

Annam
11/11/18

(Hx)
12/09/18

8.10.2018
12

Vijayakumar
12/06/18

Hx
11-12/10

~~Annam~~
8
12/06/18

Cut
14/08/18

Red
17/06/2018

• Minimum three years old valid manufacturing licence of the product quoted with latest license renewal certificate. As per clause 3(f).
 • Approved product list as per the license issued for quoted drugs for minimum three years. As per clause 3(f).
 • Manufacturing License along with approved product list must be valid till the last date of the submission of tender. As per clause 3(f).
 • In Case of those drugs which are notified first time in IP 2014 then Manufacturing and Marketing license should be in any official compendium (USP/BP/IP) along with current valid license in IP in continuation.
 • Market standing certificate & Manufacturing certificate issued by the Licensing Authority as a Manufacturer for each drug quoted for the last 3 years (Certificate should be enclosed with list of items) except for the drugs falling under the category of 'New Drug' as defined by CDSCO (Central Drugs Standard Control Organization). If permission in Form 46 from DCGI has been obtained, then the 3 years Manufacturing & Market standing clause will be relaxed. The provisions of Rule 122 E of Drugs and Cosmetics Act rule 1945 shall apply.
 • For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCGI less than two years ago. A certificate from DCGI (I) shall be required for all new regulated products to this effect.
 • FFS (Flow Fill & Seal Process) Technology will be accepted wherever applicable.

Bidders shall submit self attested copies of required manufacturing license and approved product list in support of above mentioned condition and they are required to specify the quoted product in their approved product list by highlighting it. As per Clause 3(f)

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(a) Scanned Copy of Manufacturing Licence in Form 25 [Licence to Manufacture for sale of drugs other than those specified in schedules C and C(1)] issued on 18.03.1999 by Licensing Authority, Food and Drug Administration, Madhya Pradesh is submitted wherein it is stated that Licence No. 25/2/99 of M/s Alpa Laboratories Limited Madhya Pradesh shall be in force from 18.03.1999 to 31.12.2000 (Pg. no. 48)
Note- Submitted Manufacturing Licence in Form-25 which is not in accordance to Drugs and Cosmetics Act 1940 - "Licence to manufacture for sale or for distribution of drugs other than those specified in [Schedules C and C(1) and X]"
 (b) Scanned Copy of Manufacturing Licence in Form 28 [Licence to Manufacture for sale drugs specified in schedules C and C(1)] issued on 18.03.1999 by Licensing Authority, Food and Drug Administration, Madhya Pradesh is submitted wherein it is stated that Licence No. 28/2/99 of M/s Alpa Laboratories Limited Madhya Pradesh shall be in force from 18.03.1999 to 31.12.2000 (Pg. no. 47)
Note-Submitted Manufacturing Licence in Form-28 which is not in accordance to Drugs and Cosmetics Act 1940 - "Licence to manufacture for sale or for distribution of drugs specified in Schedules C and C (1) [excluding those specified in Schedule X]"
 (c) Scanned copy of Certificate of Renewal in Form 26 issued on 17.10.2014 by Licensing Authority, FDA, Madhya Pradesh is submitted wherein it is stated that Licence no. 25/2/99 & 28/2/99 of M/s Alpa Laboratories Limited has been renewed from 01.01.2013 to 31.12.2017. (Pg. no- 45 to 46)
 (d) Scanned copy of Certificate (No V/25/1/C/A-1/2018/5 dated 01.01.2018) issued by Licensing Authority, FDA, Madhya Pradesh is submitted wherein it is stated that the firm has applied for retention of the license along with license retention fee, within stipulated time. The Firm's license is deemed to be valid under Rules 72 & 77 of the Drugs and Cosmetics Rules 1945. This Certificate shall be valid for 6 months from the date of issue. (Pg. no 44)
 (e) Scanned Copy of List of products issued on 17.10.2014 (Valid up to 31.12.2017) by Licensing Authority, Food and Drugs administration, Madhya Pradesh is submitted (Pg. no. 40 to 43)

Sr. no.	NIT Sr. no.	Product name	Specification/Strength	Page No.
01.	15	Chloramphenicol Eye Ointment IP	1% w/w	42
02	44	Miconazole Cream IP	2% w/w	40
03	48	Diclofenac Gel BP	1% w/w	41
04	51	Lignocaine Hydrochloride	10 mg/ 1ml	

Note- Submitted approved list has also Trade Name of the product (Diclofenac Gel) which is mentioned as DICLOVERON
Note- Name of product is mentioned as Lignocaine Hydrochloride Injection IP 1% in submitted approved product list.
 (f) Scanned copy of Manufacturing/ Marketing Certificate signed on 27.03.2017 issued by Licensing Authority, FDA, Madhya Pradesh is submitted wherein it is stated that the firm is manufacturing the following products since the three years. It is further Certified that the following products are also being marketed for the last three years. product at NIT sl. no 51 is mentioned in above certificate. (Pg. no-38)
 (g) Scanned copy of Manufacturing/ Marketing Certificate signed on 29.06.2016 issued by Licensing Authority, FDA, Madhya Pradesh is submitted wherein it is stated that the firm is manufacturing the following products since the three years. It is further Certified that the following products are also being marketed for the last three years. product at NIT sl. no 15,44 & 48 are mentioned in above certificate.

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The facts in clause No-1 to 10 and 17 of the provided sheet has been complied with due diligence and care, on the basis of document provided by BMSICL, inspite, some inadvertent discrepancies could have been crept in. Humble request to all concerned to bring to notice in due time if any discrepancies are observed for rectification.

Punjab
12/16/18
19K
12/10/18

Mari
12-26-18

Punjab
12/06/18

Rd.
12/06/2018

Vaidik
12/06/18

Muri
12/16/18
11.5

Pant
12/06/18