

No. HFW-H (Drugs) 344/07  
HEALTH AND FAMILY WELFARE DEPARTMENT  
HIMACHAL PRADESH.

To

M/s S.R. BIOCHEM  
PLOT NO. 10-A, PHASE-II,  
GWALTHAI INDUSTRIAL AREA,  
DISTT. BILASPUR (H.P.)

Dated, Shimla-171009, the 06-02-08

**Subject: - Grant Manufacturing Drugs Licences.**

Sir,

With reference to your application No. NIL of dated 12.12.2007  
on the subject cited above.

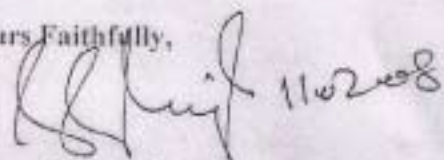
Licence No. MB/07/669 manufacturing for sale of Drugs.

- i) Biological Drugs special Products specified in scheduled &  
C (1) of the Drugs Rules, 1945.

are sent herewith duly granted.

Please acknowledge the receipt.

Yours Faithfully,

  
Drugs Controlling-Cum-  
Licensing Authority,  
H.P. Shimla-171009.

From S.R. Biochem

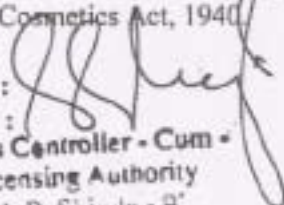
**FORM 28**  
**(See Rule 76)**

**Licence to manufacture for sale or distribution of drugs specified in Schedule C and C (1)**  
**[Excluding those specified in Sch. X].**

**Number of licence and date of issue: MB/07/669 Dated 11-02-2008.**

1. **M/s S.R. Biochem** is hereby licensed to manufacture at the premises situated at **Plot No. 10-A, Phase-II, Gwalhai Industrial Area, Distt. Bilaspur (H.P.)** the following Drugs, being drugs specified in Schedules C and C (1) excluding those specified in Sch. X to the Drugs and Cosmetics Rules, 1945.
2. Name of drugs: -  
1. **Ascorbic Acid**      **I.P. / B.P. / U.S.P.**
3. Name of approved competent technical staff:-  
1. **Mr. Bob Vasoya**                      **B. Sc.**                      **Manufacturing Chemist**  
2. **Mr. Raja Ram Sah**                      **B. Sc.**                      **Analytical Chemist**
4. The licence authorizes the sale by way of wholesale dealing and storage for sale by the license of the drugs manufactured under the licence subject to the condition applicable to licenses for sale.
5. The licence will be in force from: **11-02-2008 to 10-02-2013.**
6. The licence is subject to the condition stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

**Date of issue: 11-02-2008.**

Signature :   
Designation : **Drugs Controller - Cum -**  
**Licensing Authority**  
**H. P. Sinha - 9**


**CONDITION OF LICENCE**

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedules C and C (1) excluding those specified in Sch. X not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75(3). This licence will be deemed to extend to the items so endorsed.
3. Any change in the competent technical staff shall be forthwith reported to the Licensing Authority.
4. (\*\*\*)
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place. The current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

Approved product list to be manufactured by **M/s S.R. Biochem**  
 Goalthai, Industrial, Plot No. 10 & B, Phase-II, Distt. Bilaspur (H.P)

Office of the Licensing Authority, Drugs Control administration H.P,  
 Solan  
**Drugs Control Administration HP**  
**CMO's Office Complex, SOLAN-173212, HP**

Drug License No.		MB/07/669		NON BIOLOGICAL / BIOLOGICAL		Total Product	01	01	Comments (for office use only)
S. No.	Dosage form	Product Name	Composition	Pack size(s) & Description	Page No.	Equivalent product in the market	To be mfg for		
1.	<b>API.</b>	Ascorbic acid Coated	(1) Ascorbic acid (ii) Stearyl alcohol	IP. 50kg	96-97% 2.5-4.0%	Ascorbic acid coated			<b>Self APPROVED</b>

  
**Drugs Licensing Authority**  
**Drugs Control Administration**  
**SOLAN**

No. HFW-H(Drugs) 344/07/1224  
Health & Family Welfare Department H.P.  
Drugs Control administration HP (division),  
Office of the Zonal Licensing Authority,  
CMO's Office Complex, SOLAN-173 212, HP.

To

M/s S.R. Biochem  
Indi's Area, Gwalther  
Distt. Bilaspur

Solan, dated the 27/04/07

Subject: Approval of \_\_\_\_\_ ( 2 ) additional products

Sir,

Reference to your letter No: Nil dated 27/04/07 on the subject cited above. In this regard it is to inform you that your application has been considered for approval fully/ partially as per the provisions of the Drugs and Cosmetics Act 1940 and Rules 1945 made there under, Pharmacopoeial Monographs/ DCG(I) guidelines, etc. Approval of product(s) to be manufacture for sale or distribution under the license, granted is subject to the following conditions.

1. Licensee shall comply with the standards for patent and proprietary medicines as laid down in the Schedule V of the Drugs and Cosmetics Rules, 1945.
2. Licensee shall comply with the provisions for manner of labeling of drugs as laid down under Rule 94, 95, 96, 97, 102, 104, 104-A, 105, 105-A and 106 of the Drugs and Cosmetics Rules, 1945.
3. Please note that the TRADE/ BRAND NAMES permitted above is on the basis of your assertion that you are legally entitled to use the said trade/ brand name. For any violation of any of the provisions of the Law or infringement of any other's right, in this regard, you will be solely responsible for the same and this Department has nothing to do in this regard.
4. Licensee shall comply with the provisions of the Drugs Control (price) Order, 1995, as applicable and also to the price fixed by the National Pharmaceutical Pricing Authority (NPPA), for the products permitted under this letter
5. Licensee shall comply with the provisions as laid down under Schedule-PI, as applicable, with regards to the packing of the products covered under this letter.
6. Licensee shall make no claim, except those prescribed in the pharmacopoeia and/ or in the permission issued by the Drugs Controller General of India.
7. Licensee shall conduct periodical and accelerated stability studies for the drugs manufactured by them for at least initial three consecutive batches, in order to ensure potency and quality of drug, during its shelf life. In case of any deviation licensee shall withdraw the same from the market under intimation to the office of the Drugs Licensing Authority.
8. Licensee shall, forthwith intimate to The Licensing Authority, in the event of any adverse reaction reported by the drug.

List of additional product(s) as approved by this office is enclosed herewith.

Faithfully yours

  
Drugs Licensing Authority,  
Drugs Control Administration HP,  
SOLAN

Enclosure: as above

HFW-H (DRUGS).....

OFFICE OF THE LICENSING AUTHORITY, DRUGS CONTROL ADMINISTRATION H.P. SOLAN

List of Additional Products to be Manufactured by M/s S. R. BIO-CHEM situated at 10A, Ind. Area, Phase-II, GOALTHAI-174201 DISTT. BILASPUR H.P. Under Drugs Manufacturing Licence No. MB/07/669 on form no 28 valid w.e.f 11-02-2008 to .....

S.No.	Dosage Form	Product Name	Composition	Pack size (s) & Description	Equivalent product in the market	To be Mfg. for	comments (For office use only)
1.	API	Ferrous Ascorbate	1. Ascorbic Acid IP 70%-80% 2. Ferrous 15%-20%	50kgs	—NA—	SELF	APPROVED
2.	AIP	Sodium Ascorbate IP	1. Sodium Ascorbate IP 99.0%-101%	50kgs	—NA—	SELF	APPROVED

*Signature*

Drugs Licensing Authority  
Drugs Control Admin.Hp

27 APR 2009 SOLAN