PHARMACOPEIAL STANDARD DEVELOPMENT AND PHYSICOCHEMICAL RESEARCH STUDIES OF UNANI ANTI-PARALYTIC DRUG RAUGHAN-E-MOM (WAX OIL)

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ABSTRACT
Pharmacopeial Standard development, HPTLC. Fingerprinting and Physicochemical research studies of a Unani classical Anti-paralytic drug Raughan-e-Mom formulation used in the treatment of Falij (Paralysis) and Laqwa (Facial Paralysis) and other Neurological disorders from since ancient time. Three drugs samples of Raughan-e-Mom taken into these studies which prepared at the Pharmacy of CRIUM. (Under CCRUM. Ministry of AYUSH.) Hyderabad by employing authenticated standard methods. The quality control & quality assurance studies were conducted in accordance to the WHO., AOAC., IPC. and UPC. approved guidelines. The obtained physicochemical data showed that the drug samples contained Petroleum ether (60-80°C) Extractive, %,w/v. (84.16), Acid value (3.04), Iodine value (6.36), Peroxide value (8.62), Unsaponifiable matter (17.47), Refractive index(1.350), Weight per ml. (gm.) (0.91), Test for presence of Arachis oil, Cotton seed oil, Sesame, Mineral oil (all are negatives) were assessed in Raughan-e-Mom. The quality control
studies results revealed the absence of hazardous and toxic contamination from the drug samples. Moreover the obtained research studies data and comparative screening will provide the referential supportive information in the development of pharmacopeial standard monographs, identification, reinvestigation, quality assurance and pharmacovigilance of the drug.

**KEYWORDS:** Raughan-e-Mom, Anti-paralytic, development of pharmacopeial standards, physicochemical, comparative screening, quality control and quality assurance.

**INTRODUCTION**

The research study drug used is commonly as Anti-paralytic drug Raughan-e-Mom in Unani system of medicine by various Hakim (Physician) since ancient time as traditional and integrated medicines. The drug is reported reported to have various Action like Moharrir (Stimulant), Musakkin-e-Alam, (Analgesic) and is therapeutically used in Laqwa (Facial Paralysis), Falij (Paralysis or Hemiplegia), Waj-ul-Mafasil (Neuralgia). Raughan-e-Mom is oily viscous form, Liquid, dark brown colour, with aromatic odour.$^{[1,3,9-11]}$

**MATERIAL AND METHODS**

**Procurement of the plant material**

Raw drug samples were procured from raw drug national vendors Pharmacy CRIUM. and local Hyderabad region market. The Collected drug samples were identified and their botanical authentication were carried out by CRIUM, Hyderabad SMP. Unit and DSRU. Unit botanist and researchers. The required dried crude drug samples were procured, taken of each drug as per batch size of formula composition.

**Method of preparation**

Take both the ingredients of pharmacopoeial quality.

During preparation used Clean Mom-e-Zard waxy material and mix up it in to powdered of Namak-e-Shor then warmed and distilled it at low temperature for about 5½ hours, using distillation assembly to collect distillate of colourless viscous oily liquid Raughan-e-Mom(Wax oil). Filter it the total content while hot through a muslin cloth and allow to cool.

Then, pack in tightly closed containers protected it from light and moisture.
Description
Raughan-e-Mom is oily viscous liquid, Colorless, with aromatic odour.

Definition
Raughan-e-Mom is a viscous oil made with the ingredients in the formulation composition quantity. [1,10-11]

Sample 1, -RM1  Sample 2,-RM2  Sample 3,-RM3

Figure-1, Over view of Raughan-e-Mom formulated compound drug samples.

Formulation Composition of Raughan-e-Mom classical formulated drug.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Ingredients, Local Unani Name</th>
<th>English Name</th>
<th>Part Used</th>
<th>Quantity Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.</td>
<td>Mom-e-Zard</td>
<td>Yellow Wax</td>
<td>Bees wax</td>
<td>500 gm.</td>
</tr>
<tr>
<td>02.</td>
<td>Namak-e-Shor</td>
<td>Potassium Nitrate (Pure)</td>
<td>Mineral drug</td>
<td>1.5Kg.</td>
</tr>
</tbody>
</table>

Physicochemical screening
Physicochemical screening was carried out under the following parameters like Petroleum ether(60-80°C) Extractive, %,w/v., Acid value, Iodine value, Peroxide value, Unsaponifiable matter, Refractive Index,Weight per ml.(gm.),Test for presence of Arachis oil, Cotton seed
oil, Sesame and Mineral oil (all are negatives) were carried out as per IPC. approved standard methods.\textsuperscript{[2-3,6-7,9,11]}

**Quality Control**

Quality control was taken under the WHO, AOAC guidelines and IPC. approved format.\textsuperscript{[6-7,9,11]}

**Table-I. Uses and dose form the drug of Raughan-e-Mom formulated classical drugs.**

<table>
<thead>
<tr>
<th>Action with modern equivalents</th>
<th>Moharrik (Stimulant), Musakkin-e-lam (Analgesic).</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic uses with modern equivalents</td>
<td>Laqwa (Facial Paralysis), Falij (Paralysis or Hemiplegia), Waj-ul-Mafasil (Neuralgia)</td>
<td>([1,6-8])</td>
</tr>
<tr>
<td>Recommended dose form</td>
<td>Q.S., For external use</td>
<td></td>
</tr>
<tr>
<td>Mode of Administration</td>
<td>For local application as external use</td>
<td></td>
</tr>
</tbody>
</table>

**Table-II. Physicochemical parameters standardization of Raughan-e-Mom drug.**

<table>
<thead>
<tr>
<th>Parameters Analyzed</th>
<th>Sample 1, -RM1</th>
<th>Sample 2, -RM2</th>
<th>Sample 3, -RM3</th>
<th>Mean value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petroleu ether (60-80(^{\circ})C) Extractive,%, w/v.</td>
<td>77.69</td>
<td>86.99</td>
<td>87.81</td>
<td>84.16</td>
</tr>
<tr>
<td>Acid value</td>
<td>1.49</td>
<td>3.80</td>
<td>3.80</td>
<td>3.03</td>
</tr>
<tr>
<td>Iodine value</td>
<td>6.43</td>
<td>6.23</td>
<td>6.44</td>
<td>6.36</td>
</tr>
<tr>
<td>Peroxide value</td>
<td>7.98</td>
<td>8.72</td>
<td>9.18</td>
<td>8.62</td>
</tr>
<tr>
<td>Unsaponifiable matter</td>
<td>13.98</td>
<td>21.49</td>
<td>16.96</td>
<td>17.47</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>1.350</td>
<td>1.350</td>
<td>1.350</td>
<td>1.350</td>
</tr>
<tr>
<td>Weight per ml. (gm)</td>
<td>0.87</td>
<td>0.91</td>
<td>0.96</td>
<td>0.91</td>
</tr>
<tr>
<td>Arachis oil</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
</tr>
<tr>
<td>Cotton seed oil</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
</tr>
<tr>
<td>Mineral oil</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
</tr>
<tr>
<td>Sesame oil</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
<td>-tive</td>
</tr>
</tbody>
</table>

**Table-III. Estimation of Microbial load and contamination.**

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters Analyzed</th>
<th>Result</th>
<th>WHO. &amp; API. Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sample1, -RM1</td>
<td>Sample2, -RM2</td>
</tr>
<tr>
<td>1.</td>
<td>Total Bacterial Count</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>2.</td>
<td>Total Fungal Count</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>3.</td>
<td>\textit{Salmonella Spp.}</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>4.</td>
<td>\textit{Staphylococcus aureus}</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>5.</td>
<td>\textit{Escherichia coli}</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>
Table-IV. Estimation of Heavy metals contamination.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters Analyzed</th>
<th>Result</th>
<th>WHO. &amp; API. Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sample1, - RM1</td>
<td>Sample2, - RM2</td>
<td>Sample3, - RM3</td>
</tr>
<tr>
<td>1.</td>
<td>Arsenic</td>
<td>Not detect</td>
<td>Not detect</td>
</tr>
<tr>
<td>2.</td>
<td>Cadmium</td>
<td>Not detect</td>
<td>Not detect</td>
</tr>
<tr>
<td>3.</td>
<td>Lead</td>
<td>Not detect</td>
<td>Not detect</td>
</tr>
<tr>
<td>4.</td>
<td>Mercury</td>
<td>Not detect</td>
<td>Not detect</td>
</tr>
</tbody>
</table>

Table-V. Estimation of Aflatoxins contamination.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters Analyzed</th>
<th>Result</th>
<th>WHO. &amp; API. Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sample1, - RM1</td>
<td>Sample2, - RM2</td>
<td>Sample3, - RM3</td>
</tr>
<tr>
<td>1.</td>
<td>B1 Aflatoxin</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>2.</td>
<td>B2 Aflatoxin</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>3.</td>
<td>G1 Aflatoxin</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>4.</td>
<td>G2 Aflatoxin</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

RESULT AND DISCUSSION

Raughan-e-Mom is widely used for the treatment of Falij (Paralysis or Hemiplegia), Waj-ul-Mafasil (Neuralgia) and other Neurological disorders as Indian proprietary medicines and is available in most of Unani classical drug market of the country, Raughan-e-Mom (Wax oil) is being sold along with the light oily viscous liquid formed. Physicochemical parameters, Quality control, Quality assurance parameters of the light oily viscous Raughan-e-Mom (Wax oil) Unani drug terminology results are described and discussed respectively as follows:

Physicochemical parameters

Petroleum ether at (60-80°C) Extractive, %, w/v. (84.16) is indicated the presence of active polor bioactive phytoconstituents like alkaloids, glycosides, terpinoids, flavinoids, oil, fats Free acidity etc. Acid value (3.03), Iodine value (6.36), Peroxide value (8.62), Unsaponifiable matter (17.47), Refractive index (1.350), Weight per ml.(gm.)(0.91), Test for presence of arachis oil, cotton seed oil, mineral oil and sesame oil (all are negatives) were found with in pharmacopeial and In-House standard of single drugs which is indicated absence of any mixed foreign adulterated, spurious oily materials and also indicated that the drug samples are free from any microbial load and aflatoxins contamination. The obtained physicochemical data of the drug samples were showed in Table II.
Quality control and Quality assurance parameters

Quality Control and Quality Assurance studies of quality parameters were assessed and performed as per WHO., IPC., UPC., (API.UPI.) and AOAC. Standard methods, The microbial load (cfu./gm.) and heavy metals (ppm.) toxic contamination estimation were found within the permissible limits due to control of Quality which indicated the absence of any adulterative mixed material as well as drugs samples free from contamination appearance showed in Table- III. & IV. respectively .The Aflatoxins toxic contamination estimation were not detected from the drug samples which is showed in Table-V. Freshly Prepared drug also preserved or Store in cool and dry place in tight closed containers, protected from light and moisture.

CONCLUSION

The Pharmacopeial Standard development and Physicochemical research studies of Unani Anti-paralytic drugs Raughan-e-Mom(Wax oil) research data have showed that the collected Raughan-e-Mom(Wax oil) drug samples RM1, RM2 and RM3 from Pharmacy of CRIUM., Hyderabad (Under CCRUM., Ministry of AYUSH., Government of India) were authenticated, and can be used as the standard Classic Unani formulations. The results of quality control parameters revealed that the drug samples taken in to that studies were free from toxic substances like toxic microbes, heavy metals and aflatoxins. Moreover the obtained research studies data and comparative screening will provide the referential supportive information in the development of pharmacopeial standard monographs, identification, reinvestigation, quality assurance and pharmacovigilance of the drug.

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