

Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
(P E & R Division)

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"SAY NO TO CORRUPTION"

No.F.1-21/2019-Add:Dir.(PE&R)

Islamabad, the 03rd September, 2020

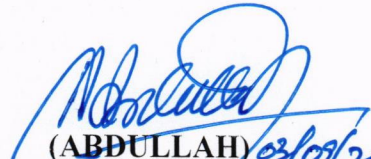
CIRCULAR

Subject: **REGISTRATION OF POTASSIUM IODIDE TABLET AS REGISTERED DRUG.**

Drug Regulatory Authority of Pakistan in its 88th meeting held on 7th August, 2020 discussed the application of Pakistan Atomic Energy Commission (PAEC) on the subject captioned above. In order to facilitate & expedite the process of registration of Potassium Iodide tablets; the Authority exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713(I)/2018 dated 8th June, 2018 allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5-F, for registration of Potassium Iodide tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions;

- i. The applicants can submit their applications till 30-09-2020 and these applications will be considered out of queue.
- ii. Registration Board shall consider grant of registration and submission of data of product development and 6months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required.

2. Accordingly, above decision of DRAP is hereby circulated for information of all pharmaceutical manufacturers/importers.


(ABDULLAH) 03/09/2020
Additional Director (PE&R)

Distribution: -

- i. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
- ii. Executive Director, Pharma Bureau, Karachi.
- iii. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
- iv. Additional Director, MIS Division, for uploading on DRAP's website.

Copy for information to: -

1. PS to Chief Executive Officer, DRAP.
2. APS to Director, PE&R, DRAP.