadchandra Pawar College of Pharmacy, At Dumbarwadi, Post Khamundi, Taluka- Junnar, 412409 Pune, Maharashtra, India
Name in Full	Dr. Manojkumar Mukundrao Nitalikar
Nationality	Indian
Country of Residence	India
Address of the Applicant	Rajarambapu College of Pharmacy, Kasegaon Dist Sangli 415404 Maharashtra India

hereby declare:

(i) that We have not made any application for the same/substantially the same invention outside India

OR

(ii) ~~that we who have made this application No. dated , alone/jointly, made for the same/substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:~~

Name of the Country	Date of Application	Application number	Status of the application	Date of publication	Date of grant

Not applicable

(iii) ~~that the rights in the application(s) has been assigned to~~ NOT APPLICABLE

That I/We undertake that up to the date of grant of patent, by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within three months from the date of filing of such application.

Dated this 24 February 2021

Amrish Chandra (IN/PA 2959)
Patent Agent for the Applicant

To,
The Controller of Patents
The Patent Office at New Delhi