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STANDARDIZATION OF ANALYTICAL PARAMETERS OF RAJAHPRAVARTINI VATI

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ABSTRACT:

Ayurvedic medicines have a long therapeutic history and are still serving many of the health needs of a large population of the world. However, the quality control and quality assurance still remains a challenge because of the high variability of chemical components involved.Ayurvedic drugs are combination of herbal,minerals,herbo-mineral and animal products.In this study *Rajahpravartini vati* subjected to organoleptic analysis,Physical tests,chemical tests, qualitative analysis to detect the presence of various functional groups, and to high performance thin layer chromatography (HPTLC) examination by optimizing the solvent systems and Quality control standards/tests for tablets**.** The results revealed Tablets were within the prescribed limit of deviation, Friability of Compressed tablets was 0.81%,Disintegration time-16min,13sec,Hardness-1.0kg/cm,Diameter-10.2mm,Total bacterial count in *RPV* was within permissible limit and free from fungal contaminations was found. In phytochemicals Carbohydartes,Anthraquinone glycosides,Tannins,Resin etc were present and spots at 366 nm were found.

Keywords: *Rajahpravartini vati*,Quality control ,Standardization,HPTLC.

INTRODUCTION: A key obstacle which has hindered the acceptance of the alternative medicines in the developed countries is the lack of documentation and rigorous quality control. There is a need for documentation of research work carried out on traditional medicines. With this backdrop, it becomes extremely important to make an effort toward standardization of the traditional medicines. Administration of drug in various dosage forms provides an opportunity to the physician to choose better options. Various dosage forms have been described in the *Ayurvedic* texts. One among them is *Kharaleeya rasayanas*.In the present study, *Rajahpravartini vati*, a known formulation used *Kashtarthava* and *Nashtarthava* mentioned in *stree rogadhikara* of Bhaishajya Ratnavali[1] and also in AFI[2] approved by Govt of India. There is a need of Standardization and documentation of formulation in present era. Hence , with the intention of standardization and quality control of the Herbo-mineral formulation, *Rajahpravartini vati* was Punched into tablet form and analyzed by various analytical parameters.

AIMS AND OBJECTIVES

- To Standardize the analytical parameters of *Rajahpravartini vati*
- To carryout physico-chemical analysis of *Rajahpravartini vati.*

MATERIALS AND METHODS

Procurement and preparation of plant material

The crude drugs mentioned in Bhaishajya Ratnavali in *stree Rogadhikara* for the preparation of *Rajahpravartini vati* were

taken from the pharmacy of Kajarekar Belagavi.All the raw drugs are checked for genuinity by API parameters and mosabbar prepared in Pharmacy of TGAMC PG dept of RS & BK Ballari.

Table 1 – Showing ingredients of *Rajahpravartini vati*

Ingredients	Quantity
Shodhita kasisa	1part
Shodhita Tankana	1part
Shodhita Hingu	1part
Kanyasaara	1part
Kumari swarasa	Q.S

Preparation of *Rajahpravartini vati:* All the ingredients are selected according to their *Grahya Lakshanas*,analysis as per API and are subjected to *Shodhana* individually with different *Dravyas*. After *Shodhana*, all drugs taken in mentioned quantity triturated by *kumari swarasa* for 3 times.The detail of this pharmaceutical study cited at Priyanka et.al[3].

Rajahpravartini vati were subjected to various analytical parameters as follows.

• Organoleptic parameters: *Rupa* (color), *Rasa* (taste),*Gandha* (odor) and *Sparsha* (touch)

• Physico-chemical parameters: pH of 5% aqueous soln[4], loss on drying at 110°C[5], ash value[6], acid insoluble ash[7], water soluble extractive[8]

• Quantitative tests for tablet: Weight variation test[9], tablet hardness test[10], tablet disintegration time[11], friability test[12]

• Preliminary phytochemicals like Tannin,Resin and etc.

• Chromatographic analysis: High Performance Thin Layer Chromatographic (HPTLC)[13]

• Microbial overload[14]: Bacterial and fungal growth study was carried out

• Reagents and chemicals: All the reagents and chemicals used for the study were of analytical grade.

Qualitative and Quantitative chemical tests of RPV-BB (*Rajahpravartini vati before bhavana*) and RPV-AB (*Rajahpravartini vati after Bhavana*) were done at ALN Rao Ayurvedic Medical College Koppa.

Quality standards of tablets and microbial load of *RPV* were done at SDM Ayurvedic Medical College and Research centre, Kuthpady, Udupi.

RESULTS

Table 2 - Showing classical Parameters for analysis of RPV-BB and RPV-AB

Test	Observation of RPV-BB	Observation of RPV-AB
Varna	Whitish cream	Brownish black
Sparsha	*Mridutva and Slakshnatva*	*Lavana*
Gandha	Characteristic	*Sukshma*
Rasa	*Lavana,Madhura*	Characteristic.

MODERN PARAMETERS

Table 3 - Showing result of Organoleptic Characters of RPV-BB and RPV-AB

Parameters	RPV-BB	RPV-AB
Color	Creamish-green	Greenish-brown

Odor	Characteristic	Characteristic
Taste	Astringent, salty, sweet	Astringent, salty
Touch	Rough fine powder	Rough fine powder

Table 4 – Showing results of Physico – chemical parameters of RPV-BB and RPV-AB

Tests	**RPV-BB**	**RPV-AB**
Loss on drying at 110^0 C	10.50%	11.50%
Total Ash	78.25%	49.00%
Acid insoluble ash	67.50%	5.50%%
Water soluble ash	23.50%	63.50%
pH	8.19±0.10	7.63±0.10%
Water soluble Extractive	36.80%	43.80%
Alcohol soluble Extractive	14.25%	13.10%

Table 5: Quality Control Standards/Tests For Tablets

TESTS	**RESULTS**
Uniformity of weight	within normal limits
Hardness Test	1.0kg/cm
Friability Test	0.81%.
Disintegration time	16min,13sec
Diameter	10.2mm

Volumetric Analysis Of Iron And Boron

IRON

- RPV-BB - 10.05%
- RPV-AB - 8.93%

BORON

- RPV-BB - 4.59%
- RPV-AB - 5.51%

Table 6: Preliminary Phytochemical tests for RPV

Test	RPV-BB	RPV-AB
Alkaloid	Present	Present
Carbohydrate	Present	Present
Flavanoids	Present	Present
Protein	Absent	Present
Cardiac Glycosides	Absent	Present
Anthraquinone Glycosides	Absent	Present
Tannin	Present	Present
Terpenoid	Present	Present
Phytosteroids	Present	Present
Saponins	Present	Present
Coumarin	Absent	Present

Phenols	Present	Present
Carboxylic acid	Absent	Present
Resin	Present	Present
Quinone	Absent	Present

Table 7 Showing R_f values of All the samples At 254 nm

Sh.Hingu	**Mosabbar**	**RPV – BB**	**RPV – AB**
0.04(D.green)	-	-	-
0.06(L.green)	-	-	-
0.10(D.green)	-	-	-
0.18(D.green)	-	-	-
-	0.25(D.green)	-	-
0.62(D.green)	-	-	-
0.85(D.green)	-	-	-

Table 8 Showing R_f values of All the samples At 366 nm

Sh.Hingu	**Mosabbar**	**RPV – BB**	**RPV – AB**
0.06(F,blue)	-	0.06(F,blue)	0.06(F,blue)
0.10(F,blue)		0.10 (F,blue)	0.10 (F,blue)
0.15(F,blue)		0.15 (F,blue)	0.15(F,blue)
0.24(F,blue)	0.24(F,Orange)	0.24(F,blue)	0.24(F,blue)
0.33(F,blue)		0.33(F,blue)	0.33(F,blue)
0.39(F,blue)	-	0.39(F,blue)	-
0.44(F,blue)	-	0.44(F,blue)	-
0.53(F,blue)	0.53(F,Red)	0.53(F,blue)	-
0.66(F,blue)	-	0.66(F,blue)	0.66(F,blue)

L – Light; D- Dark; M – Medium; F – Fluorescent.

MICROBIAL LIMIT TEST

Table 9 - Showing Total bacterial count of RPV in CFU-Colony Forming Units

Sl. No.	**Dilutions**	**Number Of Colonies (NOC)**			**CFU/g**
1	1/10 (10^{-1})	8	5	-----	6.5×10^{1}
2	1/100 (10^{-2})	0	1	----	1.0×10^{2}

Results-Total bacterial count in the received sample RPV is within permissible limit.

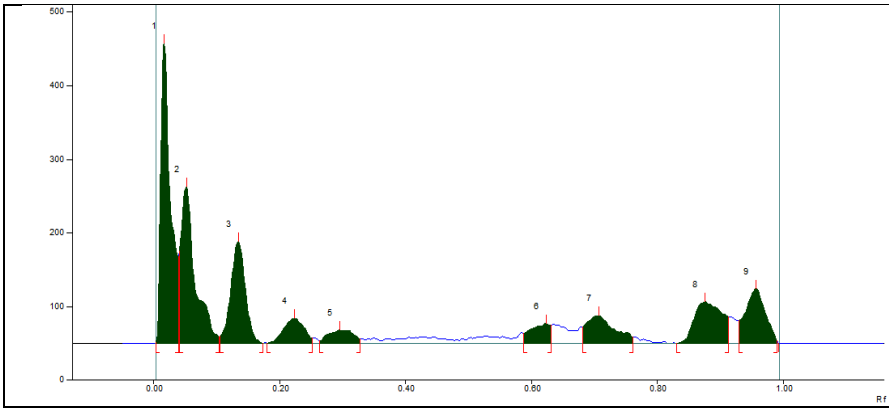
Table 10 - Showing Total fungal count of RPV in CFU-Colony Forming Units

Sl. No.	Dilutions	Number Of Colonies (NOC)			**CFU/g**
1	1/10 (10^{-1})	0	0	0	0
2	1/100 (10^{-2})	0	0	0	0
3	1/1000 (10^{-3})	0	0	0	0

Results- The received sample RPV is free from fungal contaminations.

DISCUSSION: *Rajahpravartini vati* is a Herbo-mineral formulation which is indicated in *Kashtarthava and Nashtarthava*. Here tablets are punched by dry punching. The organoleptic parameters form the basic criteria for selecting a raw drug and also to confirm the finished product. Texture of tablets was smooth indicating the surface uniformity without cracks. This is the primary character to assess the quality of tablets. Color was Greenish brown, taste was bitter and odor was characteristic due to the specific properties of the various ingredients. The pH conventionally represents the acidity and alkalinity; The pH of RPV-BB and RPV-AB are 8.19 $\pm$ 0.10 and 7.63 $\pm$ 0.10 respectively. This indicates that, RPV-AB is basic in nature. RPV contains *Tankana* which is an alkali, and Alkaloid piperine which is weak base. This may be reason of alkalinity of RPV. RPV-BB is weak acidic in nature, so here after *Kumari swarasa Bhavana* it changed basic in nature. RPV-BB and RPV-AB were evaluated for ash value and it was found to be 78.25% and 49.00% respectively which indicates less amount of inorganic material in RPV. Acid insoluble ash is 94.50% which means 94.50% of bio-active drug components are soluble. Water soluble ash increased after *Bhavana* which denotes the salivary secretions, gastric enzymes play an important role in the efficacy of RPV-AB. The drug is having least hydroscopic activity with less chances of contamination of drug. Concurrently it can be stated that the shelf life of the drug in the present study is more. It contains Iron and Boron as formulation contains source of iron i e *Kasisa* and source of Boron i e *Tankana* as a ingredients. The drug RPV is free from Bacteria and as well Fungal contamination. Rf value of *Sh.Hingu and Mosabbar* its colour banding matching with Rf value of RPV-AB at 366nm in Fluorescent, hence the bands presents in RPV is may be due to *Sh.Hingu and Mosabbar*. The present study reveals presence of Resin,tannin, saponnin, flavonoids and etc preliminary phytochemicals in the drug RPV.

Figure 1. HPTLC photo documentation of *Rajahpravartini vati*, RPV-BB, *Sh.Hingu and Mosabbar*

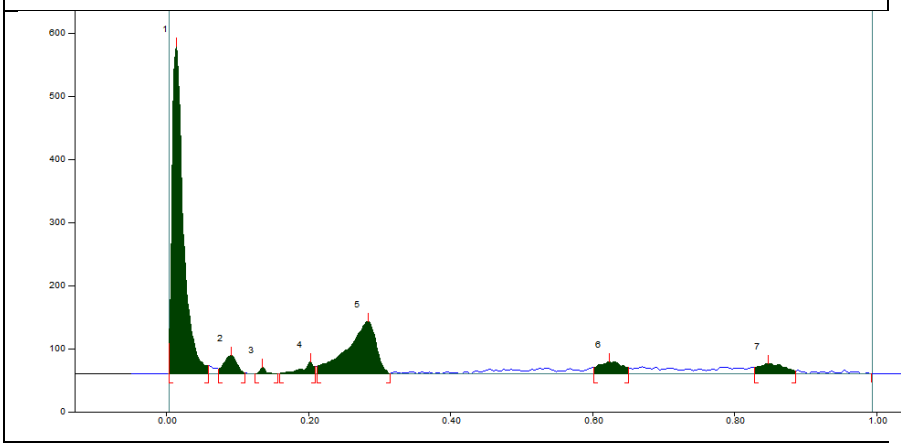


Short UV	Long UV	Post derivatization

Track 6, ID: Shoditha hingu

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	1.1 AU	0.02 Rf	408.4 AU	40.51 %	0.04 Rf	17.6 AU	4646.2 AU	27.11 %
2	0.04 Rf	124.8 AU	0.05 Rf	212.7 AU	21.10 %	0.10 Rf	9.1 AU	3478.5 AU	20.29 %
3	0.11 Rf	9.7 AU	0.14 Rf	139.1 AU	13.80 %	0.17 Rf	0.4 AU	2317.9 AU	13.52 %
4	0.18 Rf	0.5 AU	0.22 Rf	34.1 AU	3.38 %	0.25 Rf	7.0 AU	810.3 AU	4.73 %
5	0.26 Rf	3.3 AU	0.30 Rf	18.1 AU	1.79 %	0.33 Rf	5.8 AU	535.1 AU	3.12 %
6	0.59 Rf	13.3 AU	0.62 Rf	26.8 AU	2.66 %	0.63 Rf	24.3 AU	604.7 AU	3.53 %
7	0.68 Rf	22.4 AU	0.71 Rf	38.0 AU	3.77 %	0.76 Rf	8.9 AU	1228.2 AU	7.17 %
8	0.83 Rf	0.3 AU	0.88 Rf	56.4 AU	5.60 %	0.91 Rf	36.1 AU	1812.9 AU	10.58 %
9	0.93 Rf	30.7 AU	0.96 Rf	74.6 AU	7.40 %	0.99 Rf	3.5 AU	1707.0 AU	9.96 %

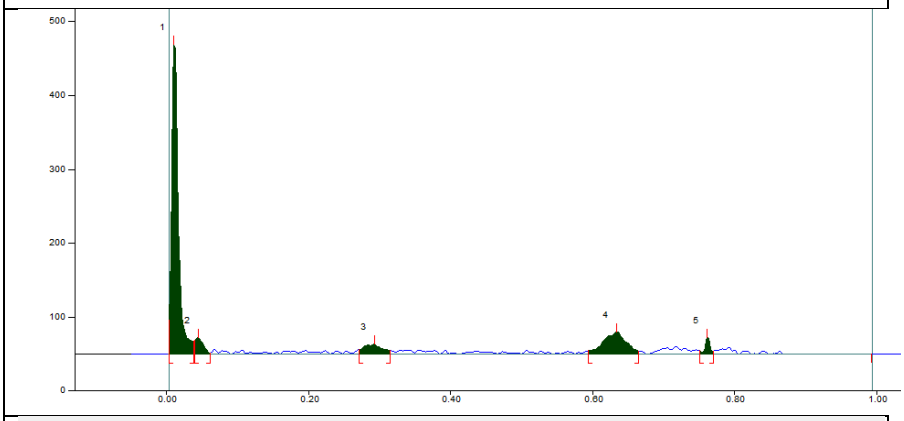
Fig 2a. Shoditha hingu



Track 7, ID: Mosabbar

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	47.3 AU	0.01 Rf	517.8 AU	74.58 %	0.06 Rf	12.3 AU	5852.8 AU	59.89
2	0.07 Rf	7.7 AU	0.09 Rf	29.5 AU	4.24 %	0.11 Rf	1.7 AU	379.8 AU	3.89
3	0.13 Rf	0.2 AU	0.14 Rf	10.4 AU	1.51 %	0.16 Rf	0.0 AU	57.6 AU	0.59
4	0.16 Rf	0.6 AU	0.20 Rf	18.2 AU	2.62 %	0.21 Rf	11.2 AU	206.1 AU	2.11
5	0.21 Rf	12.1 AU	0.29 Rf	83.0 AU	11.96 %	0.32 Rf	0.6 AU	2399.3 AU	24.55
6	0.60 Rf	9.5 AU	0.62 Rf	19.2 AU	2.77 %	0.65 Rf	9.5 AU	450.9 AU	4.61
7	0.83 Rf	9.4 AU	0.85 Rf	16.1 AU	2.32 %	0.89 Rf	4.6 AU	426.2 AU	4.36

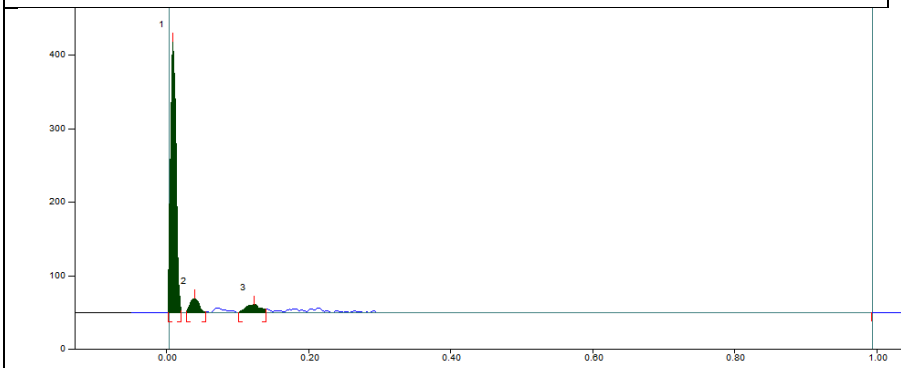
Fig 2b. Mosabbar



Track 8, ID: RPV-Before bhavana

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	45.7 AU	0.01 Rf	419.5 AU	82.68 %	0.04 Rf	17.1 AU	2880.1 AU	69.57 %
2	0.04 Rf	18.0 AU	0.05 Rf	22.0 AU	4.33 %	0.06 Rf	0.6 AU	192.3 AU	4.64 %
3	0.27 Rf	5.9 AU	0.29 Rf	13.3 AU	2.63 %	0.32 Rf	4.5 AU	252.7 AU	6.10 %
4	0.60 Rf	4.3 AU	0.64 Rf	30.0 AU	5.92 %	0.67 Rf	4.3 AU	695.5 AU	16.80 %
5	0.75 Rf	4.9 AU	0.76 Rf	22.5 AU	4.44 %	0.77 Rf	3.7 AU	119.4 AU	2.88 %

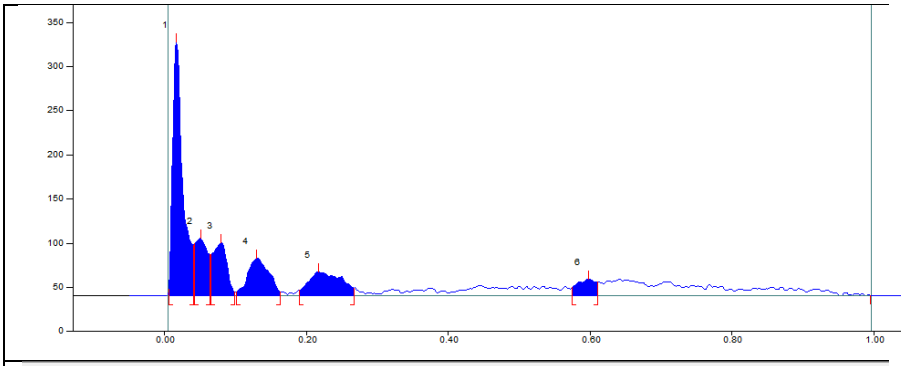
Fig 2c. RPV before Bhavana



Track 9, ID: RPV-After bhavana

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	0.0 AU	0.01 Rf	367.6 AU	92.30 %	0.02 Rf	2.6 AU	2026.8 AU	85.46 %
2	0.03 Rf	1.1 AU	0.04 Rf	19.2 AU	4.83 %	0.06 Rf	0.9 AU	177.7 AU	7.49 %
3	0.10 Rf	0.2 AU	0.12 Rf	11.4 AU	2.87 %	0.14 Rf	4.8 AU	167.2 AU	7.05 %

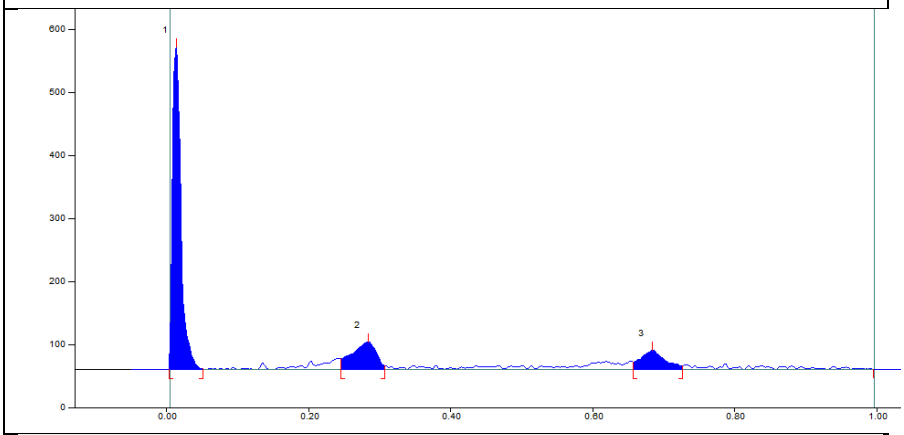
Fig 2d. RPV after Bhavana



Track 6, ID: Shoditha hingu

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01 Rf	7.2 AU	0.02 Rf	287.7 AU	57.51 %	0.04 Rf	57.3 AU	2980.3 AU	43.68 %
2	0.04 Rf	58.5 AU	0.05 Rf	64.7 AU	12.94 %	0.06 Rf	46.4 AU	809.6 AU	11.87 %
3	0.07 Rf	46.8 AU	0.08 Rf	59.5 AU	11.89 %	0.10 Rf	3.9 AU	866.6 AU	12.70 %
4	0.10 Rf	4.4 AU	0.13 Rf	42.2 AU	8.44 %	0.16 Rf	4.0 AU	922.1 AU	13.51 %
5	0.19 Rf	6.0 AU	0.22 Rf	27.3 AU	5.45 %	0.27 Rf	8.8 AU	895.5 AU	13.12 %
6	0.58 Rf	9.5 AU	0.60 Rf	18.9 AU	3.78 %	0.61 Rf	15.0 AU	349.3 AU	5.12 %

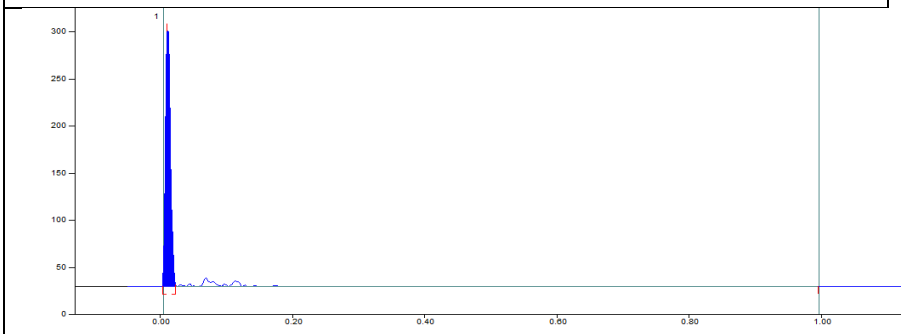
Fig 3a. Shoditha hingu



Track 7, ID: Mosabbar

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	0.0 AU	0.01 Rf	509.9 AU	87.26 %	0.05 Rf	1.1 AU	4387.7 AU	70.56 %
2	0.25 Rf	17.4 AU	0.29 Rf	43.4 AU	7.43 %	0.31 Rf	6.0 AU	1080.0 AU	17.37 %
3	0.66 Rf	11.8 AU	0.69 Rf	31.0 AU	5.30 %	0.73 Rf	5.1 AU	751.0 AU	12.08 %

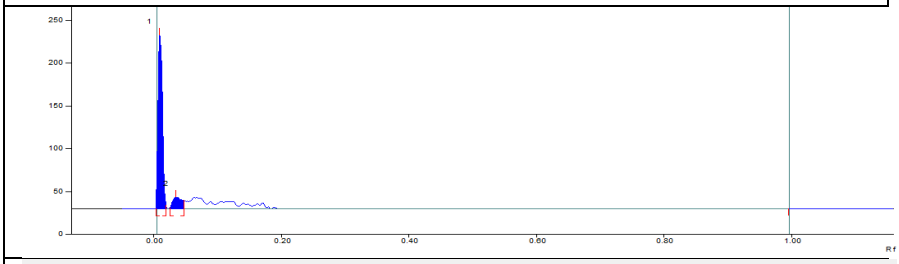
Fig 3b. Mosabbar



Track 8, ID: RPV-Before bhavana

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	0.0 AU	0.01 Rf	271.4 AU	100.00 %	0.02 Rf	2.0 AU	1510.2 AU	100.00 %

Fig 3c. RPV before Bhavana



Track 9, ID: RPV-After bhavana

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	0.0 AU	0.01 Rf	203.1 AU	93.57 %	0.02 Rf	4.0 AU	1016.8 AU	87.29 %
2	0.03 Rf	0.8 AU	0.04 Rf	14.0 AU	6.43 %	0.05 Rf	9.9 AU	148.0 AU	12.71 %

Fig 3d. RPV after Bhavana

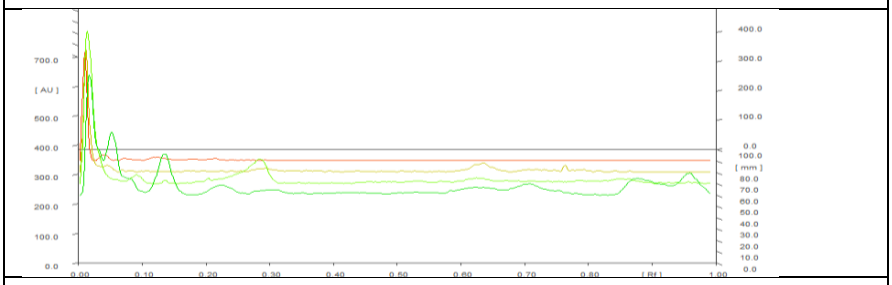


Fig 5a. At 254nm

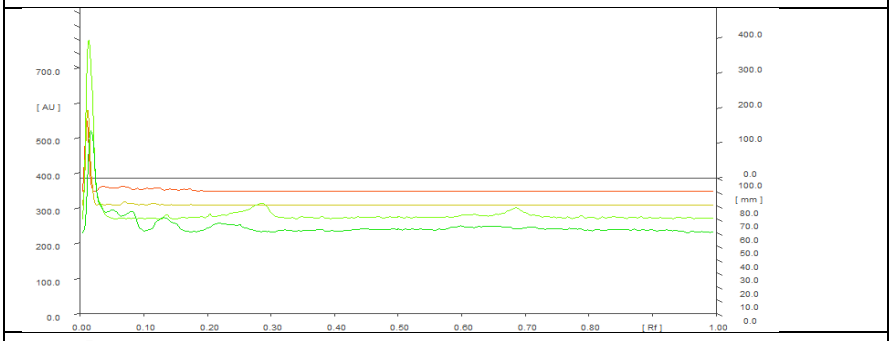


Fig 5b. At 366nm

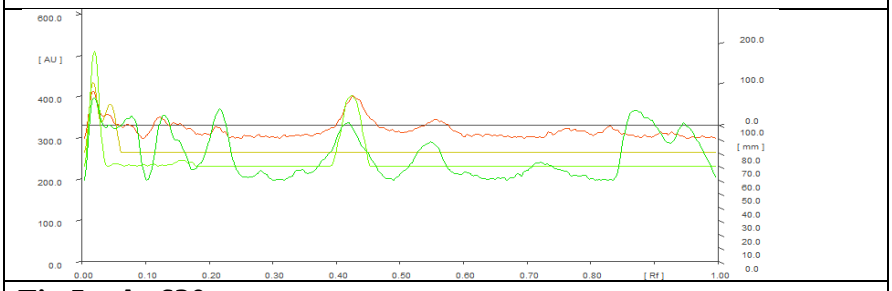
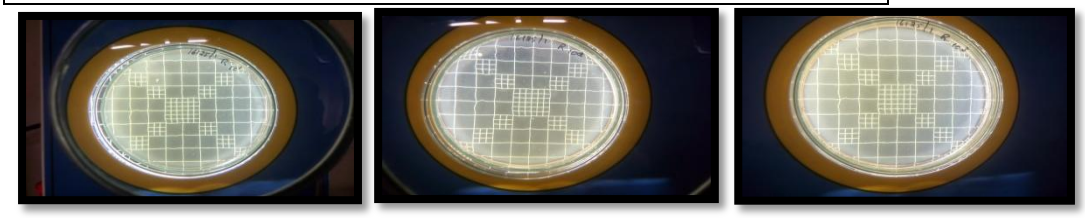


Fig 5c. At 620nm



RPV-TBC-1_10 **RPV -TBC-1_100** **RPV-TBC-1_1000**

CONCLUSION: The study reveals that sufficient quality control parameters were followed during the preparation of formulation. Organoleptic parameters, physico-chemical analysis,microbial overload analysis were carried out as per the norms of WHO guidelines and the absence of microbes in the finished product indicates the genuineness of final product. The quality standard test results were proved RPV tablets are within the normal limits. These are the parameters and reference standards for the quality control and quality assurance of *Rajahpravartini vati.*

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